

Prospectus

9,375,000 shares**Common stock**

This is an initial public offering of shares of common stock of BlossomHill Therapeutics, Inc. We are offering 9,375,000 shares of our common stock to be sold in this offering. The initial public offering price is \$16.00 per share.

Prior to this offering, there has been no public market for our common stock. Our common stock has been approved for listing on The Nasdaq Global Select Market under the symbol "BLSM."

We are an "emerging growth company" and a "smaller reporting company" as defined under the U.S. federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements.

	Per share	Total
Initial public offering price	\$ 16.00	\$ 150,000,000
Underwriting discounts and commissions ⁽¹⁾	\$ 1.12	\$ 10,500,000
Proceeds to BlossomHill Therapeutics, Inc., before expenses	\$ 14.88	\$ 139,500,000

(1) See the section titled "Underwriting" for a description of the compensation payable to the underwriters.

We have granted the underwriters an option for a period of 30 days to purchase up to an additional 1,406,250 shares of our common stock.

Investing in the common stock involves a high degree of risk. Please see the section titled "[Risk factors](#)" beginning on page 14.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares to purchasers on or about August 10, 2026.

J.P. Morgan

Leerink Partners

Guggenheim Securities

LifeSci Capital

H.C. Wainwright & Co.

August 6, 2026

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Through and including August 31, 2026 (the 25th day after the date of this prospectus), all dealers effecting transactions in our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

Neither we nor the underwriters have authorized anyone to provide you with any information or to make any representations other than those contained in this prospectus, any amendment or supplement to this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. Neither we nor the underwriters take responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date on the front cover of this prospectus, or other earlier date stated in this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock and the distribution of this prospectus outside the United States.

Prospectus summary

This summary highlights selected information included elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, including the sections titled “Risk factors,” “Management’s discussion and analysis of financial condition and results of operations” and “Special note regarding forward-looking statements,” and our financial statements and the related notes included elsewhere in this prospectus, before making an investment decision. Unless the context otherwise requires, all references in this prospectus to “BlossomHill Therapeutics,” “BlossomHill,” “Registrant,” “we,” “us,” “our” and “Company” refer to BlossomHill Therapeutics, Inc.

Overview

We are a clinical-stage biopharmaceutical company applying our intentional, chemistry-based approach to develop innovative small molecule medicines that address significant unmet medical needs in cancer treatment. With each of our programs, we combine a deep understanding of disease and protein dynamics with our structure-based rational drug design expertise to identify the specific structural liabilities that limit existing therapies or approaches, and then design novel chemical scaffolds to directly address these limitations. Our scientific founder and the team we have assembled have a proven track record of developing innovative small molecule medicines that overcome the limitations of existing therapies, including multiple approved therapies that have delivered transformational patient outcomes.

Our initial development efforts are focused on our two clinical-stage programs: BH-30643, an investigational, non-covalent, macrocyclic, brain active, mutant-selective OMNI-EGFR inhibitor for the treatment of *epidermal growth factor receptor* (EGFR)-mutant non-small cell lung cancer (NSCLC), and BH-30236, an investigational macrocyclic CDC-like kinase (CLK) inhibitor being evaluated first in relapsed or refractory acute myeloid leukemia (R/R AML) and higher-risk myelodysplastic syndromes (HR-MDS). We also have a preclinical-stage product candidate, BH-501284, that leverages a novel chemical scaffold to selectively target and modulate activated KRAS.

Our most advanced product candidate, BH-30643, is an OMNI-EGFR inhibitor being evaluated in SOLARA, a global Phase 1/2 clinical trial in patients with EGFR-mutant NSCLC. While there are commercially available drugs targeting EGFR subtypes, there is a fragmentation of care in EGFR-mutant NSCLC because no drug is effective across all EGFR mutations. Moreover, the durability of response to prior-generation EGFR tyrosine kinase inhibitors (TKIs) has frequently been limited by the emergence of acquired on-target resistance mutations, notably the T790M gatekeeper mutation for first- and second-generation EGFR TKIs and C797S-mediated resistance for third-generation EGFR TKIs, such as osimertinib. BH-30643 is designed to address a broad spectrum of EGFR mutations, including classical mutations, on-target resistance mutations such as C797S and T790M, atypical mutations and exon 20 insertion mutations, with selectivity over wild-type EGFR. The SOLARA Phase 1/2 clinical trial is currently enrolling patients across dose expansion cohorts in both TKI-pretreated and TKI-naïve settings, including a C797S resistance cohort, a population with no currently approved targeted therapy. To date, treatment with BH-30643 has been evaluated for safety, pharmacokinetics and preliminary efficacy in patients with EGFR-mutant NSCLC, including in patients with the C797S resistance mutation across diverse molecular contexts (with or without T790M) in the setting of classical or atypical mutations, and in TKI-naïve patients with classical mutations. For additional details on the results observed in patients dosed with BH-30643, please see the section titled “Business—BH-30643: OMNI-EGFR inhibitor for the treatment of EGFR-mutant NSCLC.” We believe the early clinical data observed in this trial support a near-term development path in C797S resistance and establish the foundation for BH-30643’s potential against a broad spectrum of

EGFR activating mutations. We plan to seek an end-of-Phase 1 meeting with the U.S. Food and Drug Administration (FDA) regarding the recommended Phase 2 dose and a potential accelerated approval pathway for BH-30643 in patients with advanced or metastatic C797S-positive EGFR-mutant NSCLC in the fourth quarter of 2026.

Our second clinical-stage product candidate, BH-30236, is a CLK inhibitor currently being evaluated in an ongoing Phase 1 clinical trial in patients with R/R AML and HR-MDS. BH-30236 represents a novel approach to cancer treatment through the inhibition of CLK to target aberrant alternative mRNA splicing (aberrant alternative splicing), a defining feature implicated in cancer progression and therapeutic resistance across both hematologic malignancies and solid tumors. Our Phase 1 clinical trial is currently enrolling patients in the dose escalation part of the trial and is evaluating BH-30236 as a monotherapy and in combination with the BCL-2 inhibitor venetoclax, the established standard of care therapy for acute myeloid leukemia (AML) patients. To date, BH-30236 has been evaluated for safety, pharmacokinetics and preliminary efficacy across multiple dose levels as a monotherapy and in combination with venetoclax. We expect to report updated safety and efficacy data from the BH-30236 Phase 1 trial in the first half of 2027.

We are also advancing our pan-KRAS program, initially focusing on our preclinical product candidate, BH-501284, which is designed using a novel chemical scaffold to achieve prolonged, potent and selective inhibition of KRAS mutations, but sparing HRAS and NRAS. We believe this molecule, which leverages a newly designed non-covalent scaffold, is unique in its potential to achieve tight and durable binding, a feature described as “pseudo-irreversible” binding. BH-501284 has demonstrated potent cellular pan-KRAS activity, achieved tumor regression at low oral dose levels in multiple KRAS-mutant mouse tumor models and improved oral bioavailability across species. We are currently conducting Investigational New Drug Application (IND) enabling studies of BH-501284 and plan to submit an IND in the first quarter of 2027.

Our pipeline

We are developing a wholly-owned pipeline of two clinical-stage product candidates and one preclinical-stage product candidate, as represented in the figure below.

Target	Candidate	Indication / Therapeutic Area	Design/ Discovery	IND Enabling	Phase 1	Phase 2	Phase 3	Next Anticipated Milestone
EGFR	BH-30643	EGFR-mutant NSCLC						Q4 2026: EOP1* Meeting; C797S potential accelerated approval pathway
CLK	BH-30236 +/- venetoclax	R/R AML and HR-MDS						1H 2027: Updated safety and efficacy data
Pan-KRAS	BH-501284	Solid Tumors						Q1 2027: IND Submission

* EOP1: End-of-Phase 1

BH-30643: OMNI-EGFR inhibitor for the treatment of EGFR-mutant NSCLC

Lung cancer is the leading cause of cancer-related death worldwide. NSCLC accounts for approximately 85% of all lung cancer cases, and, according to GlobalData, approximately 316,000 patients were diagnosed with EGFR-

mutant NSCLC across key global markets of the United States, Europe, Japan and China in 2025. Activating mutations in the EGFR gene represent the most common targetable oncogenic driver in NSCLC and define a clinically and molecularly distinct patient population. A wide variety of EGFR mutations broadly grouped into three categories have been reported: classical mutations (exon 19 deletion and L858R mutation, collectively representing approximately 80% of EGFR mutations), atypical mutations (such as G719X, L861Q and S768I, collectively representing approximately 10% of EGFR mutations), and exon 20 insertion mutations (approximately 10% of EGFR mutations).

Three generations of EGFR TKIs are primarily approved for classical EGFR-mutant NSCLC, with treatment durations averaging less than approximately two years, as resistance typically develops by this point and limits further treatment. Importantly, at the time treatment resistance develops, the EGFR mutations present in NSCLC can evolve further, with the emergence of on-target resistance mutations such as C797S, T790M, L718X and G724X. First and second generation EGFR TKIs have a chemical group extending beyond the T790 residue, referred to as the “back-pocket motif,” and are vulnerable to resistance driven by the T790M gatekeeper mutation; newer TKIs that utilize a similar scaffold inherit this resistance vulnerability. Third generation EGFR TKIs rely on covalent binding for potency and are vulnerable to the C797S resistance mutation which blocks the necessary covalent binding. This C797S mutation is the most common EGFR mutation driving resistance to third generation EGFR-targeted therapy and is detected in approximately 13% of patients at the time of resistance, per several recent publications.

We estimate there are approximately 3,200 NSCLC patients annually in the United States with C797S-driven resistance and considerably more globally. There are currently no approved oral targeted therapies in the United States for patients with C797S-mediated resistance to third generation EGFR TKIs, the current standard of care.

Our most advanced product candidate, BH-30643, is a non-covalent, macrocyclic, brain active, mutant-selective OMNI-EGFR inhibitor for the treatment of EGFR-mutant NSCLC. BH-30643 is designed to address a broad spectrum of EGFR mutations, including classical mutations, on-target resistance mutations such as C797S and T790M, atypical mutations and exon 20 insertion mutations, with selectivity over wild-type EGFR. BH-30643 is being evaluated in SOLARA, a global Phase 1/2, first-in-human clinical trial currently enrolling patients at over 40 sites in 10 countries. Ongoing dose expansion cohorts are enrolling in both TKI-pretreated and TKI-naïve settings, including a C797S resistance cohort. For additional information, please see the section titled “Business—BH-30643: OMNI-EGFR inhibitor for the treatment of EGFR-mutant NSCLC.” We believe the early clinical data observed in this trial support a near-term development path in C797S resistance and establish the foundation for BH-30643’s potential against a broad spectrum of EGFR activating mutations.

We plan to seek an end-of-Phase 1 meeting with the FDA regarding the recommended Phase 2 dose and a potential accelerated approval pathway for BH-30643 in patients with advanced or metastatic C797S-positive EGFR-mutant NSCLC in the fourth quarter of 2026. We expect to dose the first patient in our anticipated pivotal Phase 2 trial in the first quarter of 2027. We plan to report additional Phase 1 data on durability of response in the C797S population in the first half of 2027, the initial Phase 1 data on the chemotherapy combination cohort in the second half of 2027, and additional Phase 1 data on durability of response in the TKI-naïve cohort for EGFR classical mutations in the second half of 2027.

BH-30236: CLK inhibitor for the treatment of R/R AML and HR-MDS

AML is the most common acute leukemia in adults, with approximately 21,000 new diagnoses and 11,000 deaths annually in the United States. Approximately one-third of AML patients do not have a complete

remission or do not respond to frontline venetoclax and azacitidine combination therapy, and the majority of initial responders ultimately develop resistance and progressive disease. There is no currently approved targeted therapy for patients with resistance to venetoclax-based combination therapy in the absence of targetable genetic alterations. Patients with HR-MDS closely mirror AML in clinical course, frontline treatment, and unmet need in the relapsed and refractory setting. According to GlobalData, approximately 14,000 patients are diagnosed with HR-MDS annually in the United States.

AML and HR-MDS are, in part, diseases associated with aberrant alternative splicing. While it has been scientifically validated that CLK inhibition modulates aberrant alternative splicing across both hematologic malignancies and solid tumors, prior efforts to target alternative splicing through CLK inhibition have faced challenges clinically and encountered toxicities requiring intermittent dosing. The venetoclax-resistant and refractory segment, for which no approved therapy currently exists for broad application (or usage), represents our initial area of focus for BH-30236.

Our second clinical-stage product candidate, BH-30236, is a CLK inhibitor currently being evaluated in an ongoing Phase 1 first-in-human trial in patients with R/R AML and HR-MDS. Our Phase 1 clinical trial is currently enrolling patients in the dose escalation part of the trial and is evaluating BH-30236 as a monotherapy and in combination with the BCL-2 inhibitor venetoclax, the established standard of care therapy for AML patients. We also plan to explore the antileukemic effect of BH-30236 in additional myeloid malignancies as well as study the safety and antileukemic effect of BH-30236 with venetoclax plus azacitidine for the treatment of AML. We expect to report updated safety and efficacy data from the BH-30236 Phase 1 trial in the first half of 2027.

BH-501284: pan-KRAS inhibitor

KRAS mutations are the most frequent oncogenic driver alterations in human cancer, present in approximately 25% of all malignancies — with particularly high prevalence in pancreatic ductal adenocarcinoma (approximately 90%), colorectal carcinoma (CRC) (approximately 40%) and lung adenocarcinomas (approximately 30%).

While covalent KRAS G12C inhibitors are now approved by the FDA to treat G12C-mutant NSCLC and CRC, these agents address only a single mutant allele and leave patients harboring other frequent oncogenic KRAS mutations, including G12D, G12V, G12S and G12A, without an approved targeted therapy. Investigational KRAS inhibitors leverage several emergent design approaches, including non-covalent Switch-II pocket inhibitors and tricomplex inhibitors. Though tricomplex RAS inhibitors offer broad activity, they face a greater adverse event burden in the clinic. To deliver a clinically meaningful pan-KRAS Switch-II inhibitor, we believe a fresh chemical scaffold is required to achieve both high cell potency and a favorable pharmacology profile, offering an opportunity to achieve a more durable benefit for patients.

We are advancing our preclinical pan-KRAS product candidate, BH-501284, which utilizes a novel Switch-II chemical scaffold designed to provide prolonged, potent and selective inhibition of KRAS, sparing HRAS and NRAS. In preclinical studies, BH-501284 achieved pseudo-irreversible binding characteristics with high binding affinity and a prolonged target residence time exceeding 54 hours, while maintaining high selectivity for KRAS. We are currently conducting IND-enabling studies of BH-501284 and plan to submit an IND in the first quarter of 2027.

Discovery programs

We are also advancing multiple discovery-stage efforts focused on validated and emerging new oncology targets. In addition, we believe our drug discovery approach may also have applicability beyond oncology.

Our team and track record

We were founded by pioneers of small molecule drug design and are led by an executive and management team with deep expertise in oncology drug development and clinical research. We began operations in the summer of 2020, led by our scientific founder, President and Chief Executive Officer, J. Jean Cui, Ph.D. We have assembled a team with broad expertise, which has collectively been involved in the discovery or development of more than a dozen oncology programs and has guided multiple programs from first-in-human studies through FDA approval. Our team is united by a shared conviction that intentional, chemistry-based molecular design can deliver outcomes that broadly deployed screening-based approaches cannot and facilitates the speed of execution and capital efficiency required to successfully develop and launch new medicines.

Our scientific founder, Dr. Cui, is the lead inventor of three FDA-approved targeted cancer therapies—crizotinib (XALKORI), lorlatinib (LORBRENA) and repotrectinib (AUGTYRO)—the latter two of which leverage the macrocyclic small molecule approach that is also utilized in the design of our current clinical-stage candidates. Dr. Cui was elected to the National Academy of Engineering in 2024, one of the highest professional distinctions in engineering, and has received the American Chemical Society Heroes of Chemistry award (2013 and 2021) and the 38th Annual Inventor of the Year award (2011). Notably, lorlatinib, the second of Dr. Cui's ALK-driven NSCLC medicines to be approved, demonstrated a median progression-free survival (PFS) exceeding 84 months, compared to approximately 10.9 months with crizotinib, a first-generation therapy. Repotrectinib, the lead program at Turning Point Therapeutics, which Dr. Cui co-founded, and which was acquired by Bristol-Myers Squibb in 2022, achieved an overall response rate (ORR) of 79% and a median progression-free survival of 35.7 months in TKI-naïve ROS1-positive NSCLC. We believe the same design principles applied to develop these molecules may have the potential to produce a similarly meaningful advancement in EGFR-mutant NSCLC.

Our Chief Medical Officer, Geoffrey R. Oxnard, M.D., is a globally recognized authority on EGFR-mutant NSCLC and the co-author of the first published description of the EGFR C797S resistance mutation—the principal acquired resistance mechanism to third-generation EGFR TKIs such as osimertinib, which BH-30643 is designed to overcome. Prior to joining BlossomHill, Dr. Oxnard served as Vice President, Global Head of Thoracic Cancers at Eli Lilly and Company (formerly Loxo Oncology at Lilly), where he led early- and late-phase clinical development of a broad thoracic oncology portfolio. Before that, he served as Senior Vice President, Head of Clinical Development at Foundation Medicine, where he contributed to the FDA approval of FoundationOne Liquid CDx and oversaw the launch of an emerging circulating tumor DNA monitoring portfolio. Dr. Oxnard is a practicing oncologist who was previously on the faculty of Dana-Farber Cancer Institute and Harvard Medical School for nearly 10 years.

Our Co-Founder and Executive Chairman, Y. Peter Li, Ph.D., MBA, previously co-founded Turning Point Therapeutics and served as its Chairman and Chief Executive Officer leading up to its successful IPO in 2019. Our Chief Financial Officer, Jason Keyes, MBA, brings nearly 25 years of biotechnology finance experience, including roles as Chief Financial Officer at Equillum and Orexigen Therapeutics, and prior leadership positions at Amgen and Amylin Pharmaceuticals, as well as having served as director and Audit Committee chairman of multiple publicly-traded oncology therapeutic companies. Our General Counsel, Vincent P. Liptak, JD, Ph.D., MBA, brings over 25 years of legal experience with a focus on intellectual property law, including roles as Life Sciences Practice Co-Chair at Barnes & Thornburg, where he represented Turning Point Therapeutics as intellectual property counsel, and previously served as lead patent counsel for numerous programs at Pfizer.

Since our inception, we have raised over \$257 million in capital from experienced healthcare-focused investors, including our 5% or greater holders Cormorant Asset Management, OrbiMed, Vivo Capital, and Janus Henderson Investors. Prospective investors should not rely on the investment decisions of our existing investors, as these

investors may have different risk tolerances and purchased their shares in financings that were conducted at a significant discount to the price offered to the public in this offering.

Our strategy

We are committed to building a biopharmaceutical company focused on developing innovative small molecule medicines which address significant unmet medical needs in cancer treatment. Key elements of our strategy include:

- **Advance the clinical development of BH-30643 in C797S-resistant EGFR-mutant NSCLC.**
- **Continue to expand the clinical development of BH-30643 across the full spectrum of EGFR-mutant NSCLC, including earlier lines of therapy.**
- **Advance the clinical development of BH-30236, our CLK inhibitor, as a novel approach for the treatment of AML and HR-MDS.**
- **Advance BH-501284, our pan-KRAS inhibitor, into a first-in-human clinical trial in KRAS-mutant solid tumors.**
- **Expand and diversify our pipeline through internal discovery efforts.**
- **Build the capabilities needed to advance and commercialize our drug candidates.**

Summary of risk factors

Investing in our common stock involves significant risks. You should carefully consider the risks described in the section titled “Risk factors” immediately following this prospectus summary and elsewhere in this prospectus before making a decision to invest in our common stock. If we are unable to successfully address these risks and challenges, our business, financial condition, results of operations or prospects could be materially and adversely affected. In such case, the trading price of our common stock would likely decline, and you may lose all or part of your investment. Below is a summary of some of the more significant risks we face.

- We are a clinical-stage biopharmaceutical company with a limited operating history. We have not completed any pivotal or late-stage clinical trials and we have no history of commercializing products, which may make it difficult to evaluate our approach to the discovery and development of our product candidates and the prospects for our future viability.
- Even if this offering is successful, we will require substantial additional financing to achieve our goals, which may cause dilution to our stockholders, and failure to obtain additional capital when needed, or on acceptable terms to us, could cause us to delay, limit, reduce, or terminate our product development or future commercialization efforts.
- Our discovery and development programs are focused in part on precision medicines for patients with genetically defined cancers, which is a rapidly evolving and scientifically uncertain field, and our scientific approach, including with respect to BH-30643 and BH-30236, may never lead to marketable products.
- We are early in our development efforts and only have two product candidates, BH-30643 and BH-30236, in early clinical development. Our pan-KRAS product candidate, BH-501284, is in the preclinical stage. If we are unable to continue to advance our product candidates through or into clinical development, obtain regulatory approval and ultimately commercialize our product candidates or we experience significant delays in doing so, our business will be materially harmed.

- Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial or real-world results. Our product candidates may not have favorable results in preclinical studies or clinical trials or receive regulatory approval on a timely basis, if at all.
- We are currently developing and may in the future develop our product candidates in combination with other therapies, and safety or supply issues with combination-use products may delay or prevent development and approval of our product candidates.
- We are dependent on the services of our management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer. In addition, prior successes of our personnel may not be indicative of our future success.
- Our success depends in large part on our ability to obtain, maintain, enforce, and defend the scope, ownership or control, validity and enforceability of our intellectual property rights, and we may not be able to do so.
- We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties that we rely on to execute our preclinical studies or clinical trials do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates.
- We rely on third-party manufacturers and suppliers to supply our product candidates. The loss of our third-party manufacturers or suppliers, or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, within acceptable timeframes, or at all, would materially and adversely affect our business.
- Competitive products may reduce or eliminate the commercial opportunity for our product candidates for our current or future indications. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies are more effective or safer than ours, our ability to develop and successfully commercialize our product candidates may be adversely affected.
- Even if our product candidates receive regulatory approval, they may fail to achieve the degree of market acceptance by physicians, patients and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.
- The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels, and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates could limit our ability to market those products and decrease our ability to generate revenue.
- The trading price of our common stock may be volatile and you could lose all or part of your investment.

Corporate information

We were originally incorporated under the laws of the State of Delaware in June 2020. Our principal executive offices are located at 10255 Science Center Drive, Suite 200, San Diego, California 92121, and our telephone number is (858) 732-3880. Our website is www.bhtherapeutics.com. We have included our website in this prospectus solely as a textual reference. The information contained in, or accessible through, our website is not incorporated by reference into this prospectus, and you should not consider any information contained in, or

that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common stock.

This prospectus contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Implications of being an emerging growth company and a smaller reporting company

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act (JOBS Act), and we may remain an emerging growth company for up to five years following the closing of this offering. For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended (Sarbanes-Oxley Act), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period and, therefore, we are not subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies; however, we may adopt certain new or revised accounting standards early. We would cease to be an emerging growth company upon the earliest to occur of: (i) the last day of the fiscal year in which we have \$1.235 billion or more in annual revenue; (ii) the date on which we first qualify as a large accelerated filer under the rules of the U.S. Securities and Exchange Commission (SEC); (iii) the date on which we have, in any three-year period, issued more than \$1.0 billion in non-convertible debt securities; and (iv) the last day of the fiscal year ending after the fifth anniversary of this offering.

We are also a "smaller reporting company" as defined in the Securities Exchange Act of 1934, as amended (Exchange Act). We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as the market value of our voting and non-voting common stock held by non-affiliates is less than \$250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than \$100.0 million during the most recently completed fiscal year, and the market value of our voting and non-voting common stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter.

The offering

Common stock offered by us	9,375,000 shares.
Option to purchase additional shares	We have granted the underwriters an option to purchase up to 1,406,250 additional shares of our common stock from us at any time within 30 days of the date of this prospectus.
Common stock to be outstanding immediately after this offering	30,643,660 shares (or 32,049,910 shares if the underwriters exercise their option to purchase additional shares in full).
Use of proceeds	We estimate that the net proceeds to us from the sale of our common stock in this offering will be approximately \$134.9 million (or approximately \$155.8 million if the underwriters exercise their option to purchase additional shares in full), based on the initial public offering price of \$16.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, (i) to advance the clinical development of BH-30643 in EGFR-mutant NSCLC, including continuation of our ongoing global Phase 1/2 clinical trial and the planned initiation of a potential registrational Phase 2 clinical trial, (ii) to advance the clinical development of BH-30236, including continuation of our ongoing Phase 1 clinical trial of BH-30236 as both a monotherapy and combination therapy in AML, HR-MDS and other hematological malignancies, (iii) to complete IND-enabling studies, submit an IND and initiate a Phase 1 clinical trial of BH-501284, and (iv) the remainder for other research and development activities, as well as for capital expenditures, working capital and other general corporate purposes. See the section titled "Use of proceeds" for additional information.
Risk factors	See the section titled "Risk factors" for additional information and a discussion of factors you should carefully consider before deciding to invest in our common stock.
Directed share program	At our request, the underwriters have reserved up to 1% of the shares of common stock offered hereby, at the initial public offering price, to offer to our directors and officers and certain of our employees, business associates, investors and friends and family of our directors, officers, employees, business associates and investors. The sales will be made at our direction by J.P. Morgan Securities LLC, an underwriter of this offering, and its affiliates through a directed share program. The number of shares of common stock available for sale to the general public will be reduced to the extent these individuals purchase such reserved shares. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same basis as the other shares offered by this prospectus. Except for any shares acquired by our

directors and officers, shares purchased pursuant to the directed share program will not be subject to lock-up agreements with the underwriters. See the section titled “Underwriting” for additional information.

**Nasdaq Global Select Market
trading symbol**

“BLSM”

The number of shares of our common stock to be outstanding after this offering set forth above is based on 21,268,660 shares of our common stock outstanding as of March 31, 2026, after giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into 18,258,960 shares of our common stock in connection with the closing of this offering and (ii) the issuance of 365,374 shares of our common stock upon the exercise of outstanding options subsequent to March 31, 2026, of which 227,514 shares remain subject to a right of repurchase as of the date of this prospectus (the Exercised Option Share Issuance), and excludes:

- 1,128,299 shares of our common stock issuable upon the exercise of stock options outstanding under the 2020 Equity Incentive Plan (2020 Plan) as of March 31, 2026, with a weighted-average exercise price of \$5.54 per share, including 244,483 shares of our common stock pursuant to the Exercised Option Share Issuance, with a weighted-average exercise price of \$4.34 per share, of which 110,379 shares remain subject to a right of repurchase as of the date of this prospectus;
- 339,502 shares of our common stock issuable upon the exercise of stock options outstanding granted under the 2020 Plan subsequent to March 31, 2026, with a weighted-average exercise price of \$12.78 per share, including 120,891 shares of our common stock pursuant to the Exercised Option Share Issuance, with a weighted-average exercise price of \$13.15 per share, of which 117,135 shares remain subject to a right of repurchase as of the date of this prospectus;
- 1,544,599 shares of our common stock issuable upon the exercise of stock options to be granted to certain of our employees, executive officers and directors under our 2026 Equity Incentive Plan (2026 Plan), which became effective upon the execution and delivery of the underwriting agreement for this offering, with an exercise price per share that is equal to the initial public offering price per share in this offering (the IPO Option Grants), as more fully described in the section titled “Executive and director compensation”;
- 5,280,528 shares of our common stock reserved for future issuance under our 2026 Plan (inclusive of the shares issuable under the IPO Option Grants), which became effective upon the execution and delivery of the underwriting agreement for this offering (which shares include 3,781,612 new shares plus the number of shares (not to exceed 1,498,916 shares) that remain available for the issuance of awards under the 2020 Plan, at the time the 2026 Plan became effective, as more fully described in the section titled “Executive and director compensation—Equity incentive plans”), as well as any automatic increases in the number of shares of our common stock reserved for future issuance under the 2026 Plan; and
- 302,529 shares of our common stock reserved for future issuance under our 2026 Employee Stock Purchase Plan (ESPP), which became effective upon the execution and delivery of the underwriting agreement for this offering, as well as any annual automatic increases in the number of shares of our common stock reserved for future issuance under the ESPP.

Unless otherwise indicated, the information in this prospectus reflects and assumes the following:

- the automatic conversion, in accordance with our existing certificate of incorporation, of all outstanding shares of our convertible preferred stock into an aggregate of 18,258,960 shares of our common stock in connection with the closing of this offering;

- no exercise of the outstanding stock options other than the Exercised Option Share Issuance;
- no exercise by the underwriters of their option to purchase up to 1,406,250 additional shares of our common stock from us in this offering;
- the filing and effectiveness of our amended and restated certificate of incorporation in Delaware in connection with the closing of this offering;
- no purchases of shares of our common stock by existing stockholders or their affiliates pursuant to the directed share program or otherwise in this offering; and
- a one-for-4.6855 reverse stock split of our common stock and convertible preferred stock was effected on July 31, 2026.

Summary financial data

The following tables summarize our financial data as of and for the periods indicated. We have derived the summary statements of operations data for the years ended December 31, 2024 and 2025 from our audited financial statements included elsewhere in this prospectus. We have also derived the summary interim condensed statements of operations data for the three months ended March 31, 2025 and 2026, and the summary interim condensed balance sheet data as of March 31, 2026 from our unaudited interim condensed financial statements included elsewhere in this prospectus. Our audited financial statements and unaudited interim condensed financial statements included elsewhere in this prospectus have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP). Our unaudited interim condensed financial statements were prepared on a basis consistent with our audited financial statements and include, in our opinion, adjustments of a normal and recurring nature that are necessary for the fair statement of the financial information set forth in those statements included elsewhere in this prospectus.

Our historical results presented below are not necessarily indicative of the results to be expected for any future period. The following summaries of our financial data should be read in conjunction with the sections titled “Risk factors,” “Capitalization,” and “Management’s discussion and analysis of financial condition and results of operations,” and our financial statements and the related notes included elsewhere in this prospectus. The summary financial data included in this section are not intended to replace the financial statements and are qualified in their entirety by our financial statements and the related notes included elsewhere in this prospectus.

(in thousands, except share and per share amounts)	Year ended December 31,		Three months ended	
	2024	2025	2025	March 31, 2026
Statements of operations data:				
Operating expenses:				
Research and development	\$ 31,810	\$ 56,138	\$ 9,572	\$ 19,901
General and administrative	4,591	7,886	1,882	2,206
Total operating expenses	36,401	64,024	11,454	22,107
Loss from operations	(36,401)	(64,024)	(11,454)	(22,107)
Other income (expense), net:				
Interest income, net	5,706	3,480	976	1,102
Other expense	—	(11)	—	(3)
Total other income, net	5,706	3,469	976	1,099
Net loss	\$ (30,695)	\$ (60,555)	\$ (10,478)	\$ (21,008)
Net loss per share attributable to common stockholders, basic and diluted ⁽¹⁾	\$ (13.40)	\$ (24.83)	\$ (4.39)	\$ (8.14)
Weighted-average shares outstanding, basic and diluted ⁽¹⁾	2,290,188	2,438,357	2,386,501	2,580,106
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) ⁽²⁾		\$ (3.69)		\$ (1.01)
Pro forma weighted-average common shares outstanding, basic and diluted (unaudited) ⁽²⁾		16,405,139		20,839,066

(1) See Note 2 to our audited financial statements and Note 2 to our unaudited interim condensed financial statements included elsewhere in this prospectus for details on the calculation of net loss per share attributable to common stockholders, basic and diluted.

- (2) Pro forma net loss per share attributable to common stockholders, basic and diluted, is calculated giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into shares of our common stock and the Exercised Option Share Issuance. Pro forma net loss per share attributable to common stockholders does not include the shares expected to be sold and related proceeds to be received in this offering. Pro forma net loss per share attributable to common stockholders (unaudited) for the year ended December 31, 2025 and for the three months ended March 31, 2026 was calculated using the weighted-average number of shares of our common stock outstanding, including the pro forma effect of the automatic conversion of all outstanding shares of our convertible preferred stock into shares of our common stock and the Exercised Option Share Issuance, as if such conversion and issuance had occurred at the beginning of the period.

(in thousands)	As of March 31, 2026		
	Actual	Pro forma ⁽¹⁾	Pro forma as adjusted ⁽²⁾
Balance sheet data:			
Cash and cash equivalents	\$ 116,003	\$ 118,652	\$ 253,557
Working capital ⁽³⁾	103,545	106,194	241,545
Total assets	143,410	146,059	280,513
Total liabilities	38,707	38,707	38,261
Convertible preferred stock	256,823	—	—
Accumulated deficit	(156,037)	(156,037)	(156,037)
Total stockholders' equity (deficit)	(152,120)	107,352	242,252

- (1) Gives effect to the automatic conversion of all outstanding shares of convertible preferred stock into an aggregate of 18,258,960 shares of our common stock and the related reclassification of the convertible preferred stock to permanent equity in connection with the closing of this offering and the Exercised Option Share Issuance.
- (2) Gives effect to (i) the pro forma adjustments set forth in footnote (1) above and (ii) our sale of 9,375,000 shares of our common stock in this offering based on the initial public offering price of \$16.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.
- (3) We define working capital as current assets less current liabilities. See our unaudited interim condensed financial statements and related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

Risk factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this prospectus, including our financial statements and their related notes included elsewhere in this prospectus and the section titled “Management’s discussion and analysis of financial condition and results of operations.” If any of the following risks actually occurs, our business, prospects, operating results and financial condition could suffer materially, the trading price of our common stock could decline, and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial also may materially and adversely affect our business, prospects, operating results and financial condition.

Risks related to our limited operating history, financial position and need for additional capital

We are a clinical-stage biopharmaceutical company with a limited operating history. We have not completed any pivotal or late-stage clinical trials and we have no history of commercializing products, which may make it difficult to evaluate our approach to the discovery and development of our product candidates and the prospects for our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. We were formed in June 2020 and our operations to date have been limited to conducting research and development, staffing our company, establishing and protecting our intellectual property portfolio, scaling up manufacturing processes and supplying our product candidates and other materials for our preclinical studies and clinical trials, leasing office and laboratory space, raising capital, business planning, and providing general and administrative support for these activities.

Our initial development efforts are focused on our two clinical-stage programs: BH-30643, an investigational, non-covalent, macrocyclic, brain active, mutant-selective OMNI-EGFR inhibitor for the treatment of EGFR-mutant NSCLC, and BH-30236, an investigational macrocyclic CLK inhibitor being evaluated first in R/R AML and HR-MDS. We are also advancing our pan-KRAS program, initially focusing on our preclinical product candidate, BH-501284, which is designed using a novel chemical scaffold to achieve prolonged, potent and selective inhibition of KRAS mutations. We have not yet demonstrated an ability to successfully complete a clinical program, including large-scale, pivotal clinical trials, obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, conduct sales and marketing activities necessary for successful product commercialization or generate revenues or arrange for a third party to do so on our behalf. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical-stage biopharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

We have incurred substantial losses since our inception. We anticipate incurring substantial and increasing losses for the foreseeable future and may never achieve or maintain profitability.

Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. For the years ended December 31, 2024 and 2025, our net losses were approximately \$30.7 million and \$60.6 million,

respectively. For the three months ended March 31, 2025 and 2026, our net losses were \$10.5 million and \$21.0 million, respectively. As of March 31, 2026, we had an accumulated deficit of approximately \$156.0 million. Substantially all of our losses have resulted from expenses incurred in connection with research and development, preclinical study and clinical trial costs, and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and additional operating losses for the foreseeable future as we seek to advance our product candidates through preclinical and clinical development, expand our research and development activities, develop new product candidates, conduct clinical trials, seek regulatory approval and, if we receive regulatory approval, commercialize our products. Furthermore, the costs of advancing product candidates into each succeeding clinical phase tend to increase substantially over time. The total costs to advance any of our product candidates to regulatory approval in even a single jurisdiction would be substantial. Because of the numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to generate any revenue from the commercialization of any approved products or achieve or maintain profitability. Our expenses will also increase substantially as we operate as a public company and add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts.

We have no product candidates approved for commercial sale and have not generated any revenue from the sale of products. Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue, if any, unless and until we, either alone or with a collaborator, are able to obtain regulatory approval for, and successfully commercialize, our product candidates for their initial and potential additional indications, or any other product candidates we may develop in the future.

Successful commercialization will require achievement of many key milestones, including demonstrating each product candidate's safety and efficacy in clinical trials, obtaining regulatory approval for these product candidates, manufacturing, marketing and selling those products for which we, or any of our future collaborators, may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of expenses or when, or if, we will be able to generate any revenue, the extent of any further losses, or if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we do, or any future collaborators do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Additionally, our expenses could increase if we are required by the FDA, or any comparable foreign regulatory authority, to perform clinical trials in addition to those currently expected, or if there are any delays in completing our clinical trials or in the nonclinical or manufacturing-related activities associated with the development of our product candidates. Even if we succeed in obtaining regulatory approvals for and commercializing BH-30643, BH-30236 or any of our other product candidates, we expect to incur substantial development costs and other expenditures to develop and market additional product candidates.

We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue or raise additional capital. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and our working capital. Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business, build out our pipeline, or continue our

operations. If we continue to suffer losses as we have in the past, you may not receive any return on your investment and may lose your entire investment.

Even if this offering is successful, we will require substantial additional financing to achieve our goals, which may cause dilution to our stockholders, and failure to obtain additional capital when needed, or on acceptable terms to us, could cause us to delay, limit, reduce, or terminate our product development or future commercialization efforts.

The development of pharmaceutical product candidates is capital-intensive. We expect to continue to spend substantial amounts of cash to conduct further research and development, preclinical studies, and clinical trials of our current and any future product candidates, to seek regulatory approvals for our product candidates and to launch and commercialize any products if we receive regulatory approval.

Our operations have consumed substantial amounts of cash since our inception. As of March 31, 2026, we had \$116.0 million in cash and cash equivalents. Based on our current operating plan, we estimate that our existing cash and cash equivalents as of the date of this prospectus, together with the estimated net proceeds from this offering, will be sufficient to fund our projected operating expenses and capital expenditure requirements into the first quarter of 2028. Our future capital requirements and the period over which our existing resources will support our operations may vary significantly from what we expect, and we will in any event require additional capital in order to complete clinical development of our current programs. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our product candidates and programs is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and future commercialization activities, if any. Our future capital requirements will depend on many factors, including:

- the scope, timing, progress, costs and results of discovery, preclinical development, and clinical trials for our current or future product candidates;
- the number of clinical trials required for regulatory approval of our current or future product candidates, which may differ between the United States and other countries or regions;
- the costs, timing and outcome of regulatory review of any of our current or future product candidates;
- the costs associated with potentially acquiring or licensing additional product candidates, technologies or assets, including the timing and amount of any milestones, royalties or other payments due in connection with our acquisitions and licenses;
- the cost of manufacturing clinical and commercial supplies of our current or future product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any possible claims by third parties that we are infringing upon their intellectual property rights;
- our ability to establish and maintain possible future strategic collaborations or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution, for any product candidate for which we receive regulatory approval;
- the revenue, if any, received from commercial sales of the product candidate(s) for which we receive regulatory approval;

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- expenses to attract, hire and retain skilled personnel;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors for any products that receive regulatory approval;
- our ability to mitigate the impact of adverse macroeconomic conditions or geopolitical events and conflicts, including any health epidemics and their residual effects, bank failures or inflation and increased interest rates, on our preclinical and clinical development or operations;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies.

We will require substantial additional capital in addition to the proceeds of this offering to achieve our business objectives, which we may raise through public or private equity offerings, debt financings or other capital sources, including strategic collaborations, licenses and other similar arrangements to enable us to complete the development and potential commercialization of our product candidates. Additional funds may not be available on a timely basis, on favorable terms or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. Additionally, if we raise additional funds through future collaborations, licenses and other similar arrangements, we may have to relinquish valuable rights to our future revenue streams or product candidates or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock. Market volatility resulting from potential negative global economic conditions and disruptions in the United States and international credit and financial markets including due to geopolitical conflicts, tariffs, other fiscal and trade policy changes, bank failures, supply chain and labor disruptions, the effects of a health epidemic or pandemic or other factors may further adversely impact our ability to access capital as and when needed. Our failure to raise capital as and when needed would have a negative effect on our financial condition and our ability to pursue our business strategy. In addition, attempting to secure additional financing may divert the time and attention of our management from day-to-day activities and harm our development efforts.

In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. Any future debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we would be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

The report of our independent registered public accounting firm included a “going concern” explanatory paragraph.

We have concluded that there is substantial doubt about our ability to continue as a going concern, and the report of our independent registered public accounting firm on our financial statements as of and for the year

ended December 31, 2025 included an explanatory paragraph indicating that there was substantial doubt about our ability to continue as a going concern. If we are unable to raise additional capital as and when needed, our business, financial condition and results of operations will be materially and adversely affected, and we may be forced to delay our development efforts, limit our activities and reduce research and development costs. If we are unable to continue as a going concern, we may have to liquidate our assets, and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. The inclusion of a going concern explanatory paragraph by our independent registered public accounting firm, our limited cash resources and our potential inability to continue as a going concern may materially adversely affect our ability to raise new capital, enter into licensing and collaboration arrangements or other contractual relationships with third parties and otherwise execute our development strategy.

Risks related to the discovery, development and regulatory approval of our product candidates

Our discovery and development programs are focused in part on precision medicines for patients with genetically defined cancers, which is a rapidly evolving and scientifically uncertain field, and our scientific approach, including with respect to BH-30643 and BH-30236, may never lead to marketable products.

The discovery and development of precision medicines for patients with genetically defined cancers is an emerging field, and the scientific discoveries that form the basis for our efforts to discover and develop product candidates are relatively new. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and limited. Although we believe, based on our preclinical work and preliminary clinical trial results, that the mutations targeted by certain of our programs are oncogenic drivers, future clinical results may not confirm this hypothesis, or may only confirm it for certain mutations or certain tumor types.

The patient populations for certain of our product candidates are limited to those with specific target mutations and may not be completely defined, but are substantially smaller than the general treated cancer population. We may need to screen and identify these patients with the targeted mutations, and successful identification is dependent on several factors, including achieving certainty as to how specific genetic alterations respond to our product candidates and developing companion diagnostics to identify such genetic alterations. Even if we are successful in identifying patients, we cannot be certain that the resulting patient populations for each targeted mutation will be sufficient to allow us to successfully complete clinical trials and obtain approval for each targeted mutation type or, if approved, to successfully commercialize our product candidates and achieve profitability.

In addition, our scientific approach to design novel chemical scaffolds to overcome specific structural liabilities that limit existing therapies or approaches may not be successful in addressing these limitations or creating product candidates that ultimately succeed in development, regulatory approval or commercialization. Even if our approach demonstrates clinical benefit for tumors harboring the targeted mutations that drive the diseases for which we are developing our product candidates, we may never successfully identify additional oncogenic mutations sufficient to obtain regulatory approvals with respect to such mutations. In addition, the heterogeneity of the tumor resistance environment our clinical product candidates are targeting heightens the risk around attempting to overcome both on- and off- target tumor resistance. We may also be unsuccessful in using our approach to identify additional product candidates, and any of our product candidates may be shown to have harmful side effects or other characteristics that necessitate additional clinical testing or make them unmarketable or unlikely to receive or maintain regulatory approval. In particular, any failure of one of our development programs—or a competitor's product or program pursuing a similar approach—could create a perception that our other programs are less likely to succeed or that our overall approach is not viable.

We believe we have had favorable preclinical study and early clinical trial results; however, we are early in our development efforts, including with respect to BH-30643 and BH-30236, and may not succeed in demonstrating the efficacy and safety of any product candidate in clinical trials or in obtaining regulatory approval thereafter. We also cannot be certain that our scientific and development approach, including with respect to BH-30643 and BH-30236, will result in an approvable or marketable product with commercial value in our initial targeted indications or any other indication.

Further, the pharmaceutical industry is characterized by rapidly advancing technologies, and our future success will depend in part on our ability to maintain a competitive position. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Our competitors may render our approach obsolete or limit the commercial value of our scientific approach or product candidates through advances in existing technologies or the development of new or different approaches. Conversely, adverse developments with respect to other companies pursuing a similar approach may adversely impact the actual or perceived value of our approach and the potential of our product candidates.

Therefore, we do not know whether our approach, including development of product candidates in genetically defined cancers, will be successful, or whether our specific development programs for BH-30643 and BH-30236 will yield approvable or commercially viable products. If our approach or our individual programs are unsuccessful, the value of our company could decline significantly.

We are early in our development efforts and only have two product candidates, BH-30643 and BH-30236, in early clinical development. Our pan-KRAS product candidate, BH-501284, is in the preclinical stage. If we are unable to continue to advance our product candidates through or into clinical development, obtain regulatory approval and ultimately commercialize our product candidates or we experience significant delays in doing so, our business will be materially harmed.

We are in the early stages of our development efforts and are substantially dependent on the success of our product candidates, BH-30643 and BH-30236, which are in early clinical development. Our pan-KRAS product candidate BH-501284 is in the preclinical stage. We will need to progress BH-30643 and BH-30236 through our ongoing and planned clinical trials and progress BH-501284 and any future development program through preclinical studies and submit INDs to the FDA or comparable foreign regulatory applications to applicable foreign regulatory authorities prior to initiating their clinical development. We will also need to submit INDs or comparable foreign regulatory applications prior to expanding development of our product candidates beyond our initial development focus into other distinct patient populations.

Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual successful commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following:

- completion of preclinical studies with favorable results;
- successful enrollment in, and completion of, clinical trials with favorable results;
- sufficiency of our financial and other resources to complete necessary preclinical studies and clinical trials;
- allowance to proceed with clinical trials under INDs by the FDA or under similar regulatory submissions by applicable foreign regulatory authorities for the conduct of clinical trials of our product candidates and our proposed design of future clinical trials;
- demonstrating the safety and efficacy of our product candidates to the satisfaction of the FDA and other applicable foreign regulatory authorities;

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- receipt of regulatory approvals from applicable regulatory authorities, including new drug applications (NDAs) from the FDA and approvals from comparable foreign regulatory authorities and maintaining such approvals;
- making arrangements with third-party manufacturers, to manufacture sufficient quantities of product candidates for clinical and potential commercial use;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of any products we develop and their benefits and uses, if and when approved, by patients, the medical community and third-party payors;
- establishing and maintaining intellectual property protection, including patent and trade secret protection, or regulatory exclusivity for our product candidates;
- effectively competing with other approved therapies or therapies that may be approved in the future;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors;
- maintaining an acceptable safety profile of our products following approval; and
- building and maintaining an organization of people who can successfully develop our product candidates.

We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials or in obtaining regulatory approval thereafter. Given our early stage of development, it will take several years before we can demonstrate the safety and efficacy of a product candidate sufficient to warrant regulatory approval for commercialization, if we can do so at all. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize, our product candidates, we may not be able to generate sufficient revenue, or any revenue at all, to continue our business.

Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial or real-world results. Our product candidates may not have favorable results in preclinical studies or clinical trials or receive regulatory approval on a timely basis, if at all.

BH-30643 and BH-30236 are in clinical development and their risk of failure is high. It is impossible to predict when or if our product candidates will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize our product candidates, we must demonstrate through lengthy, complex and expensive clinical trials that our product candidates are safe and effective in patient populations for the intended indication(s) for use.

Preclinical studies and clinical trials can take many years to complete, and their outcomes are inherently uncertain. Failure can occur at any time during the preclinical study or clinical trial process, despite promising preclinical or clinical results. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, and results in one indication may not be predictive of results to be expected for the same product candidates in another indication. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unfavorable safety profiles, notwithstanding promising results in earlier trials. Such setbacks have occurred and may occur for many reasons, including, but not limited to: clinical sites and investigators may deviate from clinical trial protocols, whether due to lack of training or otherwise, and we may fail to detect any such deviations in a

timely manner; patients may fail to adhere to any required clinical trial procedures, including any requirements for post-treatment follow-up; our product candidates may fail to demonstrate effectiveness or safety in certain patient subpopulations, or even in the target patient population, which has not been observed in earlier trials due to limited sample size, lack of analysis, or otherwise; or our clinical trials may not adequately represent the patient populations we intend to treat, whether due to limitations in our trial designs or otherwise, such as where one patient subgroup is overrepresented in the clinical trial. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates achieved promising results have nonetheless failed to obtain regulatory approval of such product candidates or, upon commercialization, achieve or maintain positive real-world results.

Furthermore, because our clinical trials for BH-30643 and BH-30236 are conducted primarily in patients with advanced disease whose prior therapies have not been effective, or have failed due to resistance, including resistance mutations and resistance due to biological mechanisms partially- or un-related to their prior therapies, patients may experience disease progression independent from our product candidates, which may make them unevaluable for purposes of the clinical trial and may require additional patient enrollment. For example, certain patients enrolled in the C797S resistance cohort of our SOLARA trial of BH-30643 have progressed following treatment with a third-generation EGFR TKI, representing a population for whom prior targeted therapy has already failed. Similarly, patients enrolled in our Phase 1 clinical trial of BH-30236 have R/R AML or HR-MDS, representing a population for whom prior treatments have not been effective or on which patients have relapsed. Because we are conducting trials in patients who are already sick and for whom prior treatments have not been effective, the clinical activity and tolerability results we observe may not be representative of what could be observed in patients earlier in the treatment continuum, including patients with less advanced disease or who have not yet been exposed to prior therapies. Inclusion of patients with significant co-morbidities in our clinical trials may also result in deaths or other adverse medical events due to an underlying condition or other therapies or medications that such patients may be using, which could prevent us from obtaining regulatory approval or, if approved, achieving or maintaining market acceptance.

Additionally, development risks may be heightened for targeted indications (such as C797S-positive NSCLC) or treatment mechanisms (such as CLK inhibition for BH-30236) where no approved targeted therapies currently exist, as there is limited regulatory and clinical precedent to guide development. We will also face distinct risks in target indications where established standards of care or competing approved therapies already exist, including in first-line NSCLC where osimertinib and other approved therapies are well-established standards of care. Clinical trials designed to support approval in earlier-line settings are likely to require randomized controlled designs with active comparator arms and primary endpoints based on progression-free or overall survival, rather than the ORR endpoints that may support approval in later-line settings with no approved alternative therapies. The probability of clinical success in these trials may be materially lower than in our initial indications, where the absence of approved targeted therapies provides a more favorable regulatory and clinical benchmark.

Future expansion of our development programs into additional hematologic malignancies and/or solid tumors and commencing any future clinical trials, including for BH-501284, is subject to finalizing the clinical trial protocol and submitting an IND to the FDA or a similar application to a comparable foreign regulatory authority to initiate a clinical trial. Even after we make our submission, the FDA or comparable foreign regulatory authorities could disagree that we have satisfied their requirements to commence our clinical trials in the manner we propose or disagree with our trial design, which may require us to complete additional preclinical studies or amend our protocols or impose stricter conditions on the commencement of clinical trials, which may lead to delays and increase the costs of our preclinical development programs.

Most product candidates that commence clinical trials are never approved as commercial products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support the approval of our current or any future product candidates, or our need to raise additional capital.

We may experience delays in initiating or completing clinical trials or reporting data readouts for such trials, due to unforeseen events or otherwise, that could delay or prevent our ability to receive regulatory approval or commercialize our current and any future product candidates, including:

- regulators, such as the FDA or comparable foreign regulatory authorities, Institutional Review Boards (IRBs) or ethics committees may impose additional requirements before permitting us to initiate a clinical trial, may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site, may not allow us to amend trial protocols or regulators may disagree as to the design or implementation of our clinical trials and require that we modify or amend our clinical trial protocols or statistical analysis plans;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with contract research organizations (CROs) or with individual clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional patients or withdrawing their approval of the trial;
- changes or amendments to the clinical trial protocol;
- clinical trial sites may deviate from the trial protocol, fail to ensure the integrity of the data being collected at the site or drop out of a trial;
- failure by any of our third-party contractors to perform in accordance with good clinical practices (GCP) requirements or applicable regulatory rules and guidelines in other countries;
- the number of patients required for clinical trials may be larger than we anticipate, we may experience difficulty in finding and enrolling sufficient qualified patients for our trials, enrollment in clinical trials may be slower than we anticipate, prospective patients may fail to qualify for enrollment into our clinical trials or patients may drop out or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- patients may fail to enroll or remain in our trials at the rate we expect, or fail to return for post-treatment follow-up, including patients failing to remain in our trials due to movement;
- patients choosing an alternative product for the indications for which we are developing our product candidates, or participating in competing clinical trials;
- the cost of clinical trials may be greater than we anticipate;
- the quality or quantity of data relating to our product candidates or other materials necessary to conduct our clinical trials may be inadequate to initiate or complete a given clinical trial;
- we may experience difficulties in manufacturing, or fail to manufacture, sufficient quantities of our product candidates for use in clinical trials;
- patients experiencing severe or serious unexpected drug-related adverse effects;
- reports from clinical testing conducted by other companies of other therapies in the same class of agents that could be considered similar to our product candidates may raise safety, tolerability or efficacy concerns about our product candidates;

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- we may lack adequate funding to initiate or continue one or more of our clinical trials;
- selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently suspend production due to violations of current Good Manufacturing Practice (cGMP) regulations or other applicable requirements or cross-contaminations of product candidates in the manufacturing process;
- changes to our manufacturing processes may be necessary or desired;
- third-party contractors being unwilling or unable to satisfy their contractual obligations to us in a timely or accurate manner;
- third-party contractors could become debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our planned marketing applications; and
- clinical trials of our product candidates may fail to show appropriate safety, tolerability or efficacy, may produce negative or inconclusive results or may otherwise fail to improve on the existing standard of care, and we may decide, or regulators may require us, to conduct additional clinical trials or we may decide to abandon product development programs.

We may, in the future, conduct preclinical research and clinical trials in collaboration with other academic, pharmaceutical or biotechnology entities in which we combine our development efforts with those of prospective future collaborators. Such collaborations, if any, may be subject to additional delays because of the management of preclinical research and clinical trials, contract negotiations and the need to obtain agreement from multiple parties, which may increase our future costs and expenses.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations and guidelines, and remain subject to oversight by these governmental agencies as well as ethics committees or IRBs responsible for overseeing the conduct of clinical trials and ensuring the welfare of the patients participating in clinical trials of our product candidates. We could encounter delays if a clinical trial is suspended or terminated by us, our potential future collaborators, the IRBs of the institutions at which such trials are being conducted, the FDA or comparable foreign regulatory authorities or the Data Safety Monitoring Board for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, adverse findings from inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities, unforeseen safety issues or adverse side effects, failure to establish or achieve clinically meaningful clinical trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to regulators or to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results.

Many of the factors that cause, or lead to, a delay in the commencement or completion of, or the termination or suspension of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA may disagree with our interpretation of data from clinical trials or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials.

Our product development costs will increase if we experience delays in clinical testing or in seeking regulatory approvals. We do not know whether any of our clinical trials will begin as planned, will need to be redesigned or will be completed on schedule, or at all. Significant clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market either before we do or in a short time-frame after we do, potentially impairing our ability to successfully commercialize our product candidates, if approved. Any delays or increase in costs in our clinical development programs may harm our business, financial condition, results of operations and prospects.

We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Patient enrollment is a significant factor in the timing and success of clinical trials, and the timing of our clinical trials depends, in part, on the speed at which we can recruit and enroll patients to participate in our trials, as well as their completion of required follow-up periods. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA or comparable foreign regulatory authorities. In particular, because some of our product candidate development plans are focused on patients with specific genetic mutations, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. For example, with respect to BH-30643, we cannot be certain how many patients will have each of the genetic mutations that BH-30643 is designed to target or that the number of patients enrolled for each mutation will suffice to obtain regulatory approval for the targeted patient subset.

Patient enrollment is affected by many factors including the size and nature of the patient population, competing clinical trials in the same or similar indications or at the same trial site, the severity of the disease or condition under investigation, the availability and efficacy of approved drugs and diagnostics for the disease or condition under investigation, the number and location of clinical sites, the proximity of patients to clinical sites, willingness of patients to participate in a decentralized clinical trial that may involve remote monitoring technologies, the inclusion and exclusion criteria for the trial, perceived risks and benefits of the product candidate under study, the design of the clinical trial, continued enrollment of prospective patients by clinical trial sites, the risk that enrolled patients will not complete a clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, efforts to facilitate timely enrollment in clinical trials, patient referral practices of physicians, the ability to monitor patients adequately during and after treatment, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for, or any product candidates under investigation for, the indications we are investigating. Clinical trial recruitment and enrollment activities may also be delayed as a result of macro-factors such as public health emergencies or pandemics, natural disasters and acts of terror or war.

Even if we are able to enroll a sufficient number of patients in our clinical trials, we may have difficulty maintaining enrollment of such patients, and delays in enrollment or patients dropping out early in our clinical trials may result in increased costs or may affect the timing or outcome of our clinical trials. Any of these conditions may negatively impact our ability to complete such trials or include results from such trials in regulatory submissions, which could adversely affect our ability to advance the development of our product candidates.

Further, other pharmaceutical or biotechnology companies targeting these same diseases may be recruiting clinical trial patients from similar patient populations, which may make it more difficult to fully enroll our clinical trials. Our inability to enroll a sufficient number of patients for any of our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. In addition, we rely on

clinical trial sites to ensure proper and timely conduct of our clinical trials and, while we enter into agreements governing their services, we have limited influence over their actual performance.

We cannot assure you that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays in enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

Use of our product candidates could be associated with adverse side effects, adverse events or other safety risks, which could delay or preclude the candidate's approval, cause us to suspend or discontinue clinical trials, cause us to abandon the product candidates, limit the commercial profile of any future approved product or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics related to our product candidates. Undesirable side effects caused by our product candidates could cause us, the IRB or regulatory authorities to interrupt, delay or halt clinical trials or cause the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities, or, if such product candidate is approved, result in a more restrictive label and other post-approval requirements. Any treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or could result in potential product liability claims. Any of these occurrences may harm our business, financial condition, and prospects significantly.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in clinical trials, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

Patients in our ongoing and planned clinical trials have and in the future could suffer significant adverse events or other side effects whether or not observed in our preclinical studies or ongoing or previous clinical trials. For example, in our ongoing SOLARA Phase 1/2 clinical trial of BH-30643, treatment-related adverse events (TRAEs) were observed, including Grade 3 dose-limiting toxicities (DLTs) consisting of mucositis and bilirubin increase at higher dose levels and a Grade 4 alanine aminotransferase elevation. In our ongoing Phase 1 trial of BH-30236, TRAEs were observed, including cases of differentiation syndrome, all of which were Grade 2 and resolved with corticosteroid treatment, with or without dose interruption, and a Grade 3 DLT of diarrhea. In addition, we have and plan to continue to study our product candidates in combination with other therapies, which may exacerbate adverse events associated with such product candidates. For example, in our ongoing combination dose escalation of BH-30236 with venetoclax, TRAEs, including diarrhea, nausea, vomiting, decreased neutrophil count, decreased platelet count and decreased white blood cell count, were observed in the venetoclax combination arm. Further, patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidates but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. Furthermore, some of our product candidates may be evaluated in pediatric populations, for which safety concerns may be particularly scrutinized by regulatory agencies. Even if such side effects do not preclude the product candidates from obtaining or maintaining regulatory approval, undesirable side effects may inhibit market acceptance due to tolerability concerns as compared to other available therapies. Any of these developments could materially harm our business, financial condition and prospects.

Additionally, if our product candidates receive regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For

example, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of treatment with such product candidates outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. Other potentially significant negative consequences associated with post-marketing identification of adverse events or other safety risks include:

- we may be required to suspend marketing of a product, or we may decide to remove such product from the marketplace;
- regulatory authorities may withdraw or modify their approvals of a product;
- regulatory authorities may require additional warnings or new contraindications on the label, or may limit access of a product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of a product for patients, or to conduct post-marketing studies;
- we may be required to change the way a product is distributed or administered;
- we could be subject to fines, injunctions or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to patients; and
- a product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of our product candidates, if approved by the FDA or other regulatory authorities.

We are currently developing and may in the future develop our product candidates in combination with other therapies, and safety or supply issues with combination-use products may delay or prevent development and approval of our product candidates.

We are currently developing and may in the future develop our product candidates in combination with one or more cancer therapies. For example, we are currently evaluating the use of BH-30236 as a combination therapy with venetoclax in patients with R/R AML and HR-MDS and we are planning to evaluate the use of BH-30643 as a combination therapy with carboplatin and pemetrexed in adults with locally advanced or metastatic NSCLC harboring EGFR or HER2 mutations. Even if any product candidate we develop were to receive regulatory approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product candidates or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other drugs or for indications other than cancer. Similarly, if the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA or similar regulatory authorities outside of the United States may require us to conduct additional clinical trials, which may experience complications surrounding trial execution, such as complexities surrounding trial design, establishing trial protocols and interpretability of results, clinical trial site access and initiation, patient recruitment and enrollment, quality and supply of clinical drug product, safety issues or a lack of clinically relevant activity. The uncertainty resulting from the use of our product candidates in combination with other approved or unapproved therapies may make it difficult to accurately

predict or evaluate side effects in clinical trials, or to evaluate the contribution of each component therapy to the potential efficacy of the combination therapy. The occurrence of any of these risks could result in our own products, if approved, being removed from the market if they are not also approved as monotherapies or being less commercially successful.

We may also evaluate our product candidates in combination with one or more cancer therapies that have not yet been approved for marketing by the FDA or a similar regulatory authority outside of the United States. We may be unable to effectively identify and collaborate with third parties for the evaluation of our product candidates in combination with their therapies. We will not be able to market and sell any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain regulatory approval. The regulations prohibiting the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA and other government agencies. In addition, there are additional risks similar to the ones described for our products currently in development and clinical trials that result from the fact that such cancer therapies are unapproved, such as the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval.

If the FDA or a similar regulatory authority outside of the United States does not approve these other drugs or revokes approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval of or market such product.

Additionally, if the third-party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We may expend our limited resources to pursue a particular product candidate or a particular indication and fail to capitalize on product candidates or indications that may present a greater commercial opportunity or for which there is a greater likelihood of success.

Because we have limited resources, we must choose to pursue and fund the development of specific product candidates. Our resource allocation and other decisions may cause us to fail to identify and capitalize on viable potential product candidates or additional indications or other profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular indication or product candidate, we may relinquish valuable rights to that product candidate through collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidates.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes to the final data.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which are based on preliminary analyses of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular preclinical study or clinical trial. We also make assumptions, estimations, calculations and conclusions as part of our data analyses, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same

studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Unfavorable differences between interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and could adversely affect the success of our business. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects. Further, disclosure of interim, topline or preliminary data by us or by our competitors could result in volatility in the price of our common stock after this offering.

Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time-consuming and uncertain and may prevent us or any future collaboration partners from obtaining approvals for the commercialization of our product candidates.

Our product candidates and the activities associated with their discovery, development and commercialization, including their design, testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, import, export, marketing and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States, and by comparable foreign regulatory authorities. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we may seek to develop in the future will ever obtain regulatory approval. We have no experience in filing and supporting the applications necessary to gain regulatory approvals. Although we believe that we have the capabilities to conduct preclinical studies and clinical trials and to eventually submit regulatory approval applications using our internal resources, we selectively employ and may in the future rely on CROs or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive, often takes many years following the commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product

candidates involved, as well as the target indications and patient populations. For example, our product candidates may receive greater scrutiny because they contain novel chemical scaffolds. Changes in regulatory approval policies during the development period, changes in existing, or the enactment of additional, statutes or regulations or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Despite the time and expense invested in clinical development of product candidates, regulatory approval of a product candidate is never guaranteed. Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or execution of our clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance or persuasiveness required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected drug-related side effects may be experienced by patients in our clinical trials or by individuals using drugs similar to our product candidates;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials that are conducted at clinical facilities or in countries where the standard of care is potentially different from that of their own country;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree with us regarding the formulation, labelling and/or the product specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than those sought by us, and/or may include significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes or facilities of the third-party manufacturers with which we contract for clinical and commercial supplies; or
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods, and agreements with pricing authorities.

Even if we eventually complete clinical trials and receive approval of an NDA or comparable foreign marketing application for our product candidates, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials and/or the implementation of a REMS, which may be required because the FDA believes it is necessary to ensure safe use of the product after approval.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates, including for other targeted indications, may be harmed and our ability to generate revenues will be materially impaired.

Additionally, even if we eventually complete clinical trials and receive regulatory approval of any of our product candidates, the FDA or comparable foreign regulatory authority may approve our product candidates for a more limited indication or a narrower patient population than we originally requested. Even if regulatory approval is obtained for a particular indication, there is no guarantee that additional indications will be approved, which could materially limit the commercial potential of any approved product. In particular, there can be no assurance that BH-30643, BH-30236 or any of our other product candidates will receive regulatory approval for second-line or first-line treatment settings, and our failure to obtain approval for use in earlier lines of the treatment paradigm would materially limit our addressable patient population and could have a material adverse effect on our business, financial condition, results of operations and prospects.

We are conducting and plan to conduct additional clinical trials for our product candidates outside the United States and the FDA may not accept data from such trials.

We are conducting and plan to conduct additional clinical trials outside the United States. For example, we are conducting a global Phase 1/2 clinical trial of BH-30643 in adult patients with locally advanced or metastatic NSCLC harboring EGFR and/or HER2 mutations at sites outside of the United States, including in Australia, Canada, Hong Kong, Japan, Malaysia, Singapore, South Korea and Taiwan. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of such trial data by the FDA is subject to certain conditions.

Where data from foreign clinical trials are intended to serve as the sole basis for regulatory approval in the United States, regardless of whether such clinical trials were conducted pursuant to an IND, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice, the clinical trials were performed by clinical investigators of recognized competence and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign trial data are not intended to serve as the sole basis for approval, if the study was not otherwise subject to an IND, the FDA will not accept the data as support for an application for regulatory approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. In addition, such clinical trials would be subject to the applicable local laws of the foreign jurisdictions where the clinical trials are conducted. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept any such data, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay aspects of our development plan.

In addition, the conduct of clinical trials outside the United States could have a significant impact on us. Risks inherent in conducting international clinical trials include:

- foreign regulatory requirements that could burden or limit our ability to conduct our clinical trials;

- difficulties staffing and managing foreign operations;
- compliance with legal requirements applicable to privacy, data protection, information security and other matters;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including value-added tax, withholding and payroll taxes;
- administrative burdens of conducting clinical trials under multiple foreign regulatory schema;
- foreign exchange fluctuations;
- manufacturing, customs, shipment and storage requirements;
- impact of geopolitical events or a public health crisis on our ability to produce our product candidates and conduct clinical trials in foreign countries;
- potential liability under the Foreign Corrupt Practices Act of 1977, as amended (FCPA), or comparable foreign regulations;
- cultural differences in medical practice and clinical research; and
- diminished protection of intellectual property in some countries.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

We may seek regulatory approval for our product candidates outside the United States. Foreign regulatory authorities have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants regulatory approval of a product candidate, comparable regulatory authorities in foreign jurisdictions also must approve the manufacturing, marketing and promotion of the product candidate in those jurisdictions. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In addition, in some jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products also is subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with the regulatory requirements in international markets and/or receive and maintain applicable regulatory approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed, which could adversely affect our business, results of operations and financial condition.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates progress through clinical trials to regulatory approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize safety, efficacy, stability, purity, yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve their intended objectives and/or may lead to delays and additional costs. For example, we intend to move to a tablet formulation of BH-30643 in expansion cohorts of our ongoing clinical trial and may potentially modify the formulation of other product candidates in future clinical trials. The formulation and any other changes we may make to our product candidates may cause such candidates to perform differently than in prior clinical trials, or could negatively affect our ability to utilize or interpret our existing data. Such changes could delay initiation or completion of clinical trials, lead to negative trial results, require the conduct of bridging studies or clinical trials or the repetition of one or more studies or clinical trials, increase development costs, delay potential regulatory approval and jeopardize our ability to commercialize our product candidates or generate revenue.

We may fail to obtain orphan drug designations from the FDA for our product candidates, and even if we obtain such designations, we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs designed to address relatively small patient populations as “orphan drugs.” Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States, where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan designation entitles a party to financial incentives such as opportunities for grant funding for clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate that has orphan designation subsequently receives the first FDA approval within the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same drug for the same approved use or indication within such rare disease or condition for seven years, except in limited circumstances.

In March 2026, the FDA granted orphan drug designation to BH-30236 for the treatment of AML. We may seek orphan drug designations for BH-30236 in other diseases or conditions or for our other product candidates. There can be no assurances that we will be able to obtain such designations. Even if we, or any future collaborators, obtain orphan drug designation for a product candidate, we, or they, may not be able to obtain or maintain orphan drug exclusivity for that product candidate. Further, even if we, or any future collaborators, obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active ingredients may be approved for the same uses or indications. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same use or indication within the same rare disease or condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care with respect to the exclusivity-protected use or indication, or if the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity to meet the needs relating to the relevant indication or use. Orphan drug designation neither shortens the development or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

We may seek approval of our product candidates, where applicable, under the FDA's accelerated approval pathway. This pathway may not lead to faster development, regulatory review or approval process and it does not increase the likelihood that our product candidates will receive regulatory approval.

We may seek approval of product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug or biologic over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective.

As a condition of approval, the FDA generally requires that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled confirmatory clinical trials. These confirmatory trials must be completed with due diligence. The FDA is permitted to require that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of accelerated approval was granted. Sponsors are required to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must post this information publicly. The FDA also has authority to withdraw approval of a drug granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. The FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress. In addition, the FDA currently requires, unless otherwise informed by the FDA, pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Furthermore, if we decide to submit an application for accelerated approval for our product candidates, there can be no assurance that such application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

If we are required by the FDA to obtain approval of a companion diagnostic in connection with approval of any of our product candidates, and we do not obtain, or face delays in obtaining, FDA approval of such companion diagnostic, we will not be able to commercialize such product candidate and our ability to generate revenue will be materially impaired.

According to FDA guidance, if the FDA determines that a companion diagnostic is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic

product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. The process of obtaining or creating such diagnostic is time consuming and costly.

Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable foreign regulatory authorities, and the FDA has generally required premarket approval of companion diagnostics for cancer therapies. The approval or clearance of a companion diagnostic as part of the therapeutic product's further labeling limits the use of the therapeutic product to only those patients who express the specific characteristic that the companion diagnostic was developed to detect.

If the FDA or a comparable foreign regulatory authority requires approval or clearance of a companion diagnostic for any of our product candidates, whether before or after the product candidate obtains regulatory approval, we and/or any future third-party collaborators may encounter difficulties in developing and obtaining approval or clearance for these companion diagnostics. Any delay or failure by us or any future third-party collaborators to develop or obtain regulatory approval or clearance of a companion diagnostic could delay or prevent approval or continued marketing of the relevant product. For example, we are conducting clinical trials for BH-30643 in a genetically defined patient population having the C797S mutation in EGFR+ NSCLC, and if or when we are able to obtain clinical data supportive of approval of BH-30643 by the FDA, we may be required to obtain FDA approval for a companion diagnostic to identify patients with the C797S mutation before we are able to obtain approval for the use of BH-30643 within this patient population. We, or our future collaborators, may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our product candidates, if approved, on a timely or profitable basis, if at all.

Risks related to our business and operations

We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business.

As of March 31, 2026, we had 63 full-time employees. As we continue development and pursue the potential commercialization of our product candidates, and as we transition into operating as a public company, we expect to expand our employee base for managerial, development, regulatory, financial, legal, business development, information technology, marketing and sales capabilities, or contract with third parties to provide these capabilities for us. In the future, we expect to have to manage additional relationships with licensees or licensors, collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial, and management controls, reporting systems and procedures, which may lead to significant costs and may divert management attention. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our inability to successfully manage our growth and expand our operations could adversely affect our business, financial condition, results of operations and prospects.

We are dependent on the services of our management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer. In addition, prior successes of our personnel may not be indicative of our future success.

Our success depends in part on our continued ability to attract, retain, and motivate highly qualified management, clinical, and scientific personnel. We are highly dependent upon our Chief Executive Officer and other members of our management team. The loss of services of any of these individuals could delay or prevent

the successful development and commercialization of our product candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain "key person" life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals. In addition, although our leadership team and other key personnel previously played key roles in the design, development, and commercialization of commercially successful targeted cancer therapies, no assurance can be given that their prior successes will be indicative of our future success.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among pharmaceutical, biotechnology and other businesses, particularly in the greater San Diego area. If we are not able to attract, integrate, retain, and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our employees, independent contractors, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our current and any future employees, independent contractors, consultants, commercial partners, CROs, third-party manufacturers and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with FDA or other regulations, provide true, complete and accurate information to the FDA and other comparable foreign regulatory authorities, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. If we obtain FDA approval of our product candidates and begin commercializing one or more products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are likely to increase. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal, and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations or reputational harm.

Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could adversely affect our business, financial condition, results of operations and prospects.

As we conduct clinical trials of our current or future product candidates, we are exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of new treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in obtaining approval for, and marketing products, such claims or certain adverse event trends could result in an investigation by the FDA, comparable foreign regulatory authorities or other regulators into the safety and efficacy of our future approved products, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used, or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our future approved products, termination of clinical trial sites or entire trial programs, withdrawal of patients in our clinical trials, injury to our reputation and significant negative media attention, significant costs to defend the related litigation, a diversion of management's time and our resources from our business operations, substantial monetary awards to trial patients, loss of revenue, the inability to commercialize any products that we may develop and a decline in our stock price. We may need to obtain higher levels of product liability insurance for later stages of clinical development or marketing our product candidates. Any insurance we may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could adversely affect our business, financial condition, results of operations and prospects.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, clinical trials, and directors' and officers' liability insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, financial condition, results of operations and prospects.

If our information technology systems or those of third parties upon whom we rely, or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits and other adverse consequences.

We rely on computer systems, hardware, software, technology infrastructure and online sites and networks for both internal and external operations that are critical to our business, or collectively, information technology systems. We own and manage some of these information technology systems, but also rely on third parties for a range of information technology systems and related products and services. Additionally, in the ordinary course of business, we and the third parties upon whom we rely, collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share, or collectively, process, personal data and other sensitive information, including proprietary and confidential business information, trade secrets, intellectual property, information we collect about patients in connection with clinical trials, and sensitive third-party information, or collectively, sensitive data.

As a result, we and the third parties upon whom we rely face a variety of evolving threats that could threaten the confidentiality, integrity, and availability of our information technology systems and sensitive data, or those of the third-parties upon whom we rely. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties upon whom we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers,"

threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon whom we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our information technology systems and operations.

We and the third parties upon whom we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by artificial intelligence (AI), telecommunications failures, earthquakes, fires, floods and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

It may be difficult and/or costly to detect, investigate, mitigate, contain and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties upon whom we rely to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, sensitive data losses and disruptions of our business and information technology systems. Threat actors may also gain access to other networks and systems after a compromise of our data and information technology systems.

Remote work has increased risks to our information technology systems and sensitive data, as more of our personnel utilize network connections, computers and devices outside our premises or network, including working at home, while in transit or in public locations. Additionally, future business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities’ systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third parties could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on various third parties and technologies to operate critical information technology systems and to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, personnel email and other functions. We also rely on third parties to provide other products, services, parts or otherwise to operate our business, including with respect to our cybersecurity infrastructure. Our ability to monitor these third parties’ information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties upon whom we rely experience a security incident or other interruption, we could experience adverse consequences that materially impact our business.

While we may be entitled to damages if such third parties fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such

award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or that of the third parties upon whom we rely have not been compromised.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of or access to our sensitive data or our information technology systems, or those of the third parties upon whom we rely. For example, we have been the target of unsuccessful phishing attempts in the past, and expect such attempts to continue in the future. While to date no incidents have had a material impact on our operations or financial results, we cannot guarantee that material incidents will not occur in the future.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, regulators and investors, of security incidents, or take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience material adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant material consequences may negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage, if any, will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect or infer sensitive data about us from public sources, data brokers or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive data that we possess could be leaked, disclosed or revealed as a result of or in connection with our personnel's or vendors' use of AI Technologies (defined below) or AI-based cyber-attacks.

The adoption and deployment of AI and machine learning technologies in our operations, and in particular our R&D efforts, may not be effective and may expose us to risk.

We use AI and machine learning (AI Technologies) in our business and expect to make investments in this area.

We expect that investment will be required in the future to continuously improve our use of AI Technologies. As with many technological innovations, there are significant risks involved in developing, maintaining and

deploying these technologies and there can be no assurance that the usage of or our investments in such technologies will always enhance our products or services or be beneficial to our business, including our efficiency or profitability.

Any sensitive data that we input into a third-party generative AI Technology could be leaked or disclosed to others, including if sensitive data is used to train the third parties' AI Technology. Additionally, where an AI Technology model ingests personal data and makes connections using such data, those AI Technologies may reveal other personal or sensitive data generated by the model.

AI Technologies may create flawed, incomplete, or inaccurate outputs, some of which may appear correct. This may happen if the inputs that the model relied on were inaccurate, incomplete or flawed (including if a bad actor "poisons" the AI Technology with bad inputs or logic), or if the logic of the AI Technology is flawed. We or third parties upon which we rely may rely on outputs from AI Technologies to make certain decisions. Due to these potential inaccuracies or flaws, the model could be biased and could lead us to make decisions that could bias certain individuals (or classes of individuals), and adversely impact their rights, employment, and ability to obtain certain pricing, products, services, or benefits. Moreover, the information technology and cybersecurity risks described in the above risk factor apply to AI Technologies, which expand the potential attack surface and compound traditional cybersecurity risks. Given the nature of AI Technologies, any issues experienced by us or third parties upon whom we rely could pose significant impact across workflows or operations.

The development and use of AI Technologies also present various privacy and security risks that may impact our business. For example, AI Technologies are subject to privacy and data security laws, as well as increasing regulation and scrutiny. Several jurisdictions around the globe, including South Korea, Japan, and certain U.S. states, have proposed, enacted, or are considering laws governing the development and use of AI Technologies, such as Japan's Act on the Promotion of Research and Development and the Utilization of AI-Related Technologies, South Korea's Framework Act on the Development of Artificial Intelligence and Establishment of Trust (AI Basic Act) and the Colorado Artificial Intelligence Act (AIA). For example, the Colorado AIA sets out a risk-based framework, subjecting certain AI Technologies to numerous compliance obligations, including transparency, annual impact assessments, monitoring and human oversight requirements. Under the AIA, non-compliant companies may be subject to administrative fines of up to \$20,000 per violation (or more if the violation is committed against senior citizens) of the algorithmic discrimination provisions, as well as fines, injunctive relief, and other penalties to compensate for unfair or deceptive practices. Certain of our activities subject us to these comprehensive AI laws and depending on how these laws are implemented and interpreted, we may have to adapt our business practices, contractual arrangements, and services to comply with such obligations. We expect other jurisdictions will adopt similar laws and for existing laws to undergo amendment and evolution based on regulatory and judicial application and interpretation.

Additionally, certain privacy laws extend rights to consumers (such as the right to delete certain personal data) and regulate automated decision making, which may be incompatible with our use of AI Technologies. These obligations may make it harder for us to conduct our business using AI Technologies, lead to regulatory fines or penalties, require us to change our business practices, retrain our AI Technologies, or prevent or limit our use of AI Technologies. For example, the Federal Trade Commission has required other companies to turn over (or disgorge) valuable insights or trainings generated through the use of AI Technologies where they allege the company has violated privacy and consumer protection laws. If we cannot use AI Technologies or that use is restricted, our business may be less efficient, or we may be at a competitive disadvantage.

Our projections regarding the market opportunities for our product candidates may not be accurate and the actual market for our products may be smaller than we estimate.

The precise incidence and prevalence for the conditions we aim to address with our product candidates are unknown. Our projections of both the number of people who have these diseases, as well as the subset of

people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, which may include sales of our competitors, scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect in general, or as to their applicability to our company. Further, new clinical trials or research may change the estimated incidence or prevalence of these diseases. The total addressable market of our product candidates, if approved, will ultimately depend upon, among other things, the diagnosis criteria included in the final label for our product candidates approved for sale for these indications, if any, the ability of our product candidates to improve on the safety, convenience, cost, and efficacy of competing therapies or therapies in development, acceptance by the medical community and patients, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product, if approved, or our product candidates or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations and prospects.

Our business could be adversely affected by the effects of health pandemics, endemics or epidemics, which could cause significant disruptions in our operations and those of our current or future third-party manufacturers, CROs, and other third parties upon whom we rely.

Health pandemics, endemics or epidemics have in the past and could again in the future result in quarantines, stay-at-home orders, remote work policies or other similar events that may disrupt businesses, delay our research and development programs and timelines, negatively impact productivity and increase risks associated with cybersecurity, the future magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations. More specifically, these types of events may negatively impact personnel at third-party manufacturing facilities or the availability or cost of materials, which could disrupt our supply chain. Moreover, our clinical trials may be negatively affected. Clinical site activation and patient enrollment may be delayed due to prioritization of hospital resources. Some patients may not be able or willing to comply with trial protocols if quarantines impede patient movement or interrupt healthcare services. Our ability to recruit and retain patients, principal investigators and site staff (who as healthcare providers may have heightened exposure) may be hindered, which would adversely affect our clinical trial operations. Disruptions or restrictions on our ability to travel to monitor data from our clinical trials, or to conduct clinical trials, or the ability of patients enrolled in our clinical trials or staff at clinical trial sites to travel, as well as temporary closures of our clinical trial partners and third-party manufacturers' facilities, would negatively impact our clinical trial activities. In addition, we rely on independent clinical investigators, CROs and other third-party service providers to assist us in managing, monitoring and otherwise carrying out certain of our preclinical studies and clinical trials, including the collection of data from our clinical trials, and the effects of health pandemics, endemics or epidemics may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us. Similarly, our clinical trials could be delayed and/or disrupted. As a result, the expected timeline for data readouts, including incompleteness in data collection and analysis and other related activities, and certain regulatory filings may be negatively impacted, which would adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, if approved, increase our operating expenses, and adversely affect our business, financial condition, results of operations and prospects. In addition, impact on the operations of the FDA or comparable foreign regulatory authorities could negatively affect our planned clinical trials and approval processes. Finally, economic conditions and business activity may be negatively impacted and may not recover as quickly as anticipated.

Our business could be affected by litigation, government investigations and enforcement actions.

We currently operate in a number of jurisdictions in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States or

foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, contract, employment and other claims and legal proceedings that may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time-consuming. An adverse outcome resulting from any legal proceedings, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Even if such a proceeding, investigation or enforcement action is ultimately decided in our favor, the investigation and defense thereof could require substantial financial and management resources.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets, for which we may rely on collaboration with third parties. We are not permitted to market or promote our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market and may never receive such regulatory approval for our product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and do not receive applicable regulatory approvals on a timely basis, if at all, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. Our failure to obtain approval of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of such product candidates and our business, financial condition, results of operations and prospects could be adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements, and reduced protection of intellectual property rights in some foreign countries.

Our operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by a wildfire and earthquake or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are predominantly located in California. Any unplanned event, such as a flood, wildfire, explosion, earthquake, extreme weather condition, epidemic, endemic or pandemic, power outage, telecommunications failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities could adversely impact our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Any similar impacts of natural or manmade disasters on our third-party contract manufacturing organizations (CMOs) and CROs could cause delays in our clinical trials and may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. If a natural disaster, power outage or other event occurred that prevented us from using our clinical sites, impacted clinical supply or the conduct of our clinical trials, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or

that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we and our CMOs and CROs have in place may prove inadequate in the event of a serious disaster or similar event. In the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance we currently carry will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our CMOs or CROs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our development programs may be harmed. Any business interruption could adversely affect our business, financial condition, results of operations and prospects.

Risks related to our intellectual property

Our success depends in large part on our ability to obtain, maintain, enforce, and defend the scope, ownership or control, validity and enforceability of our intellectual property rights, and we may not be able to do so.

Our success depends in large part on our ability to obtain and maintain protection of the intellectual property we own (or may license in the future) including pursuing, obtaining and maintaining patent protection in the United States and other countries intended to cover the composition of matter of our product candidates, their manufacture, their methods of use, related technologies, and other inventions important to our business. In addition to patent protection, we may also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Accordingly, if we do not adequately pursue, obtain, maintain, protect or enforce our intellectual property rights to prevent the manufacture, sale or use of our inventions by others, including our competitors, our competitive advantage will be eroded, which will have a material adverse effect on our business, financial condition, results of operations and prospects.

We seek to protect our proprietary position by filing patent applications and enforcing resulting patents related to our product candidates and other technologies that are important to our business in the United States and select other countries. However, we cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our product candidates, the methods of use or the manufacture of those product candidates. If we are unable to obtain and maintain meaningful patent protection in jurisdictions important to our business for our product candidates, their respective components, formulations, methods of use, including combination therapies, methods used to manufacture them, or other proprietary technologies, our business, the financial condition, results of operations and prospects of our company could be adversely affected. The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain or license, if applicable, all necessary or desirable patent applications or enforce or defend resulting patents at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent rights of pharmaceutical and biotechnology companies, like ours, generally are highly uncertain, involve complex legal and factual questions and have been the subject of extensive litigation. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents, particularly those related to oncology, has emerged in the United States. The relevant patent laws and their interpretation outside of the United States are also uncertain. Various courts, including the U.S. Supreme Court, have rendered decisions that affect, for example, the scope of patent claims or the patent eligibility of certain inventions or discoveries relating to biotechnology. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. In addition, patent eligibility and the scope of patent protection outside the United States is uncertain, and laws of foreign countries may not protect our rights to the same extent as the laws of the United States or vice versa. For example, several foreign countries,

including India and countries in the Andean Community, severely limit or completely prohibit the patentability of methods of treatment of the human body. We cannot predict whether the patent applications we are currently pursuing will issue as patents that protect our technology and product candidates, in whole or in part, in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. Changes in either the patent laws or interpretation of the patent laws in the United States or other countries may diminish the value of our patents and our ability to obtain, maintain, protect, defend and enforce our patent rights, narrow the scope of our patent protection and, more generally, affect the value of our patent rights.

Further, third parties may have filed or will file patent applications on aspects of our technology that, once published or patented, may negatively affect our ability to pursue our own patent protection. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases are not published at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in the patents or patent applications we own or any patents or patent applications we may own in the future, or that we were the first to file for patent protection of such inventions. If a third party can establish that we were not the first to make or the first to file for patent protection of such inventions, our patent applications may not issue as patents and, even if issued, may be challenged and invalidated or rendered unenforceable. As a result, the issuance, ownership, inventorship, scope, validity, enforceability and commercial value of our patent rights are uncertain. For example, currently unpublished patent applications may later publish and limit our ability to obtain valid and enforceable patents.

Moreover, any issued patents we do obtain may be challenged, invalidated, or circumvented. We or any of our future licensors may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office (USPTO), or to a foreign patent office, or become involved in opposition, derivation, revocation, reexamination, inter partes review, post-grant review, interference proceedings, or litigation challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. If the breadth or strength of protection provided by any patents we obtain and patent applications we have filed is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Moreover, our competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents we may obtain.

Additionally, the breadth of the claims in a patent application can be significantly reduced during prosecution, and the scope of the granted claims can be reinterpreted after issuance. Even if our owned or any possible future in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and any patents we do obtain may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such challenges also may result in substantial cost and require significant time from our management and employees, even if the eventual outcome is favorable to us. Furthermore, our competitors may be able to circumvent any patents we obtain by developing similar or alternative technologies or products in a non-infringing manner. For these reasons, even if we are successful in obtaining patents in the future, our patent portfolio may not provide us with sufficient rights to exclude others

from using or commercializing technology and products similar or identical to any of our technology and product candidates for any period of time.

Patent terms may not protect our competitive position on our product candidates for an adequate amount of time.

Issued patents can provide protection for varying periods of time, depending, for example, upon the type of patent, the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. However, patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application filing date. The term of a patent outside of the U.S. varies in accordance with the laws of the foreign jurisdiction. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired we may be subject to competition from competitive products, including generics. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are approved for use or commercialized.

Third parties may allege that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on our business.

Our commercial success depends, in part, upon our ability and the ability of our possible future collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. There is considerable amount of patent and other intellectual property litigation in the pharmaceutical and biotechnology industries. We may become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to product candidates, including interference proceedings, post grant review, inter partes review and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, including our competitors, exist in the fields in which we are pursuing product candidates. In particular, the fields of molecularly targeted oncology therapies, including inhibition of oncogenic signaling pathways, as well as macrocyclic small molecule design are characterized by extensive patent portfolios held by established pharmaceutical and biopharmaceutical companies, and we cannot be certain that our product candidates, including BH-30643, BH-30236 and BH-501284, do not infringe existing or future patents held by such parties. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our technologies or product candidates or commercializing activities may be subject to claims that they infringe the patent rights of third parties. Our competitors and others may have significantly larger and more mature patent portfolios than we have. In addition, future litigation may be initiated by patent holding companies or other third parties who do not have a relevant product or service revenue and against whom our current and future patents, if any, may provide little or no deterrence or protection. Competitors may also assert that our product candidates infringe their intellectual property rights as part of a business strategy to impede our successful entry into those markets.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources and management attention to defend. The risks of being involved in such litigation and proceedings may increase if and as our product candidates near commercialization and as we gain greater visibility as a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future,

regardless of merit. Because patent applications can take many years to issue, and some may not publish prior to being granted, pending patent applications may result in issued patents that our product candidates may infringe. For example, there may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture, methods for use or methods for treatment related to the discovery, use or manufacture of our product candidates or technology. We may not be aware of all such intellectual property rights potentially relating to our technology and product candidates, or we may incorrectly conclude that a third-party's intellectual property is invalid and unenforceable or that our activities and product candidates do not infringe the intellectual property rights of third parties. Thus, we do not know with certainty that our technology and product candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third party's intellectual property rights. Parties making claims against us may also obtain injunctive or other equitable relief. For example, if any third-party patents were held to cover the manufacturing process of our product candidates, including any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidates. In the event of a successful claim of infringement against us, we may be enjoined from developing or commercializing the infringing products or technology; we may also have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, indemnify customers, future collaborators or other third parties, seek new regulatory approvals, and redesign our infringing products, which may not be possible or practical. If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we may be required to obtain a license from such third party to continue developing, manufacturing and marketing our technology and product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and the license terms could require us to make substantial licensing fees or royalty payments or both. Claims that we have misappropriated the confidential information, trade secrets or other intellectual property rights of third parties could have a similar material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims by third parties asserting that our employees, consultants or contractors have wrongfully used or disclosed confidential information of such third parties, or that they have wrongfully used or disclosed alleged trade secrets of their current or former employers, or that we have misappropriated their intellectual property, or that they own what we regard as our own intellectual property.

Many of our employees, physician or scientist partners, consultants and contractors are or were previously employed at or engaged by universities or other pharmaceutical or biotechnology companies, including our competitors or potential competitors. Many of them executed proprietary rights, non-disclosure and/or non-competition agreements in connection with such present or previous employment or engagement. A significant number of our key scientific and management personnel, including members of our founding team, previously worked at major pharmaceutical companies, and we cannot guarantee that prior employment agreements applicable to such individuals do not reach inventions or technologies that these individuals developed for us. Although we try to ensure that the individuals who work for us do not use the intellectual property rights, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or they have, inadvertently or otherwise, used, infringed, misappropriated or otherwise violated the intellectual property rights, or disclosed the alleged trade secrets or other proprietary and/or confidential information, of their former employers, competitors or other third parties. We may also be subject to claims that we have improperly used or obtained such trade secrets or other proprietary and/or confidential information. Litigation may be necessary to defend against these claims. Any litigation or the threat of litigation may adversely affect our ability to hire employees or engage consultants or contractors. A loss of key personnel or their work product could hamper or prevent us from developing and commercializing product candidates, which could harm our business.

In addition, while it is our policy to require our employees, physician or scientist partners, consultants and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in obtaining such an agreement from each party who in fact develops intellectual property that we regard as our own. Our intellectual property assignment agreements with them may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Additionally, assignment agreements and related agreements may be interpreted under the laws of the U.S. or a foreign country in a manner which may be unpredictable and may result in outcomes that negatively affect our claim to ownership. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we fail in prosecuting or defending any such claims, we may be required to pay monetary damages, and we may also lose valuable intellectual property rights or personnel, which could have a material adverse effect on our competitive position and prospects. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products, which license may not be available on commercially reasonable terms, or at all, or such license may be non-exclusive thereby giving our competitors and other third parties access to the same technologies licensed to us, and could require us to make substantial licensing fees or royalty payments or both. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and employees.

If we are unable to obtain, maintain, defend or enforce patent or other intellectual property protection for BH-30643, BH-30236, BH-501284, or any other of our product candidates that we may pursue or if the scope of the intellectual property protection we currently have or obtain in the future is not sufficiently broad, our competitors could develop and commercialize product candidates similar or identical to ours, and our ability to successfully commercialize BH-30643, BH-30236, BH-501284 and any other of our product candidates that we may pursue may be impaired.

In some instances, we submit patent applications directly with the USPTO as provisional patent applications. However, U.S. provisional patent applications are not eligible to become issued patents unless and until, among other things, we file a non-provisional patent application within 12 months of the provisional application filing date. With regard to such U.S. provisional patent applications, if we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. Failure to timely convert any such application could result in the loss of priority dates that are material to the protection of our product candidates. Any pending and future patent applications that we own may not result in patents being issued that protect our product candidates or technology, in whole or in part, or that effectively prevent others from commercializing competitive product candidates. The claimed scope in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage.

In addition, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or USPTO or foreign patent offices. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical product candidates to ours or limit the duration of the patent protection of our product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our

patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

If we are unable to protect the confidentiality of our trade secrets and other proprietary information, our business and competitive position would be adversely affected.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information to maintain our competitive position. We seek to protect our trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, our unpublished patent applications or other confidential research, and we may not be able to obtain adequate remedies for such breaches. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate such trade secrets, from using that technology or information to compete with us.

Furthermore, we expect that, over time, our trade secrets, know-how and proprietary information may be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel to and from academic and industry scientific positions. Consequently, without costly efforts to protect our proprietary technology, we may be unable to prevent others from exploiting that technology, which could affect our ability to expand in domestic and international markets. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely affected.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. These security measures may be breached or otherwise accessed in an unauthorized manner, and we may not have adequate remedies for any breach.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on any issued patent or application are due to be paid to the USPTO and patent agencies in foreign countries in several stages over the lifetime of the patent. The USPTO and patent agencies in foreign countries require compliance with a number of procedural, documentary, fee payment and other requirements during the patent application process. We currently maintain many pending patent applications and issued patents across numerous jurisdictions worldwide, including jurisdictions in North America, Europe, Asia-Pacific, the Middle East, Latin America and Africa, and the breadth and complexity of this portfolio significantly increases our maintenance and prosecution compliance obligations. In the future, we may rely on licensing partners to pay these fees due to U.S. and non-U.S. patent agencies and to comply with these other requirements with respect to any future licensed patents and patent applications. While an inadvertent lapse can sometimes be cured by payment of a

late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of a patent or patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to timely file the application in the relevant jurisdiction, failure to respond to official actions within prescribed time limits, non-payment of fees related to patent procurement in patent offices in the relevant jurisdiction, failure to properly legalize and submit formal documents in the relevant jurisdiction and failure to pay annuities and/or maintenance fees in the relevant jurisdiction.

In addition, public health pandemics, geopolitical instability, natural disasters, or similar events may impair our ability to comply with these procedural, document submission, fee payment, and other requirements imposed by government patent agencies, which may materially and adversely affect our ability to obtain or maintain patent protection for our product candidates. There could also be delays at the USPTO caused by staffing cuts and other U.S. government actions as a result of the U.S. Department of Government Efficiency or other executive actions to reduce the size of the U.S. government.

The USPTO and various foreign agencies require compliance with certain foreign filing requirements during the patent application process. For example, in some countries, including the United States, China, India and some European countries, a foreign filing license is required before certain patent applications are filed. The foreign filing license requirements vary by country and depend on various factors, including where the inventive activity occurred, citizenship status of the inventors, the residency of the inventors and the invention owner, the place of business for the invention owner and the nature of the subject matter to be disclosed (e.g., items related to national security or national defense). In some, but not all cases, for example in China and India, a foreign filing license cannot be obtained retroactively in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment of a pending patent application or can be grounds for revoking or invalidating an issued patent, resulting in the loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the relevant markets with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects. We may also be dependent on our licensors to take the necessary actions to comply with these requirements with respect to our licensed intellectual property.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, which if granted could extend the term of our marketing exclusivity for any product candidates we may develop, our business may be materially and adversely affected.

In the United States, the term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits limited patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration date of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. In addition, the patent term of only one patent applicable to an approved drug may be extended, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar provisions are available in Europe and certain other non-U.S. jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when our product candidates receive FDA approval or regulatory approval in any foreign country, we expect to apply for patent term extensions on patents covering those product candidates and methods for use thereof, and that are eligible for such patent term extension, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted and, even if granted, the length of such extensions. We may not be granted patent term extension either in the United States or in any foreign

country, even where we obtain a patent that is eligible for patent term extension, if, for example, an applicable government authority determines that we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we obtain such an extension, it may be for a shorter period than we had sought. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the expiration of our patent rights, and our business, financial condition, results of operations and prospects could be materially and adversely affected.

Furthermore, for any patents we may in-license in the future, we may not have the right to control prosecution, including filing with the USPTO, of a petition for patent term extension under the Hatch-Waxman Act, or the filing of any petition for patent term extension in any foreign country where such extensions are available. Thus, if a patent that we in-license in the future is eligible for patent term extension under the Hatch-Waxman Act or in any foreign country under similar legislation, we may not be able to control whether a petition to obtain a patent term extension is filed or whether the requested extension is obtained from the USPTO or from the relevant jurisdiction.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. We may be unable to obtain or in-license patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we or our future licensors submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of such product candidate.

If we are unable to obtain licenses from third parties on commercially reasonable terms, our business could be adversely affected.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from such third parties. The in-licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may also be pursuing strategies to in-license or acquire third-party intellectual property rights that we may consider attractive or necessary to our business. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to sell, assign or license intellectual property rights to us. Moreover, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for product candidates that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. If we are unable to license such technology, or if we are forced to in-license such technology on unfavorable terms, such as substantial licensing fees or royalty payments, our business could be materially and adversely affected. If we are unable to obtain a necessary license, the third parties owning such intellectual property rights could seek an injunction prohibiting our manufacturing, use, and/or sales or we may be unable to otherwise develop or commercialize the affected product candidates, which could materially harm our business. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

If we are unable to obtain rights to required third-party intellectual property rights, we may be required to expend significant time and resources to redesign our technology, product candidates, the methods for manufacturing them, the methods of using them or to develop or in-license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and product candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents. Under the Leahy Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first-inventor-to-file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This regime requires us to be cognizant of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions. Since patent applications in the United States and most other countries are confidential for a period after filing or until issuance, we cannot be certain that we or our future licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications filed after March 2013 are prosecuted, challenged, and litigated and provided more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the current laws governing patents in the United States, including the America Invents Act, and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our current or future issued patents, all of which could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biopharmaceuticals are particularly uncertain. For example, U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to

obtain, maintain, protect and enforce our intellectual property in the future. For example, certain decisions, including by the U.S. Court of Appeals for the Federal Circuit, raise questions regarding the award of patent term adjustment (PTA), for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will or will not be viewed in the future and whether patent expiration dates may be impacted.

In the European Union (EU), a new unitary patent system took effect on June 1, 2023, which may significantly impact European patents, including those based on European patent applications filed after introduction of the new system. Under the new system, the proprietor of a European patent can opt for that patent to become a unitary patent which will cover all of the EU states that have ratified the Agreement on the Unified Patent Court at that point in time (UPC Countries), and the European patent will then be subject to the jurisdiction of a new unitary patent court (UPC). During a transition period of the first seven years of the UPC's existence (which under the current legislation could potentially be extended by an administrative committee for up to seven additional years), European patent applications can be opted out of the jurisdiction of the UPC, and validated as exclusively national patents in any one or more of the UPC Countries, even if those patents grant after the end of the transition period.

We may decide to opt out future European patents from the UPC, but doing so may preclude us from realizing some benefits of the UPC. If we do opt a European patent out of the jurisdiction of the UPC, we may decide to opt that European patent back into the jurisdiction of the UPC in the future if we do wish to take advantage of certain benefits of the UPC, but we will only be able to do this if no actions have been brought before a national court in relation to the European patent concerned. In addition, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC.

We may decide not to opt out future European Patents from the UPC, but not opting out will put our European patent under the jurisdiction of the UPC for all UPC Countries and we will still be required to validate the European patent in countries that are not signatories to the unitary patent system, such as Spain, Switzerland and the United Kingdom, and failure to validate would prevent us from securing patent rights in those countries. European patents that are under the jurisdiction of the UPC may be challenged in a single UPC-based revocation proceeding that, if successful, could invalidate the patent in all UPC countries.

The UPC will also provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunction against us in infringement proceedings, in at least all countries which are signatories to the UPC. Further, because the UPC is a new court system having little established precedent for the court's decisions, there is increased uncertainty regarding the outcome of any patent litigation. We are unable to predict what impact the new patent regime may have on our ability to exclude competitors in the European market.

We may not be able to protect our intellectual property rights throughout the world.

Patents are of national or regional effect. Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. In addition, intellectual property rights in some countries outside the United States can be less extensive than those in the United States. Prosecution of foreign patent applications may be a longer process and patents may grant at a later date, and therefore with a shorter term of enforceability, than in the United States and the requirements for patentability differ in certain jurisdictions and countries. Moreover, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in countries where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our

inventions in and into the United States or other jurisdictions. In addition, competitors may use our product candidates in jurisdictions where we have not obtained patent protection to develop their own products and may also export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Furthermore, some jurisdictions, such as Europe, Japan and China, may have different (and potentially heightened) examination guidelines or requirements for securing a patent than in the United States, including, for example, the requirement of claims having literal support in the original patent filing, different support requirements for making claim amendments and different requirements regarding the ability to provide post-patent application filing evidence to support the patentability of the claims under examination. Thus, due to these different requirements or restrictions, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in the United States and other jurisdictions.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. For example, in European Union countries, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws, which could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or may in-license in the future.

In addition, geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any future licensors and the maintenance, enforcement or defense of our issued patents or those of any future licensors. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022 allowing Russian companies and individuals to exploit inventions owned by patentees from the United States without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be materially and adversely affected by certain geopolitical actions.

We may become involved in lawsuits to protect or enforce our patent or other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors and other third parties may infringe, misappropriate or otherwise violate patents or other intellectual property rights that we own or may in-license in the future. As a result, we may need to file infringement, misappropriation or other intellectual property claims against those entities, which can be expensive and time-consuming and divert the time and attention of our management and other employees. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any claims we assert against others could provoke them to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property rights. Our ability to stop competitors and other third parties from making, using, selling, offering to sell, or importing products that infringe our intellectual property rights will depend in part on the extent to which we obtain and enforce patent claims that cover our product candidates, technology, inventions, and improvements.

Furthermore, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. In a patent infringement proceeding, the perceived infringers could counterclaim that the patents we or our future licensors have asserted are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are common. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, insufficient written description, or failure to claim patent-eligible subject matter. Grounds for an unenforceability assertion include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions, such as opposition proceedings in the European Patent Office. The outcomes of allegations of invalidity or unenforceability are unpredictable. With respect to validity, for example, even if we are successful in obtaining patents or in-licensing patents, we cannot be certain that there is no invalidating prior art of which the patent examiner and we or our future licensing partners were unaware during prosecution that is ultimately used to invalidate our or our future licensors' patents.

An adverse result in any such proceeding could put one or more of the patents that we own or may own in the future at risk of being invalidated or interpreted narrowly, and could put any of our present or future owned or in-licensed patent applications at risk of not yielding any issued patent. A court may also refuse to stop the third party from using the technology at issue in a proceeding, for example, on the basis that our patents do not cover that technology, or decide that the other party's use of our patented technology falls under an exemption to patent infringement including, for example, research exemptions such as the safe harbor to patent infringement under 35 U.S.C. § 271(e)(1). Furthermore, if the breadth or strength of protection provided by our present or future patents or patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

In addition, interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our present or future patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be adversely affected if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our

management and other employees. In addition, the uncertainties associated with defended interference or derivation proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research and discovery programs, or enter into development partnerships that would help us bring our product candidates to market.

Furthermore, because of the substantial amount of discovery required in connection with patent office proceedings and intellectual property litigation, there is a risk that some of our confidential information or trade secrets could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. Any of the foregoing could allow third parties to develop and commercialize competing technologies and products and have a material adverse impact on our business, financial condition, results of operations and prospects.

Moreover, there is no assurance that we will have sufficient financial or other resources to file and pursue such infringement, misappropriation, or violation claims, which typically last for years before they are concluded. Further, we may not obtain an injunction against further infringing activity and instead may only be awarded monetary damages, which may or may not be an adequate remedy. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and other employees could outweigh any benefit we receive as a result of the proceedings.

If we fail to comply with our obligations in any future intellectual property licenses with third parties that we may enter into, or otherwise experience disruptions to our business relationships with our future licensors, we could lose intellectual property rights that are important to our business.

Although we do not currently hold any in-licenses and our intellectual property portfolio is wholly owned by us, we may in the future enter into licensing and funding arrangements with third parties that may impose, among other things, diligence, development, and commercialization timelines, milestone payment, royalties, insurance and other obligations on us. If we fail to comply with those obligations or we are subject to bankruptcy-related proceedings, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product candidate that is covered by these agreements or we may be subject to litigation for breach of these agreements or face other penalties under such agreements, or our counterparties may require us to grant them certain rights. Such an occurrence could materially adversely affect the value of any product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, which would have a material adverse effect on our business, financial condition, results of operations, and prospects, or impede, delay or prohibit the further development or commercialization of, one or more product candidates that rely on such agreements.

If we or our future licensors fail to adequately protect our licensed intellectual property, our ability to develop and commercialize product candidates under such agreements could suffer. We may not have complete control over the maintenance, prosecution and litigation of the in-licensed patents and patent applications and may have limited control over future intellectual property that may be in-licensed. For example, we cannot be certain that activities such as the maintenance and prosecution by our future licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. It is possible that our future licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves or may not be conducted in accordance with our best interests.

In addition, intellectual property license agreements are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we may license prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected technology and product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

For example, disputes may arise regarding intellectual property that is or becomes subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other matters of contract interpretation;
- whether and the extent to which our technology and processes infringe the intellectual property rights of the licensor that are not subject to the licensing agreement;
- whether our licensor or its licensor had the right to grant the license agreement;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the intellectual property rights without their authorization;
- our involvement in the prosecution of licensed patents and our licensors' overall patent enforcement strategy;
- the amounts of royalties, milestones or other payments due under the license agreement;
- the sublicensing of patent and other rights under collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If we do not prevail in such disputes, we may lose any or all of our rights under such license agreements.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, diluted, circumvented, declared generic or determined to be infringing, misappropriating or violating on other marks. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition or cancellation proceedings. This can be time-consuming and expensive, particularly for a company of our size. In addition, in an infringement proceeding, a court may decide that a trademark of ours is not valid or is unenforceable, or may determine another trademark is not infringing our trademarks. We may not be able to obtain, protect or enforce our rights to these trademarks and trade names or may be forced to stop using these trademarks or trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors or other third parties may adopt trademarks or trade names similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trademark or trade

name infringement, misappropriation, dilution or other claims brought by owners of other registered trademarks or trade names that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks and trade names may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations. Our current trademark applications and additional trademark applications we may file in the future may not proceed to registration and/or may be opposed by third parties. Even if such applications proceed to registration, third parties may challenge our use of such trademarks or seek to invalidate our registration in the future. Other companies in our industry may be using trademarks that are similar to ours and may in the future allege that the use of our trademarks in connection with our products infringes or otherwise violates their trademark rights. Trademark-granting authorities may decide to investigate our trademarks on their own initiative if they believe that there may be potential issues to be resolved. In addition, failure to maintain our trademark registrations, or to obtain new trademark registrations in the future, could limit our ability to protect and enforce our trademarks and impede our marketing efforts in the countries in which we operate. Over the long term, if we are unable to establish brand recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products similar to any drug candidates we may develop or utilize similarly related technologies that are not covered by the claims of the patents that we may license or may own in the future;
- we, or any future licensing partners or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we may license or own in the future;
- we, or any future licensing partners or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating any of our owned or future-licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- if we enter into license agreements or other collaboration agreements in the future on a non-exclusive basis, others may have access to the same intellectual property rights licensed to us;
- our competitors or other third parties might conduct research and development activities in countries where we or our future licensing partners or collaborators do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;

- we may fail to identify potential patentable subject matter and/or may fail to file on it;
- the patents or other intellectual property rights of others may harm our business; and
- we may choose not to file for patent protection in order to maintain certain trade secrets or know how, and a third party may subsequently file a patent application covering such intellectual property or disclose information resulting in a loss of protection of such trade secret.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks related to our reliance on third parties

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties that we rely on to execute our preclinical studies or clinical trials do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We do not independently conduct our preclinical studies or clinical trials. We rely on medical institutions, contract laboratories and other third parties, such as CROs, to conduct or otherwise support our preclinical studies and clinical trials for our product candidates. We rely heavily on these parties for execution of our preclinical studies and clinical trials for our product candidates and control only certain aspects of their activities. Though we expect to carefully manage our relationships with such CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future, or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. Further, while we have and will have agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol and legal and regulatory requirements and scientific standards, and our reliance on CROs and other third parties will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our preclinical studies and clinical trials, we could be subject to untitled letters, warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and the third parties on which we rely for clinical trials are required to comply with regulations and requirements, including good laboratory practices (GLP) and GCP for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA and comparable foreign regulatory authorities for any drugs in clinical development. The FDA and comparable foreign regulatory authorities enforce GCP requirements through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or these third parties fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or comparable foreign regulatory authorities will determine that any of our future clinical trials will comply with GCP. In addition, our clinical trials must be conducted with product candidates produced under cGMP regulations. Our failure or the failure of the third parties on which we rely to comply with these regulations may require us to terminate, delay or repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action. We also are required to register certain ongoing clinical trials and provide certain information, including information relating to the trial's protocol, on

a government-sponsored database, www.clinicaltrials.gov, within specific timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we design our clinical trials for our product candidates, we will rely on third parties to conduct our clinical trials. As a result, many important aspects of our clinical development, including clinical trial conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff.

Communicating with third parties can also be challenging, potentially leading to mistakes, as well as difficulties in coordinating activities. Third parties may:

- have staffing difficulties or turnover of key personnel;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

If third parties do not perform our clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, we would be unable to rely on clinical data collected by these third parties and may be required to repeat, extend the duration of or increase the size of any clinical trials we conduct, which could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach and under other specified circumstances. If third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such third parties are associated with may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the interpretation of the trial. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, refusal to accept or rejection of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of regulatory approval of our product candidates.

We may, from time to time, establish partnerships in relation to our clinical trials, receiving advisory services and other support from third parties. Although we believe that these partnerships will enable us to accelerate the development of our product candidates and clinical trials, we cannot guarantee that such collaborations will be successful and, in the event they are not, we may lose our competitive advantage and/or incur additional costs.

We rely on third-party manufacturers and suppliers to supply our product candidates. The loss of our third-party manufacturers or suppliers, or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, within acceptable timeframes, or at all, would materially and adversely affect our business.

We do not own or operate facilities for drug manufacturing, storage, distribution, or quality testing and have no current plans to develop our own clinical or commercial-scale manufacturing capabilities. We currently rely, and expect to continue to rely, on third-party contract developers and manufacturers to manufacture bulk drug substances, drug products, raw materials and other components for our product candidates, as well as for commercial manufacture if our product candidates receive regulatory approval. Any change in our relationships with our third-party manufacturers or changes to contractual terms of our agreements with them could adversely affect our business, financial condition, results of operations and prospects.

Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture the product candidates ourselves. There can be no assurance that our clinical development product supplies will not be limited, interrupted, terminated or will be of satisfactory quality or be available at acceptable prices. In addition, any replacement of our manufacturer could require significant effort and time because there may be a limited number of qualified replacements. Further, we do not have any long-term commitments or supply agreements with our third-party manufacturers. We may be unable to establish any long-term supply agreements with third-party manufacturers or to do so on acceptable terms or at all, which increases the risk of failing to timely obtain sufficient quantities of our product candidates or such quantities at an acceptable cost.

Establishing additional or replacement suppliers for these supplies, and obtaining regulatory clearance or approvals that may result from adding or replacing suppliers, could take a substantial amount of time, result in increased costs and impair our ability to produce our products, which would adversely impact our business, financial condition, results of operations and prospects. Any such interruption or delay may force us to seek similar supplies from alternative sources, which may not be available at reasonable prices, or at all. Any interruption in the supply of limited source components for our product candidates would adversely affect our ability to meet scheduled timelines and budget for the development and commercialization of our product candidates, could result in higher expenses and would harm our business. Although we have not experienced any significant disruption as a result of our reliance on our suppliers, we have a limited operating history and cannot assure you that we will not experience disruptions in our supply chain in the future as a result of such reliance or otherwise.

The manufacturing process for our product candidates will be subject to the FDA's review and, in the future, may be subject to comparable foreign regulatory authority review. We, our suppliers and our manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMP, and to ensure the quality and safety of our product candidates. Securing regulatory approval for our product candidates will also require the submission of detailed information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA and comparable foreign regulatory authorities. If our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, they will not be able to secure and/or maintain regulatory approval for the use of their manufacturing facilities to produce our product candidates. Moreover, we do not conduct the manufacturing process ourselves and are completely dependent on our third-party manufacturers for manufacturing our product candidates in compliance with cGMP and other applicable requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing, or otherwise, or if our projected manufacturing capacity or supply of materials becomes limited, interrupted or more costly than anticipated, we may be forced to enter into an agreement with another third party, which we may not be able to do timely or on reasonable terms, if at all.

If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with applicable quality standards and regulations and guidelines; and we may be required to repeat some of the development program with the new manufacturer. The delays and costs associated with the verification of a new manufacturer could negatively affect our ability to develop our product candidates in a timely manner or within budget, or obtain regulatory approval for or market our product candidates.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our product candidates will be subject to periodic review and inspection by the FDA and comparable foreign regulatory authorities, including for continued compliance with cGMP requirements, quality control, quality assurance and corresponding maintenance of records and documents. If we are unable to obtain or maintain third-party manufacturing for our product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements, comply with cGMP or maintain a compliance status acceptable to the FDA or comparable foreign regulatory authorities could adversely affect our business in a number of other ways, including:

- an inability to initiate or complete clinical trials of a product candidate in a timely manner;
- delay in submitting regulatory applications, or receiving regulatory approvals, for a product candidate;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- loss of the cooperation of existing or future collaborators;
- requirements to cease development or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

If our third-party manufacturers are unable to increase the scale of their production of our product candidates, and/or increase the product yield of their manufacturing, then our costs to manufacture our product candidates may increase, we may not achieve sufficient manufacturing capacity to support our clinical trials or commercial demand if any of our products are approved, and commercialization may be delayed.

Reliance on third-party manufacturers entails additional risks such as limitations on supply availability resulting from capacity and scheduling constraints of third parties; the possible breach of manufacturing agreements by third parties because of factors beyond our control; the possible termination or non-renewal of the manufacturing agreements by the third party, at a time that is costly or inconvenient to us; failure to manufacture our product according to our schedule or at all; and the possible misappropriation of our proprietary information, including our trade secrets and know-how. Additionally, our third-party manufacturers may experience difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If any of our third-party manufacturers were to encounter any of these difficulties, our ability to provide our product candidates to patients in clinical trials, or to provide product for treatment of patients if approved, would be jeopardized. Any performance failure on the part of our existing or future manufacturers could delay clinical development or regulatory approval, and any related remedial measures may be costly or time-consuming to implement, which would have a material adverse impact on our financial position.

We may form or seek collaborations or strategic alliances, enter into licensing arrangements or other business transactions in the future, and we may not realize the benefits of such transactions.

We may enter into licensing arrangements and strategic transactions to acquire and advance new assets or product candidates in the future, including strategic partnerships, in-licensing or out-licensing of product candidates, strategic collaborations, joint ventures, restructurings, divestitures, acquisitions of companies, asset purchases, business combinations, and investments.

Any future transactions that we enter into may not be successful. In particular, the success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- licensees or collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- licensees or collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- licensees or collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a licensee or a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our licensees or collaborators that would prevent us from collaborating with others;
- licensees or collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a licensee or a collaborator that cause the delay or termination of the research, development or commercialization of our future product candidates or that results in costly litigation or arbitration that diverts management attention and resources;
- licensees or collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable future product candidates;
- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Additionally, we may have conflicts with our future collaborators, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property

developed during our collaboration. If any conflicts arise with any of our collaborators, such collaborator may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenue: disputes regarding milestone payments or royalties; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the collaborator to cooperate in the development or manufacture of a product candidate, including providing us with data or materials; unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement. Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates. In addition, any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations.

Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could adversely affect our business, financial condition, results of operations and prospects.

We have vendors and service providers located outside of the United States that subject us to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects.

Currently, we have vendors and service providers located outside of the United States. As a result of our global supplier network, we are subject to risks associated with doing business abroad, including:

- political unrest, terrorism, labor disputes and economic instability resulting in the disruption of trade from foreign countries in which our product candidates are manufactured;
- the imposition of new laws and regulations, including those relating to labor conditions, quality, and safety standards, imports, duties, taxes and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate;
- greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and manufacturers' compliance with cGMPs or status acceptable to the FDA or comparable foreign regulatory authorities;
- reduced protection for intellectual property rights, including trademark protection, in some countries;
- disruptions in operations due to global, regional or local public health crises or other emergencies or natural disasters;
- disruptions or delays in shipments; and

- changes in local economic conditions in countries where our manufacturers or suppliers are located.

These and other factors beyond our control could interrupt our vendor and service providers' operations, influence the ability of these companies to render services and export our clinical supplies cost-effectively or at all, and inhibit their ability to procure certain materials.

CMOs may become subject to legislation, trade restrictions, sanctions, tariffs and other regulatory requirements by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to us. For example, the U.S. Congress has recently passed legislation known as the BIOSECURE Act (BIOSECURE Act) to prohibit U.S. federal executive agencies from procuring or obtaining any biotechnology equipment or service produced or provided by a "biotechnology company of concern" (BCC) or entering into or renewing a contract, loan, or grant with an entity that uses such biotechnology equipment or services. Specifically, on December 18, 2025, President Trump signed the National Defense Authorization Act for fiscal year 2026 into law, which includes the BIOSECURE Act. The BIOSECURE Act prohibits the U.S. government from procuring or obtaining biotechnology equipment or services produced or provided by a BCC; entering into, extending, or renewing government contracts with an entity that directly or indirectly (e.g., via a subcontractor) uses biotechnology equipment or services from a BCC in performance of that federal contract; and/or issuing grants or loans to purchase, obtain, or use biotechnology equipment or services produced by a BCC. The BIOSECURE Act also prohibits U.S. government loan and grant recipients from using federal loan or grant money to enter into contracts with entities that use equipment from BCCs in the performance of any federal prime contract or subcontract. Companies designated as a BCC include those that are identified on the U.S. Department of Defense's annual List of Chinese Military Companies, also known as the 1260H List, and the U.S. government also has the ability to designate entities as BCCs through a separate designation process. While the U.S. BIOSECURE Act has a grandfathering period of five years for existing contracts and has carveouts for manufacture of drugs for supply under Medicaid and Medicare Part B, subject to the Secretary of Veteran Affairs' discretion, the impact of the U.S. BIOSECURE Act on the biotechnology industry is uncertain. Given the BIOSECURE Act, we may be restricted in our ability to work with certain Chinese biotechnology companies to the extent we would contract with, or otherwise receive funding from, the U.S. government. Such disruption could have adverse effects on the development of our product candidates. Furthermore, any U.S. executive action, legislative action or potential sanctions including the imposition of higher tariffs on imports into the United States and other governmental regulations affecting trade between the United States and China, and any retaliatory actions by China could materially impact our work or potential work in the future with Chinese biotechnology companies. In addition, U.S. executive agencies may designate entities and individuals on various governmental prohibited and restricted parties lists. Depending on the designation, potential consequences can range from a comprehensive prohibition on all transactions or dealings with designated parties, or a limited prohibition on certain types of activities, such as exports and financing activities, with designated parties. Such disruption could have adverse effects on the development of our product candidates. We are actively engaging alternative suppliers or manufacturers outside of China for our active pharmaceutical ingredients (APIs). Additionally, although drug product for our product candidates are not currently manufactured in China, we may explore future manufacturing of our drug product for our product candidates in China. Without an alternative manufacturing plan for our APIs and possible future drug product for our product candidates, there is a risk that, if supplies are interrupted, or the quality of ingredients provided by such alternative sources is not to our specification, it would cause delays in our supply chain and increase the cost of manufacturing our drugs, which could materially harm our business.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we currently rely on third parties to manufacture our product candidates and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including trade

secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets and despite our efforts to protect our trade secrets, a competitor's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks related to commercialization of our product candidates

Competitive products may reduce or eliminate the commercial opportunity for our product candidates for our current or future indications. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies are more effective or safer than ours, our ability to develop and successfully commercialize our product candidates may be adversely affected.

The pharmaceutical industry is characterized by rapid innovation and intense competition. While we believe that our clinical programs provide us with competitive advantages, we face competition from multiple companies that are similarly working to develop therapeutics targeting similar indications, as well as from academic institutions, governmental agencies, and public and private research institutions. Many of our potential competitors, either alone or with collaboration partners, have significantly greater financial resources than we do, as well as equal or greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our potential competitors may be more successful than we are in achieving regulatory approvals and commercializing their products. We anticipate that we will face intense and increasing competition from existing, approved drugs, as well as new drugs entering the market and emerging technologies that become available. The following sets forth the currently known competitive landscape impacting our product candidates.

BH-30643 (OMNI-EGFR). The EGFR-mutant NSCLC landscape is particularly competitive, with multiple approved therapies and numerous investigational agents in active clinical development across modalities.

- **C797S-resistant population.** There are currently no approved targeted therapies for patients with C797S-mediated resistance to osimertinib or other third-generation EGFR TKIs. The most recently approved post-osimertinib regimen—amivantamab (RYBREVA) in combination with platinum-based chemotherapy—was approved in September 2024. Platinum-based chemotherapy remains the predominant systemic option for C797S-resistant patients. We are aware of numerous companies targeting C797S-mediated resistance to EGFR TKIs or broader EGFR resistance mutations in early clinical development, such as Abbisko Therapeutics, Betta Pharma, Black Diamond Therapeutics, Bridge Therapeutics, Chia Tai Tianqing, Dizal Pharmaceuticals Co., Hansoh Pharma, J INTS BIO, Qilu, Voronoi and Wayshine Biopharm. Additionally, Blueprint Medicines advanced two programs targeting C797S into clinical development; both programs have been discontinued.
- **Classical mutation setting.** Osimertinib (TAGRISSO), marketed by AstraZeneca is the current standard of care in the first-line setting for classical EGFR mutations. Amivantamab (RYBREVA) in combination with lazertinib, marketed by Johnson & Johnson, is also approved in the first-line classical mutation setting and would represent additional competition in any first-line program we may pursue. We are aware of numerous

companies developing EGFR TKIs in the classical mutation setting, such as ArriVent BioPharma, Black Diamond Therapeutics, TYK Medicines and Voronoi.

- **Uncommon EGFR mutation settings (including atypical and exon 20 insertion).** Afatinib (GILOTRIF), marketed by Boehringer Ingelheim, is the only FDA-approved TKI specifically indicated for a subset of atypical mutations (G719X, L861Q, and S768I). Amivantamab (RYBREVA) in combination with platinum-pemetrexed chemotherapy is approved as a first-line regimen for EGFR exon 20 insertion-positive NSCLC. Mobocertinib, the first oral agent approved in this setting, was voluntarily withdrawn from the U.S. market in 2024 following its failure to demonstrate a benefit over chemotherapy. We are aware of numerous companies developing inhibitors against uncommon EGFR mutations (including atypical mutations including exon 20 insertions), such as ArriVent BioPharma, Avistone Pharma, Black Diamond Therapeutics, Cullinan Therapeutics, Dizal Pharmaceuticals Co., ORIC Pharmaceuticals, Taiho Oncology and Voronoi.

BH-30236 (CLK inhibitor). The AML and HR-MDS landscapes are competitive, with multiple approved therapies and numerous investigational agents across our target patient populations.

- **CLK inhibitor class.** There are currently no approved CLK inhibitors. We are aware of several companies developing CLK inhibitors, including Biosplice Therapeutics and Chordia Therapeutics.
- **R/R AML and HR-MDS; venetoclax-resistant setting.** Although multiple therapies are approved for AML and HR-MDS in earlier lines of treatment or in molecularly defined subsets, there are currently no approved targeted therapies specifically indicated for patients whose disease is resistant to or has relapsed following venetoclax-based therapy. In this setting, treatment typically consists of salvage chemotherapy, hypomethylating agents (e.g., azacitidine (VIDAZA), marketed by Bristol Myers Squibb), FLT3 inhibitors for patients with FLT3-mutant disease, IDH inhibitors for patients with IDH1- or IDH2-mutant disease, or supportive care. Allo-HCT may be potentially curative for a subset of patients, but is available only to a minority given the age, fitness, comorbidities, donor availability and disease-control requirements of the affected population.
- We are aware of several approved agents that may compete for patients in R/R AML including gilteritinib (XOSPATA), marketed by Astellas Pharma, for FLT3-mutant AML; ivosidenib (TIBSOVO), marketed by Servier, for IDH1-mutant AML; enasidenib (IDHIFA), marketed by Bristol Myers Squibb, for IDH2-mutant AML; and menin inhibitors in molecularly defined subsets, including ziftomenib (KOMZIFTI), marketed by Kura Oncology, for NPM1-mutant AML, and revumenib (REVUFORJ), marketed by Syndax Pharmaceuticals, for NPM1-mutant AML and acute leukemia with a KMT2A translocation. In HR-MDS, approved therapies include hypomethylating agents and other agents used in selected settings, but there remains no approved targeted therapy specifically indicated for the broader population following hypomethylating agent failure or venetoclax-based treatment failure.
- **Combination setting and broader competition.** A key component of our development strategy for BH-30236 is combination therapy with venetoclax. As a result, we expect competition not only from monotherapy approaches in R/R AML and HR-MDS, but also from investigational combination regimens intended to improve upon or restore sensitivity to venetoclax-based treatment, including BCL-2 pathway-directed regimens, FLT3-directed therapies, menin inhibitors, TP53-associated approaches and other targeted therapies intended to address leukemic survival and resistance mechanisms. Although these programs may not directly inhibit CLK, they may compete for the same patients, clinical trial sites, investigators, and future treatment settings.

BH-501284 (pan-KRAS). The KRAS inhibition landscape is competitive, with multiple approved therapies and numerous investigational agents in active clinical development.

- **KRAS G12C / G12D inhibitors:** There are two approved KRAS G12C inhibitors – sotorasib (LUMAKRAS), marketed by Amgen, and adagrasib (KRAZATI), marketed by Bristol-Myers Squibb. We are aware of numerous companies developing inhibitors targeting a single mutant allele, such as KRAS G12C and KRAS G12D, such as Astellas, D3 Bio, Eli Lilly, Frontier Medicines, Genfleet, Hansoh Pharma Quanta, Revolution Medicines and Roche.
- **Pan-KRAS tricomplex inhibitors:** There are currently no approved pan-RAS inhibitors. We are aware of numerous companies developing pan-RAS tricomplex inhibitors, such as Adlai Nortye, Betta Pharmaceuticals, Erasca, Revolution Medicines and Roche.
- **Pan-KRAS (non-covalent Switch-II pocket inhibitors and degraders):** We are aware of numerous companies developing pan-KRAS non-covalent Switch-II pocket inhibitors and/or degraders, such as Amgen, Astellas, AstraZeneca, BeOne, Boehringer Ingelheim, BridgeBio Oncology Therapeutics, Erasca, Eli Lilly, PAQ Therapeutics, Pfizer and Roche.

The development of pan-KRAS inhibitors across these modalities by established and well-resourced competitors could significantly reduce the commercial opportunity for BH-501284.

Additionally, established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. Any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving regulatory approval for or commercializing drugs before we do, which would have an adverse impact on our business and results of operations. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our profitability and financial position will suffer if our product candidates receive regulatory approval but cannot compete effectively in the marketplace.

Even if our product candidates receive regulatory approval, they may fail to achieve the degree of market acceptance by physicians, patients and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.

We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, our product candidates may not gain acceptance among patients, patients' families, advocacy groups, physicians, third-party payors and others in the medical community. If the product candidates for which we obtain regulatory approval do not gain an adequate level of market acceptance, we may not generate sufficient product revenue or become profitable. Further, the number of patients that our product candidates is designed to treat may be smaller than expected.

The degree of market acceptance of our product candidates, if approved and commercialized, will depend on a number of factors, some of which are beyond our control, including:

- the pricing and cost-effectiveness of our product candidates, as well as the ease of administration, time burden and market acceptance;
- the safety, efficacy and tolerability of our product candidates;
- acceptance of our product candidates by patients and their families, prescribing physicians and the broader medical community and third-party payors;
- changes in the standard of care for the indications we are developing our product candidates for and the reluctance of physicians to switch their patients' current standard of care;

- the reluctance of patients to switch from their existing therapy regardless of the safety and efficacy of newer products;
- the clinical indications for which our product is approved and the scope of efficacy/safety claims that we may make for the product;
- any restrictions on the use of our product, and the prevalence and severity of any adverse effects;
- any distribution and use restrictions imposed by the FDA in connection with any regulatory approval;
- the availability of adequate coverage and reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement;
- the extent and strength of our marketing and distribution of such product candidate;
- the timing of market introduction of such product candidate, as well as competitive products;
- our ability to offer our product candidates for sale at competitive prices;
- adverse publicity about our product or favorable publicity about competitive products; and
- potential product liability claims.

Our efforts to educate the medical community and third-party payors about the benefits of our product candidates may require significant resources and may never be successful. Even if our product candidates, if approved, are safe and effective for their approved indications, physicians and patients (and their families, as applicable) may not immediately be receptive to such product candidates and may be slow to adopt them as an accepted treatment for the approved indications. If our current or future product candidates are approved, but do not achieve an adequate level of acceptance among physicians, patients and third-party payors, we may not generate meaningful revenue from our product candidates and may never become profitable.

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If any of our product candidates ultimately receives regulatory approval, we must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming, or collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We have no prior experience as a company in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third

parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels, and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers, and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our product(s) by third-party payors will have an effect on our ability to successfully commercialize any products we may successfully develop. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products, if approved, and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. Regulatory approvals, pricing and reimbursement for new drug products vary widely from country to country. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require prior authorization before covering new or innovative drug therapies and reimbursing healthcare providers who use such therapies. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. It is difficult to predict at this time what third-party payors will decide with respect to coverage and reimbursement for our products, if approved.

Obtaining and maintaining reimbursement status is time-consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and

adequate reimbursement will be applied consistently or obtained in the first instance. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. For example, the U.S. Department of Health and Human Services (HHS), imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven (7) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. Drugs that are granted one or more orphan drug designation (ODD) by FDA are exempt from such Medicare Drug Price Negotiation Program. Unless we are able to obtain orphan drug designation for our product candidates, in the future, we may face price negotiation to the extent the Medicare Drug Price Negotiation Program remains in effect in its current form. We also expect to experience pricing pressures in connection with the sale of our product candidates, if approved for marketing, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Risks related to government regulation

Our relationships with healthcare providers and third-party payors may be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to significant penalties, including criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, including physicians, and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Our current and future arrangements with healthcare providers, third-party payors and customers can expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research, and if approved, sell, market and distribute our products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of a future approved product, is subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring, and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate now or in the future include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or

indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, or recommendation of any good, facility, item, or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other;

- the civil monetary penalties statute which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to, among others, a federal healthcare program that the person knows or should know is for a medical or other item or service that was not provided as claimed or is false or fraudulent;
- the federal civil and criminal false claims laws, including the federal False Claims Act (FCA), which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government healthcare programs if they are deemed to “cause” the submission of false or fraudulent claims. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact, or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating the health care fraud statute under HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and its implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually identifiable health information of covered entities, including health plans, healthcare clearinghouses and certain healthcare providers and their business associates, independent contractors of a covered entity that perform certain services involving the use or disclosure of individually identifiable health information for or on their behalf, as well as their covered subcontractors;
- the federal Physician Payments Sunshine Act and its implementing regulations, which require some manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services (CMS) information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors),

certain non-physician practitioners (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state laws that require the licensure or registration in order to distribute or manufacture pharmaceutical products; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and local laws that require the registration of pharmaceutical sales representatives.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Distribution of prescription drug samples to licensed prescribers is also highly regulated within the United States.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal, state and foreign enforcement bodies have continued their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, significant fines and penalties and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and may divert our management's attention from the operation of our business.

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal, and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future marketed products could adversely affect our business, results of operations and financial condition.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If our product candidates are approved, they will be subject to extensive and ongoing regulatory requirements for manufacturing, labeling, packaging, distribution, storage, advertising, promotion, import, export, sampling,

record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMPs and similar requirements outside the United States and GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs or similar regulations. As such, we and our contract manufacturers will be subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities to assess compliance with cGMPs or similar requirements and adherence to commitments made in any NDA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, and such approvals may be subject to significant limitations on the approved indicated uses for which the product may be marketed (e.g., use restrictions for specified age groups, warnings, precautions or contraindications), and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS program as a condition of approval of our product candidates or similar risk management measures, which could entail requirements for long-term patient follow-up, a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

The FDA or comparable foreign regulatory authorities may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, such as adverse events of unanticipated severity or frequency, or problems with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on that product, the manufacturing facility or us, including revisions to the approved labeling to add new safety information, contraindications or a "black box" warning, imposition of post-market studies or clinical trials to assess new safety risks, or imposition of distribution restrictions or other restrictions under a REMS. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA or comparable foreign regulatory authorities to approve pending applications or supplements to approved applications submitted by us or suspension or revocation of approvals;
- product seizure or detention or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The policies of the FDA and comparable regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and our business, results of operations and financial condition could be adversely affected.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA and comparable foreign regulatory authorities strictly regulate the marketing, labeling, advertising, and promotion of prescription drugs. These regulations include standards for direct-to-consumer advertising (in the United States only), industry-sponsored scientific and educational activities and promotional activities involving the internet, as well as restrictions on promoting approved drugs for unapproved uses or patient populations (known as “off-label promotion”). Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. While physicians in the United States may choose, and are generally permitted, to prescribe drugs for off-label uses in their independent professional judgment, manufacturers may not market or promote such uses. However, companies may share truthful and not misleading information that is not inconsistent with the labeling, and the FDA has published guidance with recommendations for how drug manufacturers can share scientifically sound and clinically relevant information on unapproved uses with health care providers so long as such presentations are not promotional.

If we are found to have promoted any off-label uses of our future approved products, or to have engaged in the promotion of an unapproved product candidate, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our future approved products, we could become subject to significant liability, which would materially adversely affect our business, results of operations and financial condition.

Ongoing healthcare legislative and regulatory reform measures may adversely affect our business, results of operations and financial condition.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. By way of example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, (collectively, ACA), was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers.

Other legislative changes have been proposed and adopted in the United States since the ACA. These changes include aggregate reductions to Medicare payments to providers, which began in 2013 and will remain in effect until 2032 unless additional Congressional action is taken. Additionally, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory cap on drug manufacturers’ Medicaid drug rebate liability, previously set at 100% of a drug’s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. More recently, on July 4, 2025, the One Big Beautiful Bill Act (the OBBBA) was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA

also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform (TrumpRx), U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again (MAHA) Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager (PBM) payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's *Loper Bright* decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program. At the state level, individual states in the United States have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards with the goal of imposing price limits on certain drugs in these states, while some states are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. We cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, if approved, any of which could adversely affect our business, results of operations and financial condition.

Disruptions to the operations of the FDA, the SEC, other U.S. governmental agencies or comparable foreign regulatory authorities caused by funding shortages, leadership changes, staffing cuts or other staffing shortages, along with uncertainty regarding the potential for new initiatives, laws, regulations, policies and guidance affecting our product candidates or other aspects of our business, could materially and adversely affect our business.

The ability of the FDA or other comparable foreign regulatory authorities to review and approve new products or take action with respect to other regulatory matters can be affected by a variety of factors, including government budget and funding levels, leadership changes, the ability to hire and retain key personnel and accept payment of user fees, the availability of personnel and other resources, changes in statutes, regulations and policies that affect the FDA's or comparable foreign regulatory authorities' ability to perform routine functions, and other business disruptions. Average review times at the FDA and comparable foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. In addition, there have recently been terminations of large numbers of federal employees at various federal agencies, including the FDA. Changes and cuts in FDA staffing could result in delays in the FDA's responsiveness or in its ability to review INDs, NDAs, or other submissions or applications, issue regulations or guidance or implement or enforce regulatory requirements in a timely fashion, or at all. If a prolonged government shutdown occurs and/or employee terminations or resignations could significantly impact the ability of the FDA or other federal agencies to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns and/or employee terminations or resignations at the SEC could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

There is substantial uncertainty as to whether and how the current U.S. Presidential administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval. This uncertainty could present new challenges as we navigate development and approval of our product candidates. Some of these efforts have manifested to date in the form of personnel cuts and measures that could impact the FDA's ability to hire and retain key personnel, which could result in delays or limitations on our ability to obtain guidance from the FDA regarding our product candidates and obtain the requisite regulatory approvals in the future. There is uncertainty as to whether we will be materially and negatively impacted by governmental orders, regulations, policies or guidance or disruptions to the normal operations of government agencies.

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.

We operate in a global economy, which includes using third-party suppliers in several countries outside the United States. There is inherent risk, based on the complex relationships among the United States and the countries in which we conduct our business, that political, diplomatic and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic

and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects. The Bureau of Industry and Security, U.S. Department of Commerce, has initiated an investigation to determine whether pharmaceutical ingredients, including finished drug product, manufactured outside the United States pose a national security risk and should be subject to additional tariffs.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for clinical testing, as well as for manufacture of any products that we may commercialize, if approved. Currently, our suppliers are located outside of the United States, and the APIs for BH-30643 and BH-30236 are manufactured in China. We also rely on specialized laboratory equipment, supplies, materials and precursor compounds, all or part of which we believe may be ultimately sourced from multiple countries outside the United States, to advance our research and development efforts.

Current or future tariffs will result in increased research and development expenses, including with respect to increased costs associated with APIs, raw materials, laboratory equipment and research materials and components. In addition, such tariffs will increase our supply chain complexity and could also potentially disrupt our existing supply chain. Unlike consumer goods, pharmaceuticals face unique regulatory constraints that make rapid supply chain adjustments particularly difficult and costly. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, as we advance toward commercialization in the future, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our customers or suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity on our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, tariffs and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this prospectus.

We and the third parties upon whom we rely are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our (or the third parties upon whom we rely) actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, sensitive third-party data, business plans, transactions, financial information (collectively, sensitive data). Such data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations relating to data privacy and security.

For example, in the United States, federal, state and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) and other similar laws (e.g., wiretapping laws). We may obtain personal health information from third parties, such as research institutions with which we collaborate, that are subject to privacy and security requirements under HIPAA. Although we do not believe that we are directly subject to HIPAA, other than potentially with respect to providing certain employee benefits, we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA. In addition, other federal and state laws have established and may in the future establish requirements for protecting the privacy and security of health information that is not protected by HIPAA. Additionally, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. Although there are minimum revenue or personal data processing thresholds for entities to be subject to many of these laws and there are limited exemptions for clinical trial data under the U.S. state comprehensive privacy laws, such laws may impact (possibly significantly) our business activities depending on how they are interpreted and if we become subject to such state comprehensive privacy laws in the future. In addition, similar laws are being considered, in other states, as well as at the international, federal and local levels, and we expect more laws related to personal data to become effective in the future. These developments may further complicate compliance efforts and increase our legal risk and compliance costs for us and the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security, including in relation to clinical trial data. For example, China's Personal Information Protection Law (PIPL), Australia's Privacy Act 1988 (Cth) and the Australian Privacy Principles (APPs), as well as comprehensive privacy and data protection laws in other jurisdictions where we operate, have staff, or otherwise process sensitive data about local residents, each of which impose strict requirements for processing personal data of individuals within China, Australia, and other relevant jurisdictions. These data protection laws impose comprehensive data privacy compliance obligations in relation to our collection and use of data relating to an identifiable living individual or "personal data", including a principle of accountability and the obligation to demonstrate compliance through policies, procedures, training and audit, as well as regulating cross-border transfers of personal data out of China, Australia, and other relevant jurisdictions. In addition, some of the personal data we process in respect of clinical trial patients is special category or sensitive personal data under the PIPL, the APPs, or other relevant laws, and subject to additional compliance obligations and to local law derogations.

Each of these foreign data protection laws carries significant fines and penalties for failure to comply. For example, failure to comply with PIPL can result in fines of up to RMB 50 million or 5% of the prior year's total annual revenue for the personal information processor and/or a suspension of services or data processing activities. Other potential penalties include a fine of up to RMB 1 million on the person in charge or directly responsible personnel and, in serious cases, individuals and entities may be exposed to criminal liabilities under other local Chinese law, such as the Criminal Law of the People's Republic of China. The PIPL also prohibits responsible personnel for violations of the PIPL from holding high level management or data protection officer positions in relevant enterprises. Similar such fines and penalties can arise under the APP or other data protection laws.

In addition, we may be unable to transfer personal data or we may have to implement additional measures to enable the transfer of data to the United States or other countries due to data localization requirements or limitations on cross-border data flows. For example, the PIPL imposes data localization requirements on important data processors and critical information infrastructure operators and personal information processors which process personal information above a certain threshold prescribed by the relevant authorities, unless a security assessment (Security Assessment) is passed. The PIPL also requires data processors to rely on a data export mechanism and comply with certain requirements prior to the transfer of Personal Information outside of China, such as compliance with a Security Assessment or certification by an agency designated by the relevant authorities or entering into standard form model contracts approved by the relevant authorities with the overseas recipient, unless an exemption applies. Other data protection laws may require specific consent to export sensitive data, among other risk assessments, contractual language, enhanced safeguards for the sensitive data, or other mechanisms or practices. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we operate our business, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Additionally, the U.S. Department of Justice (DoJ) issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons (i.e., individuals and entities who are designated as such by the U.S. Attorney General or are (1) foreign entities organized under the laws of, or with a principal place of business in, a country of concern or 50% or more owned, individually or in the aggregate, by one or more countries of concern or other covered persons; (2) foreign entities 50% or more owned, individually or in the aggregate, by a country of concern or another covered person; (3) foreign individuals that are employees or contractors of a country of concern or covered person; and (4) foreign individuals who are primarily a resident in a country of concern) that may impact certain business or management activities such as vendor engagements, licensing arrangements, partnership engagements, sale or sharing of data, employment of certain individuals and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. We may in the future engage in data transactions that could be subject to the rule. Although the DoJ issued compliance guidance and responded to industry questions, we are not aware of the existence of enforcement data or case law that would provide additional guidance on how the rule will be interpreted, and there is a risk that our interpretation of its applicability, scope and requirements could be incorrect, incomplete, or misapplied. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to enter into certain agreements.

Our employees and personnel use AI Technologies to perform their work, and the disclosure and use of personal data in AI Technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws and regulations regulating AI Technologies. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use AI Technologies, it could make our business less efficient and result in competitive disadvantages.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

We do and may in the future publish privacy policies and other statements concerning data privacy, and security. Regulators are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail (or be perceived to have failed) to comply with such obligations, which could negatively impact our business operations. If we or the third parties upon whom we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans or restrictions on processing personal data; or orders to destroy or not use personal data.

In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations.

Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations; loss of customers; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; potentially significant financial penalties if we are found to be in violation of our privacy obligations; adverse publicity; or substantial changes to our business model or operations.

We are subject to certain U.S. and foreign anti-corruption, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

We are subject to anti-corruption laws and regulations, including the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act and other state and national anti-bribery laws in the countries

in which we may conduct activities in the future. Anti-corruption laws are interpreted broadly and generally prohibit companies and their employees, agents, contractors and other third-party collaborators from offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly through third parties, to any person in the public or private sector to obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Compliance with anti-corruption laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, anti-corruption laws present particular challenges in the pharmaceutical industry, because in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. We have direct or indirect interactions with officials and employees of government authorities or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase over time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals, and we can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities. Any violation of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

We are also subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments and persons targeted by U.S. sanctions.

There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors or collaborators, or those of our affiliates, will comply with all applicable anti-corruption, export and import control, and sanctions laws and regulations. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results and financial condition.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Risks related to this offering and ownership of our common stock

There has been no public market for our common stock. An active trading market for our common stock may not develop or be sustained, or we may in the future fail to satisfy the continued listing requirements of the Nasdaq Global Select Market (Nasdaq) and our stock may be delisted, and you may not be able to resell your shares of our common stock at or above the public offering price, if at all.

Prior to this offering, there has been no public market for our common stock. Our common stock has been approved for listing on Nasdaq under the symbol "BLSM." An active trading market for our shares may never develop or be sustained following this offering. The initial price for our common stock in this offering was determined through negotiations with the underwriters. This price does not necessarily reflect the price at which investors in the market will be willing to buy and sell our shares following this offering. The lack of an active market may impair the value of your shares, your ability to sell your shares at the time you wish to sell them and the prices that you may obtain for your shares. Further, an inactive trading market for our common stock may also impair our ability to raise capital by selling shares of our common stock or enter into strategic partnerships and transactions by issuing shares of our common stock as consideration. If an active trading market for our common stock does not develop, or is not sustained, you may not be able to sell your shares quickly or at the market price, or at all, and it may be difficult for you to sell your shares without depressing the market price for our common stock.

Moreover, if, after listing, we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the listing requirements of Nasdaq.

Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts or any guidance we may publicly provide, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly and annual fluctuations which may, in turn, cause the price of our common stock to fluctuate substantially. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of BH-30643, BH-30236, BH-501284 or future research and development programs;
- results and timing of preclinical studies and ongoing and future clinical trials, or the addition or termination of any such clinical trials;

- variations in the level of expenses associated with other aspects of our operations including the costs of manufacturing our product candidates, organizational growth and retention and the associated costs of compensation and benefits, fluctuations in the costs of insurance, especially director and officer insurance, changes in tax expenses, and the costs of any potential future legal claims against the company;
- the timing of payments we may make or receive under existing license and collaboration arrangements or the termination or modification thereof;
- our execution of any strategic transactions, including acquisitions, collaborations, licenses or similar arrangements, and the timing and amount of payments we may make or receive in connection with such transactions;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- recruitment and departures of key personnel;
- if our product candidates receive regulatory approval in the future, the terms of such approval and market acceptance and demand for such products;
- regulatory developments affecting our product candidates or those of our competitors;
- global or regional public health emergencies, including any health epidemics and their residual effects, natural disasters or major catastrophic events;
- adverse macroeconomic conditions or geopolitical events and conflicts, any health epidemics and their residual effects, bank failures, or inflation and increased interest rates, on our preclinical and clinical development or operations;
- the impacts of inflation and rising interest rates on our business and operations; and
- changes in general market, and economic conditions.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts or any forecasts or guidance we may provide to the market, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide. We believe that quarterly or annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

The trading price of our common stock may be volatile and you could lose all or part of your investment.

The trading price of our common stock after this offering is likely to be volatile. The stock market in general and the market for stock of biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your shares of our common stock at or above the initial public offering price. The market price for our common stock may be influenced by those factors discussed in this “Risk factors” section and many other factors, including:

- volatility and instability in the financial and capital markets;
- announcements relating to our product candidates, including the results of clinical trials by us or our collaborators;
- market acceptance of our product candidates, if approved, and the recognition of our brand;

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- introduction of proposed products, technologies or treatment techniques by us or our competitors;
- announcements of significant contracts, acquisitions, divestitures or partnerships by us, our competitors or our collaboration partners;
- regulatory clearance, certification or approval of our product candidates or those products of our competitors or collaboration partners, or the failure to obtain such clearances, certifications or approvals on the projected timeline or at all;
- the announcement of a product recall, suspension or other safety notice associated with our products or the products of our competitors, or other similar regulatory enforcement actions;
- financial and operating results relative to the expectations of securities analysts and other market participants and the issuance of securities analysts' reports or recommendations;
- threatened or actual litigation, regulatory proceedings or government investigations;
- the costs and timing of manufacturing for our product;
- the success and market acceptance of existing or new competitive therapies, products or technologies;
- development of new products that may address our markets and make our product candidates less attractive;
- failure or discontinuation of any of our research or development programs;
- changes in the level of expenses related to any of our research or development programs;
- developments related to any existing or future collaborations;
- the recruitment or departure of key personnel;
- regulatory or legal developments in the United States and other countries;
- announcements by us, our partners or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- changes in the structure of healthcare payment systems;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- actual or expected changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales of common stock by us, our executive officers, directors or principal stockholders, or others;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the pharmaceutical and biotechnology sector;
- general economic, political and market conditions and other factors;
- changes in accounting principles; and

- the other factors described in this “Risk factors” section and elsewhere in this prospectus.

Following price volatility, holders of securities may institute securities class action litigation against the issuer. If any holders of our common stock were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our board of directors and senior management would be diverted from the operation of our business. Any adverse determination in litigation could also subject us to significant liabilities. If the market price of our common stock following this offering does not exceed the initial public offering price, you may not realize any return on, or you may lose some or all of your investment. Broad market and industry factors such as these could materially and adversely affect the market price of our stock, regardless of our actual operating performance.

After this offering, our executive officers, directors and principal stockholders, if they choose to act together, will continue to have the ability to control or significantly influence all matters submitted to stockholders for approval.

Upon the closing of this offering, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock before this offering and their respective affiliates will, in the aggregate, hold approximately 41.8% of our outstanding common stock (based on the number of shares of our common stock outstanding as of March 31, 2026 and assuming no purchase of shares in this offering by any of this group, no exercise of the underwriters’ option to purchase additional shares of our common stock and no exercise of outstanding options other than the Exercised Option Share Issuance). As a result, if these stockholders choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors, the composition of our management and approval of any merger, consolidation, sale of all or substantially all of our assets or other business combination that other stockholders may desire. The interests of these stockholders may not always coincide with your interests or the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock. Any of these actions could adversely affect the market price of our common stock.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares of our common stock, could reduce the market price of our common stock. After this offering, we will have 30,643,660 shares of common stock outstanding (assuming no exercise of the underwriters’ option to purchase additional shares of our common stock). This includes the shares that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. Substantially all of the remaining 21,268,660 shares of our common stock initially will be restricted as a result of securities laws, market standoff provisions or lock-up agreements, but will become eligible to be sold after this offering as described in the section titled “Shares eligible for future sale.” We, our directors, our officers and substantially all of the holders of our common stock or securities convertible into, exercisable for, or exchangeable for our common stock have entered into market standoff agreements with us and have entered or will enter into lock-up agreements under which we have agreed or will agree, subject to specific exceptions described in the section titled “Underwriting,” not to offer, sell, or transfer such securities for 180 days following the date of this prospectus. We refer to such period as the lock-up period. The underwriters may, in their sole discretion and at any time or from time to time before the termination of the lock-up period release all or any portion of the securities subject to lock-up agreements.

Moreover, after this offering, certain holders of shares of our common stock will have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, until such shares can otherwise be sold without restriction under Rule 144 under the Securities Act of 1933, as amended (Securities Act), or until the rights terminate pursuant to the terms of the stockholder agreements between us and such holders. See the section titled “Description of capital stock—Registration rights.” Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. We also intend to register all shares of our common stock subject to equity awards issued or reserved for future issuance under our equity compensation plans on a registration statement on Form S-8. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates under Rule 144 under the Securities Act and the market standoff provisions and lock-up agreements described above. Any sales of securities by these stockholders could have a negative impact on the trading price of our common stock.

If you purchase common stock in this offering, you will suffer immediate and substantial dilution of your investment.

The initial public offering price of our common stock is substantially higher than the net tangible book value per share of our outstanding common stock immediately after the closing of this offering. Based on the initial public offering price of \$16.00 per share, you will experience immediate dilution of \$8.09 per share as of March 31, 2026, representing the difference between our pro forma as adjusted net tangible book value per share, after giving effect to this offering and the initial public offering price. This dilution is due to our investors who purchased shares prior to this offering having paid a price for their shares that is substantially less than the price offered to the public in this offering, as well as the exercise of stock options granted to our employees, directors and consultants. To the extent any outstanding options are exercised, you will experience further dilution. As a result of this dilution, investors purchasing stock in this offering may receive significantly less than the full purchase price that they paid for the shares purchased in this offering in the event of a liquidation. See the section titled “Dilution” for additional information.

We are an emerging growth company and a smaller reporting company, and the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act (JOBS Act). For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements, and (iii) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements and two years of selected financial data in this prospectus.

We could be an emerging growth company for up to five years following the year in which we complete this offering, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the closing of this offering, (b) in which we have total annual gross revenue of at least \$1.235 billion and (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed \$700.0 million as of the prior June 30th, and (ii) the date on which we have issued more

than \$1.0 billion in non-convertible debt during the prior three-year period. Investors may find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies also can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption, and, as a result, our operating results and financial statements may not be comparable to the operating results and financial statements of companies who have adopted the new or revised accounting standards.

We also are a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than \$700.0 million and our annual revenue is less than \$100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our stock held by non-affiliates is less than \$250.0 million or (ii) our annual revenue is less than \$100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our annual report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Future sales and issuances of our securities, including pursuant to our equity incentive plans, may cause dilution to our stockholders or decrease our stock price.

We expect that significant additional capital may be necessary to continue our planned operations, including to expand product development and commercialize our products. We may seek additional capital through public or private equity or debt financings or other capital sources, which may include strategic collaborations and other strategic arrangements with third parties, to enable us to complete the development and potential commercialization of our product candidates. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder.

Pursuant to our 2026 Plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. Additionally, the number of shares of our common stock reserved for issuance under our 2026 Plan will automatically increase on January 1 of each calendar year, beginning on January 1, 2027 and continuing through and including January 1, 2036, by 5.0% of the total number of shares of our common stock (including shares issuable upon exercise, conversion, or exchange of all then-outstanding pre-funded warrants, or other rights exercisable for or convertible into, directly or indirectly, shares of common stock (whether vested or unvested), but excluding shares issuable upon the exercise of then-outstanding options and the shares reserved and available for issuance under our then-existing equity incentive plan(s) and employee stock purchase plan(s), if any) outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. In addition, pursuant to our ESPP, the number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2027 and continuing through and including January 1, 2036, by the lesser of (i) 1.0% of the total number of shares of our common stock (including shares issuable upon exercise, conversion, or exchange of all then-outstanding pre-funded warrants, or other rights exercisable for or convertible into, directly or indirectly, shares of common stock (whether vested or unvested), but excluding shares issuable upon the exercise of then-outstanding options

and the shares reserved and available for issuance under our then-existing equity incentive plan(s) and employee stock purchase plan(s), if any) outstanding on the last day of the calendar month before the date of the automatic increase and (ii) 907,587 shares; provided that before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

Participation in this offering by our existing stockholders and/or their affiliated entities may reduce the public float for our common stock.

To the extent certain of our existing stockholders and their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our shares, meaning the number of shares of our common stock that are not held by officers, directors and controlling stockholders. A reduction in the public float could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our common stock and depressing the price at which you may be able to sell shares of our common stock purchased in this offering.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. We expect that we will use the net proceeds of this offering as set forth in the section titled "Use of proceeds." However, our use of these proceeds may differ substantially from our current plans. The failure by our management to apply these funds effectively could result in financial losses that could have a negative impact on our business, cause the price of our common stock to decline and delay the development and commercialization of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, would be your sole source of gain.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock would be your sole source of gain on an investment in our common stock for the foreseeable future. See the section titled "Dividend policy" for additional information.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws which will become effective immediately prior to and upon the closing of this offering could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to the closing of this offering, may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);

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- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66-2/3% of the voting power of all of our then outstanding common stock;
- divide our board of directors into three classes, with each class serving staggered three-year terms;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights, therefore allowing the holders of a majority of the shares of our common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose; and
- provide that special meetings of our stockholders may be called only by the Chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66-2/3% of our then-outstanding common stock.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law (DGCL). These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult or costly for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

For information regarding these and other provisions, see the section titled "Description of capital stock."

Our amended and restated certificate of incorporation that will become effective immediately prior to the closing of this offering will provide that the Court of Chancery of the State of Delaware and any appellate court therefrom will be the exclusive forums for substantially all disputes between us and our stockholders, other than any complaint asserting a cause of action arising under the Exchange Act or the Securities Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation that will become effective immediately prior to the closing of this offering will provide that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws;
- any action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws;
- any action to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. Additionally, investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation will further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and the provisions may not be enforced by a court in those other jurisdictions. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business, results of operations and financial condition.

This exclusive forum provision may result in increased costs to stockholders to bring a claim. Further, this exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

General risk factors

Our ability to use our net operating loss (NOL) carryforwards and certain other tax attributes to offset taxable income or taxes may be limited.

We have incurred significant losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. As of December 31, 2025, we had federal NOL carryforwards of \$72.3 million and state NOL carryforwards of \$23.5 million. Certain of these NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Internal Revenue Code of 1986, as amended (Code), federal NOL carryforwards arising in taxable years beginning after December 31, 2017 will not expire and may be carried forward indefinitely, but the deductibility of such federal NOL carryforwards is generally limited to no more than 80% of current year taxable income (with certain adjustments). As of December 31, 2025, we also had U.S. federal and state research and development tax credit carryforwards of \$4.8 million and \$2.6 million, respectively, which may be available to reduce future tax liabilities. The U.S. federal research and development tax credit carryforward will expire beginning in 2041 and the state research and development tax credits will expire beginning in 2039. For state income tax purposes, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California imposed limits on the usability of California state NOLs to offset taxable income and certain business credits to offset California state tax liabilities in tax years beginning after 2023 and before 2027.

In addition, under Sections 382 and 383 of the Code, if a corporation undergoes an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation’s ability to use its pre-change NOL carryforwards and certain other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. We have not completed a Section 382 study to assess whether one or more ownership changes have occurred since our formation, due to the complexity and cost associated with such a study. In addition, we may also experience ownership changes in the future including in connection with this offering or as a result of subsequent changes in our stock ownership, some of which may be outside of our control. As a result, if we undergo (or already have undergone) an ownership change, and our ability to use our pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes is limited, it could harm our future results of operations by effectively increasing our future tax obligations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. Even if we attain profitability, we may be unable to use all or a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows.

Changes and evolving requirements in tax laws or their interpretation could adversely affect our business.

The tax regimes we are subject to or operate under, including with respect to income and non-income taxes, are unsettled and may be subject to significant change. The OBBBA enacted in 2025, the Inflation Reduction Act enacted in 2022, the Coronavirus Aid, Relief, and Economic Security Act enacted in 2020, and the Tax Cuts and Jobs Act enacted in 2017 made many significant changes to the Code. Future guidance from the Internal Revenue Service and other tax authorities with respect to any legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation or sunset in future years. It is possible that changes in or interpretations under the OBBBA or other tax legislation, or the enactment of new tax legislation, could increase our future tax liability, which could in turn adversely impact our business and future profitability. The U.S. government may enact further changes to the taxation of business entities including, among others, an increase in the corporate income tax rate, the imposition of minimum taxes or surtaxes on certain types of income and significant changes to the taxation of income derived from international operations. We are unable to predict what changes to the tax laws of the United States and other jurisdictions

may be proposed or enacted in the future or what effect such changes would have on our business. Any of these or similar developments or changes to tax laws or rulings (which changes may have retroactive application) could result in adverse impacts to our financial condition, operating results and prospects and a material change to the tax considerations described herein.

Unstable economic and market conditions may have serious adverse consequences on our business, financial condition and stock price.

Global economic and business activities continue to face widespread uncertainties, and global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, bank failures, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks and uncertainty about economic and geopolitical stability (such as the geopolitical tensions between the United States and China, the Russia/Ukraine conflict, conflicts in the Middle East, which has recently included actions by Iran, Israel and the United States). While we do not expect further developments with any such banks to have a material impact on our cash and cash equivalents balance, expected results of operations or financial performance for the foreseeable future, if further failures in financial institutions occur where we hold deposits, we could experience additional risk. Any such loss or limitation on our cash and cash equivalents would adversely affect our business.

The extent of the impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments which are uncertain and cannot be predicted. There can be no assurance that further deterioration in economic or market conditions will not occur, or how long these challenges will persist. If the current equity and credit markets further deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

We will incur increased costs and become subject to additional regulations and requirements as a result of becoming a public company, and our management will be required to devote substantial time to compliance with our public company responsibilities and corporate governance practices, which could impact our financial condition and results of operations and make it more difficult to run our business.

As a public company, and particularly after we are no longer an emerging growth company or smaller reporting company, we will incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also have incurred and will continue to incur costs associated with the Sarbanes-Oxley Act, and related rules implemented by the SEC and Nasdaq. The expenses generally incurred by public companies for reporting and corporate governance purposes have been increasing. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. These laws and regulations also could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees or as our executive officers. Furthermore, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions, other regulatory action and potentially civil litigation. Accordingly, increases in costs incurred as a result of becoming a publicly-traded company may adversely affect our business, financial condition and results of operations.

If we fail to maintain effective internal control over financial reporting, we may not be able to accurately report our financial results or prevent or detect misstatements, whether due to fraud or error. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

SEC rules that implement Section 404(a) of the Sarbanes-Oxley Act require that, beginning with our second annual report following our initial public offering, management assess and report annually on the effectiveness of our internal control over financial reporting and identify any material weaknesses in our internal control over financial reporting. Although SEC rules that implement Section 404(b) of the Sarbanes-Oxley Act require our independent registered public accounting firm to issue an annual report that addresses the effectiveness of our internal control over financial reporting, we have opted to rely on the exemptions provided in the JOBS Act, and consequently will not be required to comply with SEC rules that implement Section 404(b) of the Sarbanes-Oxley Act until such time as we are no longer an emerging growth company or smaller reporting company.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inadequate internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Upon the closing of this offering, we will be subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement, causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business. Additionally, the increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements and damages awarded to plaintiffs.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no or only very few securities analysts commence coverage of us, or if industry analysts cease coverage of us, the trading price for our common stock would be negatively affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

Our insurance policies may be inadequate, may not cover all of our potential liabilities and may potentially expose us to unrecoverable risks.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, fiduciary liability workers' compensation, clinical trials/products liability, cyber security liability, directors' and officers' and employment practices insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. No assurance can be given that an insurance carrier will not seek to cancel or deny coverage after a claim has occurred. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations. For example, although we maintain product liability insurance coverage that also covers our clinical trials, this insurance may not be adequate to cover all liabilities that we may incur, and we may be required to increase our product liability insurance coverage. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and successfully commercialize any product candidate. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify. However, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur. Any significant uninsured liability may require us to pay substantial amounts, which would materially adversely affect our business, financial condition, results of operations and growth.

Special note regarding forward-looking statements

This prospectus contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical fact contained in this prospectus, including statements regarding our plans, objectives, goals, strategies, future events, future revenues or performance, financing needs, plans, or intentions relating to our product candidates and development programs and markets and business trends are forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections. In some cases, you can identify forward-looking statements because they contain words such as “aim,” “anticipate,” “assume,” “believe,” “can,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “might,” “objective,” “plan,” “positioned,” “potential,” “predict,” “project,” “seek,” “shall,” “should,” “target,” “will,” “would” or the negative of these words or other similar terms or expressions.

These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the initiation, timing, progress and results of our research and development programs, preclinical studies and clinical trials;
- our ability to develop and advance BH-30643, BH-30236, BH-501284 and any future product candidates as both monotherapy and combination therapy regimens;
- the timing of and costs involved in obtaining and maintaining regulatory approval of BH-30643, BH-30236, BH-501284 and any future product candidates that we may identify or develop;
- the beneficial characteristics, including potential safety, efficacy and therapeutic effects of BH-30643, BH-30236 and BH-501284;
- our ability to efficiently and cost-effectively conduct our current and future preclinical studies and clinical trials;
- our ability to obtain funding for our operations necessary to complete further development and, if approved, commercialization of BH-30643, BH-30236 and BH-501284;
- our ability to identify and develop BH-30643, BH-30236 and BH-501284 for the treatment of additional indications;
- the performance of our third-party service providers, including our suppliers and manufacturers;
- the rate and degree of market acceptance and clinical utility for BH-30643, BH-30236, BH-501284 and any other product candidates we may develop;
- the effects of competition with respect to BH-30643, BH-30236 and BH-501284 or any other product candidates we may develop, as well as innovations by competitors in our industry;
- our estimates regarding the potential market opportunities and the number of patients for BH-30643, BH-30236, BH-501284 and any future product candidates, if approved for commercial use;
- the implementation of our strategic plans for our business, BH-30643, BH-30236, BH-501284 and any future product candidates we may develop;

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- our intellectual property position, including the scope of protection we are able to establish, maintain, defend and enforce for intellectual property rights covering BH-30643, BH-30236, BH-501284 and any future product candidates we may develop;
- our ability to attract and retain key scientific or management personnel;
- regulatory and legal developments in the United States;
- our ability to attract and retain employees and collaborators with development, regulatory and commercialization expertise;
- the accuracy of our estimates regarding future expenses, future revenue, capital requirements and need for additional financing;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;
- our expectations regarding the impact of global health pandemics, geopolitical conflicts and economic uncertainty, including interest rate changes and inflation on our business and operations, including clinical trials, collaborators, clinical research organizations (CROs) and employees;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act; and
- our anticipated use of the proceeds from this offering.

These forward-looking statements reflect our management's beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this prospectus and are subject to risks and uncertainties. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. We discuss many of the risks associated with the forward-looking statements in this prospectus in greater detail in the section titled "Risk factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

You should carefully read this prospectus and the documents that we have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events, or otherwise.

Market, industry and other data

Certain market, industry and competitive data included in this prospectus were obtained from our own internal estimates and research, as well as from publicly available information, reports of governmental agencies and industry and academic publications and research conducted by third parties. In some cases, we do not expressly refer to the sources from which this data is derived. Information that is based on estimates, forecasts, projections, market research, or similar methodologies is inherently subject to uncertainties and involves a number of assumptions and limitations; as a result, actual events or circumstances may differ materially from events and circumstances that are assumed in this information, and you are cautioned not to give undue weight to such information.

The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled “Risk factors.” These and other factors could cause results to differ materially from those expressed in estimates made by third parties or by us.

Dividend policy

We have never declared or paid any cash dividends on our capital stock and we do not currently intend to pay any cash dividends on our capital stock for the foreseeable future. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. Any future determination to pay dividends will be made at the discretion of our board of directors, subject to applicable laws and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions and capital requirements.

Use of proceeds

We estimate that we will receive net proceeds from this offering of approximately \$134.9 million (or approximately \$155.8 million if the underwriters exercise their option to purchase additional shares in full) based on the initial public offering price of \$16.00 per share of our common stock, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for our common stock and to facilitate our future access to the public equity markets. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately \$70.0 million to advance the clinical development of BH-30643 in EGFR-mutant NSCLC, including continuation of our ongoing global Phase 1/2 clinical trial and the planned initiation of a potential registrational Phase 2 clinical trial;
- approximately \$20.0 million to advance the clinical development of BH-30236, including continuation of our ongoing Phase 1 clinical trial of BH-30236 as both a monotherapy and combination therapy in AML, HR-MDS and other hematological malignancies;
- approximately \$15.0 million to complete IND-enabling studies, submit an IND and initiate a Phase 1 clinical trial of BH-501284; and
- the remaining amounts for other research and development activities, as well as for capital expenditures, working capital and other general corporate purposes.

We may also use a portion of the net proceeds for strategic investments in complementary businesses, products, technologies or assets. However, we do not have agreements or commitments to enter into any such acquisitions or investments at this time.

Based on our current operating plans, we estimate that our existing cash and cash equivalents as of the date of this prospectus, together with the estimated net proceeds from this offering, will be sufficient to fund our projected operating expenses and capital expenditure requirements into the first quarter of 2028. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

The expected net proceeds from this offering, together with our existing cash and cash equivalents, will not be sufficient for us to fund our product candidates through clinical trials, regulatory approval and commercialization, and we will need to raise substantial additional capital in order to do so.

We cannot predict with certainty all of the particular uses for the proceeds of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including the progress, cost, and results of our preclinical and clinical development programs, our ability to obtain additional financing and other factors described under “Risk factors” in this prospectus, as well as the amount of cash used in our operations and any unforeseen cash needs. Therefore, our actual expenditures may differ materially from the estimates described above. We may find it necessary or advisable to use the net proceeds for other purposes. Our management will have broad discretion over the use of the net proceeds of this offering and investors will be relying on the judgment of our management regarding the use of those net proceeds.

Pending the use of proceeds from this offering described above, we intend to invest the net proceeds in short- and intermediate-term, interest-bearing, investment-grade investments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

Capitalization

The following table sets forth our cash and cash equivalents and our capitalization as of March 31, 2026 on:

- an actual basis;
- a pro forma basis, giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock as of March 31, 2026 into 18,258,960 shares of our common stock upon the closing of this offering and the related reclassification of the carrying value of our convertible preferred stock to permanent equity in connection with the closing of this offering, (ii) the Exercised Option Share Issuance and (iii) the filing and effectiveness of our amended and restated certificate of incorporation upon the closing of this offering; and
- a pro forma as adjusted basis, giving effect to (i) the pro forma adjustments set forth above and (ii) the issuance and sale of shares of our common stock in this offering at the initial public offering price of \$16.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

You should read the information in this table together with our financial statements and the related notes included elsewhere in this prospectus and the section titled "Management's discussion and analysis of financial condition and results of operations" and other financial information contained in this prospectus.

	As of March 31, 2026		
	Actual	Pro forma	Pro forma as adjusted
	(in thousands, except share and per share data)		
Cash and cash equivalents	\$ 116,003	\$ 118,652	\$ 253,557
Convertible preferred stock, \$0.0001 par value; 85,552,612 shares authorized, 18,258,960 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	\$ 256,823	\$ —	\$ —
Stockholders' equity (deficit):			
Common stock, \$0.0001 par value; 110,000,000 shares authorized, 2,644,326 shares issued and outstanding, actual; 700,000,000 shares authorized, pro forma and pro forma as adjusted; 21,268,660 shares issued and outstanding, pro forma; 30,643,660 shares issued and outstanding, pro forma as adjusted	1	3	4
Additional paid-in capital	3,916	263,386	398,285
Accumulated deficit	(156,037)	(156,037)	(156,037)
Total stockholders' equity (deficit)	(152,120)	107,352	242,252
Total capitalization	\$ 104,703	\$ 107,352	\$ 242,252

Except as otherwise indicated, the information in the table above excludes:

- 1,128,299 shares of our common stock issuable upon the exercise of stock options outstanding under the 2020 Plan as of March 31, 2026, with a weighted-average exercise price of \$5.54 per share, including 244,483 shares of our common stock pursuant to the Exercised Option Share Issuance, with a weighted-average exercise price of \$4.34 per share, of which 110,379 shares remain subject to a right of repurchase as of the date of this prospectus;

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- 339,502 shares of our common stock issuable upon the exercise of stock options outstanding granted under the 2020 Plan subsequent to March 31, 2026, with a weighted-average exercise price of \$12.78 per share, including 120,891 shares of our common stock pursuant to the Exercised Option Share Issuance, with a weighted-average exercise price of \$13.15 per share, of which 117,135 shares remain subject to a right of repurchase as of the date of this prospectus;
- 1,544,599 shares of our common stock issuable upon the exercise of the IPO Option Grants, as more fully described in the section titled “Executive and director compensation”;
- 5,280,528 shares of our common stock reserved for future issuance under our 2026 Plan (inclusive of the shares issuable under the IPO Option Grants), which became effective upon the execution and delivery of the underwriting agreement for this offering (which shares include 3,781,612 new shares plus the number of shares (not to exceed 1,498,916 shares) that remain available for the issuance of awards under the 2020 Plan, at the time the 2026 Plan became effective, as more fully described in the section titled “Executive and director compensation”), as well as any automatic increases in the number of shares of our common stock reserved for future issuance under the 2026 Plan; and
- 302,529 shares of our common stock reserved for future issuance under our ESPP, which became effective upon the execution and delivery of the underwriting agreement for this offering, as well as any annual automatic increases in the number of shares of our common stock reserved for future issuance under the ESPP.

Dilution

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after the closing of this offering.

As of March 31, 2026, we had a historical net tangible book value (deficit) of approximately \$(152.1) million, or \$(57.53) per share of our common stock based on 2,644,326 shares of our common stock outstanding as of such date. Our historical net tangible book value (deficit) per share represents the amount of our total tangible assets less our total liabilities and convertible preferred stock, divided by the total number of shares of our common stock outstanding as of March 31, 2026.

After giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into 18,258,960 shares of our common stock and the related reclassification of the carrying value of our convertible preferred stock to permanent equity in connection with the closing of this offering and assuming the occurrence of such conversion as of March 31, 2026 and (ii) the Exercised Option Share Issuance assuming the occurrence of such issuance as of March 31, 2026, our pro forma net tangible book value as of March 31, 2026, would have been approximately \$107.4 million, or approximately \$5.05 per share of our common stock.

Net tangible book value dilution per share to new investors represents the difference between the amount per share paid by purchasers of shares of our common stock in this offering and the pro forma as adjusted net tangible book value per share of our common stock immediately after closing of this offering. After giving further effect to the sale of 9,375,000 shares of our common stock that we are offering based on the initial public offering price of \$16.00 per share, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2026 would have been \$242.3 million, or approximately \$7.91 per share of our common stock. This amount represents an immediate increase in pro forma net tangible book value of \$2.86 per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately \$8.09 per share to new investors participating in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution:

Initial public offering price per share	\$ 16.00
Historical net tangible book value (deficit) per share as of March 31, 2026	\$(57.53)
Pro forma increase in historical net tangible book value per share as of March 31, 2026	62.58
Pro forma net tangible book value per share as of March 31, 2026, before this offering	5.05
Increase in pro forma net tangible book value per share attributed to new investors purchasing shares in this offering	2.86
Pro forma as adjusted net tangible book value per share immediately after this offering	7.91
Dilution per share to new investors in this offering	\$ 8.09

If the underwriters exercise their option to purchase up to 1,406,250 additional shares of our common stock in full in this offering, the pro forma as adjusted net tangible book value after the offering would be \$8.21 per share, the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be \$3.16 per share and the dilution per share to new investors would be \$7.79 per share, in each case based on the initial public offering price of \$16.00 per share, and after deducting the underwriting discounts and commissions payable by us.

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To the extent that outstanding options with an exercise price per share that is less than the pro forma as adjusted net tangible book value per share are exercised, new investors will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

The following table summarizes, on the pro forma as adjusted basis described above, as of March 31, 2026, the differences between the number of shares of our common stock purchased from us by our existing stockholders and common stock by new investors purchasing shares in this offering, the total consideration paid to us in cash and the weighted-average price per share paid by existing stockholders for shares of our common stock issued prior to this offering and the price to be paid by new investors for shares of our common stock in this offering. The calculation below is based on the initial public offering price of \$16.00 per share, before deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares purchased		Total consideration		Weighted-average price per share
	Number	Percent	Amount	Percent	
Existing stockholders	21,268,660	69.4%	\$ 261,413,475	63.5%	\$ 12.29
New investors ⁽¹⁾	9,375,000	30.6%	\$ 150,000,000	36.5%	\$ 16.00
Total	30,643,660	100.0%	\$ 411,413,475	100.0%	\$ 13.43

(1) The presentation in this table regarding ownership by existing stockholders does not give effect to any purchases that existing stockholders may make through our directed share program or otherwise purchase in this offering.

The table above assumes no exercise of the underwriters' option to purchase additional shares of our common stock in this offering. If the underwriters were to fully exercise their option to purchase additional shares of our common stock from us, the percentage of our common stock held by existing stockholders after this offering would be reduced to 66.4% of the total number of shares of our common stock outstanding after this offering, and the percentage of our common stock held by new investors would be increased to 33.6% of the total number of shares of our common stock outstanding after this offering.

Except as otherwise indicated, the discussion and the tables above assume no exercise of the underwriters' option to purchase additional shares of our common stock and excludes:

- 1,128,299 shares of our common stock issuable upon the exercise of outstanding stock options as of March 31, 2026, with a weighted-average exercise price of \$5.54 per share, including 244,483 shares of our common stock pursuant to the Exercised Option Share Issuance, with a weighted-average exercise price of \$4.34 per share, of which 110,379 shares remain subject to a right of repurchase as of the date of this prospectus;
- 339,502 shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to March 31, 2026, with a weighted-average exercise price of \$12.78 per share, including 120,891 shares of our common stock pursuant to the Exercised Option Share Issuance, with a weighted-average exercise price of \$13.15 per share, of which 117,135 shares remain subject to a right of repurchase;
- 1,544,599 shares of our common stock issuable upon the exercise of the IPO Option Grants, as more fully described in the section titled "Executive and director compensation";
- 5,280,528 shares of our common stock reserved for future issuance under our 2026 Plan (inclusive of the shares issuable under the IPO Option Grants), which became effective upon the execution and delivery of the

underwriting agreement for this offering (which shares include 3,781,612 new shares plus the number of shares (not to exceed 1,498,916 shares) that remain available for the issuance of awards under the 2020 Plan at the time the 2026 Plan became effective, as more fully described in the section titled “Executive and director compensation—Equity incentive plans”), as well as any automatic increases in the number of our common stock reserved for future issuance under the 2026 Plan; and

- 302,529 shares of our common stock reserved for future issuance under our ESPP, as well as any annual automatic increases in the number of shares of our common stock reserved for future issuance under the ESPP, which became effective upon the execution and delivery of the underwriting agreement for this offering.

We may choose to raise additional capital through the sale of equity or convertible debt securities due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that stock options are exercised or we issue additional shares of our common stock or other equity or convertible debt securities in the future, there will be further dilution to investors participating in this offering.

Management's discussion and analysis of financial condition and results of operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the financial statements and the related notes and other financial information included elsewhere in this prospectus. In addition to historical financial information, the following discussion and analysis contains forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed in the section titled "Risk factors" and elsewhere in this prospectus. You should carefully read the section titled "Risk factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Special note regarding forward-looking statements."

Overview

We are a clinical-stage biopharmaceutical company applying our intentional, chemistry-based approach to develop innovative small molecule medicines that address significant unmet medical needs in cancer treatment. With each of our programs, we combine a deep understanding of disease and protein dynamics with our structure-based rational drug design expertise to identify the specific structural liabilities that limit existing therapies or approaches, and then design novel chemical scaffolds to directly address these limitations. Our scientific founder and the team we have assembled have a proven track record of developing innovative small molecule medicines that overcome the limitations of existing therapies, including multiple approved therapies that have delivered transformational patient outcomes.

Our initial development efforts are focused on our two clinical-stage programs: BH-30643, an investigational, non-covalent, macrocyclic, brain active, mutant-selective OMNI-EGFR inhibitor for the treatment of *epidermal growth factor receptor* (EGFR)-mutant non-small cell lung cancer (NSCLC), and BH-30236, an investigational macrocyclic CDC-like kinase (CLK) inhibitor being evaluated first in relapsed or refractory acute myeloid leukemia (R/R AML) and higher-risk myelodysplastic syndromes (HR-MDS). We also have a preclinical-stage product candidate, BH-501284, that leverages a novel chemical scaffold to selectively target and modulate activated KRAS.

Our most advanced product candidate, BH-30643, is an OMNI-EGFR inhibitor being evaluated in SOLARA, a global Phase 1/2 clinical trial in patients with EGFR-mutant NSCLC. While there are commercially available drugs targeting EGFR subtypes, there is a fragmentation of care in EGFR-mutant NSCLC because no drug is effective across all EGFR mutations. Moreover, the durability of response to prior-generation EGFR tyrosine kinase inhibitors (TKIs) has frequently been limited by the emergence of acquired on-target resistance mutations, notably the T790M gatekeeper mutation for first- and second-generation EGFR TKIs and C797S-mediated resistance for third-generation EGFR TKIs, such as osimertinib. BH-30643 is designed to address a broad spectrum of EGFR mutations, including classical mutations, on-target resistance mutations such as C797S and T790M, atypical mutations and exon 20 insertion mutations, with selectivity over wild-type EGFR. The SOLARA Phase 1/2 clinical trial is currently enrolling patients across dose expansion cohorts in both TKI-pretreated and TKI-naïve settings, including a C797S resistance cohort, a population with no currently approved targeted therapy. Our second clinical-stage product candidate, BH-30236, is a CLK inhibitor currently being evaluated in an ongoing Phase 1 clinical trial in patients with R/R AML and HR-MDS. Our Phase 1 clinical trial is currently enrolling patients in the dose escalation part of the trial and is evaluating BH-30236 as a monotherapy and in combination with the BCL-2 inhibitor venetoclax, the established standard of care therapy for AML patients. We

are also advancing our pan-KRAS program, initially focusing on our preclinical product candidate, BH-501284, which is designed using a novel chemical scaffold to achieve prolonged, potent and selective inhibition of KRAS mutations, but sparing HRAS and NRAS. We are currently conducting Investigational New Drug Application (IND) enabling studies of BH-501284.

We commenced our operations in 2020 and have devoted substantially all of our resources to date to conducting research and development, staffing our company, establishing and protecting our intellectual property portfolio, scaling up manufacturing processes and supplying our product candidates and other materials for our preclinical studies and clinical trials, leasing office and laboratory space, raising capital, business planning, and providing general and administrative support for these activities. Our operations to date have been funded primarily through the issuance and sale of shares of our convertible preferred stock. From our inception through March 31, 2026, we have raised aggregate gross proceeds of \$257.2 million. As of March 31, 2026, we had cash and cash equivalents of \$116.0 million. Based on our current operating plan, we estimate that our existing cash and cash equivalents as of the date of this prospectus, together with the estimated net proceeds from this offering, will be sufficient to fund our projected operating expenses and capital expenditures into the first quarter of 2028. However, this estimate is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect.

Since our inception, we have incurred significant operating losses. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates. Our net losses were \$30.7 million and \$60.6 million for the years ended December 31, 2024 and 2025, respectively, and \$10.5 million and \$21.0 million for the three months ended March 31, 2025 and 2026, respectively. As of March 31, 2026, we had an accumulated deficit of \$156.0 million. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing and extent of our clinical development activities, other research and development activities and capital expenditures. We expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future as we seek to advance our product candidates through clinical and preclinical development, expand our research and development activities, seek regulatory approval, hire additional personnel and protect our intellectual property. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. We may also incur expenses in connection with the in-licensing or acquisition of additional product candidates. Furthermore, following the closing of this offering, we expect to incur increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, board of director costs and investor relations costs associated with operating as a public company that we did not incur as a private company.

We have never generated any revenue from product sales and do not expect to generate any revenue from product sales unless and until we successfully complete development of and obtain regulatory approval for our product candidates, which will not be for several years, if ever. Accordingly, until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through public or private equity or debt financings or other capital sources, which may include future strategic collaborations and other strategic arrangements with third parties. However, we may not be able to raise additional funds or enter into such other arrangements when needed or on favorable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take

specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through future collaboration or licensing arrangements with third parties or other strategic transactions, we may have to relinquish rights to our intellectual property, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional capital or enter into such arrangements when needed, we could be forced to delay, limit, reduce or terminate our research and development programs or future commercialization efforts, or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We have engaged, and expect to continue to rely on, third-party contract manufacturers to produce and supply our product candidates for use in our preclinical studies and clinical trials. Because we are responsible for ensuring all aspects of our product candidates' compliance and quality but rely on third-party contract manufacturers and analytical testing laboratories, we must employ personnel with extensive technical, manufacturing, analytical, and quality experience to oversee our contract manufacturing and testing activities, and to compile manufacturing and quality information for our regulatory submissions. We believe our current third-party manufacturers have the scale, systems and experience to supply our currently planned clinical trials. None of our product candidates have been approved for sale. If and when our product candidates receive marketing approval, we intend to commercialize them on our own, or jointly with a partner, in the United States and potentially in other geographies. We plan to continually evaluate the economics of commercializing our product candidates versus other strategic commercialization arrangements.

Financial overview

Components of results of operations

Operating expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and development

Our research and development expenses consist primarily of external and internal costs related to the discovery and development of product candidates.

External costs include:

- expenses incurred in connection with the discovery and preclinical development of our product candidates, including under agreements with third parties, such as consultants and CROs;
- expenses incurred in connection with conducting clinical trials including investigator grants, site payments, pass-through expenses and expenses incurred under agreements with CROs, central laboratories and other service providers engaged to support the conduct of our trials;

- the cost of consultants engaged in research and development related services;
- costs related to the outsourced development of CMC processes, scale-up of drug substance manufacturing and procuring our product candidates and other investigational materials for use in our clinical trials and preclinical studies; and
- costs related to regulatory compliance and quality assurance.

Internal costs include:

- personnel-related expenses, including salaries, bonuses, benefits, travel and stock-based compensation expenses for personnel engaged in research and development functions; and
- facilities, depreciation, and other expenses, which include allocated expenses for rent and maintenance of facilities, insurance and supplies.

We expense research and development costs in the periods in which they are incurred. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the level of service that has been performed at each reporting date. Payments made prior to the receipt of goods or services to be used in research and development are recorded as prepaid expenses on the balance sheet until the goods are received or services are performed. We track external research and development costs of specific programs once a specific product candidate has been identified for development. We do not track our internal research and development costs on a program-by-program basis because these costs are associated with multiple programs and, as such, are not separately identified.

Research and development activities are central to our business model, and the successful development of our product candidates is highly uncertain. There are numerous factors associated with the approval and successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Potential future changes to regulatory factors beyond our control may impact our development programs. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. In addition, we cannot predict which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Preclinical and clinical development timelines, the probability of success and total development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates and indications to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory developments, and our ongoing assessments as to each product candidate's commercial potential. Therefore, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development and commercialization of any of our product candidates or any future product candidates. However, we expect that our research and development expenses will increase substantially as we advance the preclinical and clinical development of our current and potential future product candidates.

Our future development costs may vary significantly based on factors, including, but not limited to:

- the number and scope of preclinical and IND-enabling studies;
- the number of clinical trials required for approval;

- the number of sites included in the clinical trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the clinical trials;
- the number of doses evaluated in the clinical trials;
- the costs of manufacturing our product candidates and the costs of procuring any third-party products for use in clinical trials of combination therapies;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the clinical trials and follow-up;
- the phase of development of the product candidate; and
- the efficacy, safety and tolerability profile of the product candidate.

A change in the outcome of any of these variables may significantly impact the costs and timing associated with the development of our product candidates.

General and administrative

General and administrative expenses support our key business functions as we grow and mature as a company. General and administrative expenses consist of personnel-related expenses, including salaries, bonuses, benefits, travel and stock-based compensation expenses for personnel engaged in executive, finance, legal and other administrative functions. Other significant general and administrative expenses include facilities-related costs, legal fees relating to intellectual property and corporate matters, audit costs, information technology-related costs and insurance costs.

We expect that our general and administrative expenses will increase substantially for the foreseeable future to support our continued and potentially growing research and development activities, pre-commercial preparation activities for our product candidates, and, if any product candidate receives marketing approval, commercialization activities.

Following the closing of this offering, we also anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, board of director costs and investor relations costs associated with operating as a public company.

Interest income, net

Interest income, net consists primarily of interest on our cash equivalents held in money market funds.

Other expenses, net

Other expenses, net consists primarily of foreign exchange gains and losses.

Results of operations for the three months ended March 31, 2025 and 2026

The following table summarizes our results of operations for the three months ended March 31, 2025 and 2026 (in thousands):

	Three Months Ended March 31,		
	2025	2026	Change
Operating expenses:			
Research and development	\$ 9,572	\$ 19,901	10,329
General and administrative	1,882	2,206	324
Total operating expenses	11,454	22,107	10,653
Loss from operations	(11,454)	(22,107)	(10,653)
Other income (expense), net:			
Interest income, net	976	1,102	126
Other expense	—	(3)	(3)
Total other income, net	976	1,099	123
Net loss	\$ (10,478)	\$ (21,008)	(10,530)

Research and development expenses

We track external research and development costs of specific programs once a specific product candidate has been identified for development. We do not track internal research and development costs on a program-by-program basis.

The following table summarizes our research and development expenses by program for the three months ended March 31, 2025 and 2026 (in thousands):

	Three Months Ended March 31,		
	2025	2026	Change
External research and development expense:			
BH-30643	\$ 1,782	\$ 9,550	\$ 7,768
BH-30236	1,048	1,747	699
BH-501284	—	585	585
Other preclinical programs and discovery	1,842	1,012	(830)
Internal research and development expense:			
Personnel-related	4,202	5,435	1,233
Facilities, overhead and other	698	1,572	874
Total research and development expense	\$ 9,572	\$ 19,901	\$ 10,329

Research and development expenses were \$9.6 million for the three months ended March 31, 2025, compared to \$19.9 million for the three months ended March 31, 2026. The increase of \$10.3 million was primarily due to increases in both external and internal research and development costs, which are described in more detail below.

For BH-30643, external costs were \$1.8 million for the three months ended March 31, 2025, compared to \$9.6 million for the three months ended March 31, 2026. The increase of approximately \$7.8 million was primarily due to significant growth in clinical trial enrollment and sites activated and an increase in

manufacturing costs related to the clinical development of BH-30643. For BH-30236, external costs were \$1.0 million for the three months ended March 31, 2025, compared to \$1.7 million for the three months ended March 31, 2026. The increase of approximately \$0.7 million was primarily due to the advancement of our ongoing clinical trial. For BH-501284, external costs were \$0.6 million for the three months ended March 31, 2026. There were no related costs in 2025. The increase of \$0.6 million was primarily comprised of manufacturing-related expenses to support IND-enabling studies and potential future clinical development. These increases in external research and development costs were partially offset by a decrease of \$0.8 million in external expenses related to our other programs and discovery, as we focused investment toward the development of our most advanced product candidates.

Internal costs were \$4.9 million for the three months ended March 31, 2025, compared to \$7.0 million for the three months ended March 31, 2026. The increase of approximately \$2.1 million was due to a \$1.2 million increase in personnel-related expenses driven by our additional headcount as we expanded the number of research and development employees to support our programs, and an increase of approximately \$0.9 million in facilities, overhead and other expenses.

General and administrative expenses. General and administrative expenses were \$1.9 million for the three months ended March 31, 2025, compared to \$2.2 million for the three months ended March 31, 2026. The increase of \$0.3 million was comprised of a \$0.4 million increase in personnel-related expenses and a \$0.2 million increase in facilities-related expenses, partially offset by a decrease in legal expenses of \$0.2 million and a decrease in general overhead and outside services expense of \$0.1 million.

Interest income, net. Interest income, net was \$1.0 million for the three months ended March 31, 2025, compared to \$1.1 million for the three months ended March 31, 2026. The increase of \$0.1 million was primarily due to an increase in interest income on our invested cash equivalents held in our money market funds, driven by an increase in average balance held in money market funds and to a lesser extent by changing interest rates.

Results of operations for the years ended December 31, 2024 and 2025

The following table summarizes our results of operations for the years ended December 31, 2024 and 2025 (in thousands):

	Year ended December 31,		
	2024	2025	Change
Operating expenses:			
Research and development	\$ 31,810	\$ 56,138	\$ 24,328
General and administrative	4,591	7,886	3,295
Total operating expenses	36,401	64,024	27,623
Loss from operations	(36,401)	(64,024)	(27,623)
Other income (expense), net:			
Interest income, net	5,706	3,480	(2,226)
Other expense, net	—	(11)	(11)
Total other income, net	5,706	3,469	(2,237)
Net loss	\$ (30,695)	\$ (60,555)	\$ (29,860)

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Research and development expenses

The following table summarizes our research and development expenses by program for the years ended December 31, 2024 and 2025 (in thousands):

	Year ended December 31,		
	2024	2025	Change
External research and development costs:			
BH-30643	\$ 5,958	\$ 20,648	\$14,690
BH-30236	3,841	6,829	2,988
BH-501284	—	891	891
Other preclinical programs and discovery	6,691	4,363	(2,328)
Internal research and development costs:			
Personnel-related	12,056	18,360	6,304
Facilities, overhead and other	3,264	5,047	1,783
Total research and development expense	\$ 31,810	\$ 56,138	\$24,328

Research and development expenses were \$31.8 million for the year ended December 31, 2024, compared to \$56.1 million for the year ended December 31, 2025. The increase of \$24.3 million was primarily due to increases in both external and internal research and development costs, which are described in more detail below.

For BH-30643, external costs were \$6.0 million for the year ended December 31, 2024, compared to \$20.6 million for the year ended December 31, 2025. The increase of approximately \$14.7 million was primarily due to our advancing the development of this product candidate, including the initiation of a clinical trial. For BH-30236, external costs were \$3.8 million for the year ended December 31, 2024, compared to \$6.8 million for the year ended December 31, 2025. The increase of approximately \$3.0 million was primarily due to our advancing the development of this product candidate, including the ongoing clinical trial. For BH-501284, external costs were \$0.9 million for the year ended December 31, 2025. There were no related costs in 2024. The increase of \$0.9 million was primarily comprised of manufacturing-related expenses to support IND-enabling studies and potential future clinical development. These increases in external research and development costs were partially offset by a decrease of \$2.3 million in external expenses related to our other programs and discovery, as we focused investment toward the development of our most advanced product candidates.

Internal costs were \$15.3 million for the year ended December 31, 2024, compared to \$23.4 million for the year ended December 31, 2025. The increase of approximately \$8.1 million was due to a \$6.3 million increase in personnel-related expenses driven by our additional headcount as we expanded the number of research and development employees to support our programs, and an increase of approximately \$1.8 million in facilities, overhead and other expenses.

General and administrative expenses. General and administrative expenses were \$4.6 million for the year ended December 31, 2024, compared to \$7.9 million for the year ended December 31, 2025. The increase of \$3.3 million was comprised of a \$1.3 million increase in personnel-related expenses, a \$1.1 million increase in legal expenses, a \$0.4 million increase in general overhead, a \$0.3 million increase in outside services and a \$0.2 million increase in facilities-related expenses.

Interest income, net. Interest income, net was \$5.7 million for the year ended December 31, 2024, compared to \$3.5 million for the year ended December 31, 2025. The decrease of \$2.2 million was primarily due to a decrease

in interest income on our invested cash equivalents held in our money market funds in 2025, driven by a decrease in average balance held in money market funds and to a lesser extent by changing interest rates.

Liquidity and capital resources

Sources of liquidity

We have incurred net losses and negative cash flows from operations since our inception and expect to continue to incur significant and increasing operating losses for the foreseeable future. We have never generated any revenue from product sales and do not expect to generate any revenue from product sales unless and until we successfully complete development of and obtain regulatory approval for one or more of our product candidates, which will not be for several years, if ever. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

From our inception through March 31, 2026, we have raised aggregate gross proceeds of \$257.2 million to fund our operations, comprised primarily from our issuance of convertible preferred stock.

Cash flows

The following table sets forth a summary of the net cash flow activity for the periods indicated (in thousands):

	Year ended December 31,		Change	Three months ended March 31,		Change
	2024	2025		2025	2026	
Net cash provided by (used in):						
Operating activities	\$ (31,416)	\$ (46,925)	\$ (15,509)	\$ (10,979)	\$ (20,940)	\$ (9,961)
Investing activities	(92)	(1,067)	(975)	(402)	(13)	389
Financing activities	17,560	84,527	66,967	39	274	235
Net increase (decrease) in cash	\$ (13,948)	\$ 36,535	\$ 50,483	\$ (11,342)	\$ (20,679)	\$ (9,337)

Operating activities

Net cash used in operating activities for the three months ended March 31, 2025 was \$11.0 million, consisting primarily of our net loss of \$10.5 million, adjusted for \$0.5 million in non-cash charges, primarily related to non-cash lease expense, stock-based compensation expense, and depreciation, as well as \$1.0 million in net changes in operating assets and liabilities.

Net cash used in operating activities for the three months ended March 31, 2026 was \$20.9 million, consisting primarily of our net loss of \$21.0 million, adjusted for \$0.8 million in non-cash charges, primarily related to non-cash lease expense, stock-based compensation expense, and depreciation, as well as \$0.7 million in net changes in operating assets and liabilities.

Net cash used in operating activities for the year ended December 31, 2024 was \$31.4 million, consisting primarily of our net loss of \$30.7 million, adjusted for \$1.6 million in non-cash charges, primarily related to non-cash lease expense, stock-based compensation expense, and depreciation, as well as \$2.3 million in net changes in operating assets and liabilities.

Net cash used in operating activities for the year ended December 31, 2025 was \$46.9 million, consisting primarily of our net loss of \$60.6 million, adjusted for \$2.8 million in non-cash charges, primarily related to non-cash lease expense, stock-based compensation expense, and depreciation, as well as \$10.8 million in net changes in operating assets and liabilities.

Investing activities

Net cash used in investing activities was \$0.4 million and \$13,000 for the three months ended March 31, 2025 and 2026, respectively, consisting primarily of purchases of property and equipment.

Net cash used in investing activities was \$0.1 million and \$1.1 million for the years ended December 31, 2024 and 2025, respectively, consisting primarily of purchases of property and equipment.

Financing activities

Net cash provided by financing activities for the three months ended March 31, 2025 was \$39,000, consisting of proceeds from the exercise of stock options.

Net cash provided by financing activities for the three months ended March 31, 2026 was \$0.3 million, consisting of proceeds from the exercise of stock options.

Net cash provided by financing activities for the year ended December 31, 2024 was \$17.6 million, consisting primarily of proceeds, net of issuance costs, of \$17.1 million from the issuance and sale of shares of our Series B convertible preferred stock, and from proceeds of \$0.4 million from the exercise of stock options.

Net cash provided by financing activities for the year ended December 31, 2025 was \$84.5 million, consisting of proceeds, net of issuance costs, of \$83.9 million from the issuance and sale of shares of our Series B convertible preferred stock, and proceeds of \$0.6 million from the exercise of stock options.

Future funding requirements

Our financial statements included elsewhere in this prospectus have been prepared on a going concern basis, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from the outcome of this uncertainty.

As of March 31, 2026, we had cash and cash equivalents of \$116.0 million. We have incurred significant losses and negative cash flows from operations since our inception. As of March 31, 2026, we had an accumulated deficit of \$156.0 million. Based on the current cash forecast, management has determined that there is uncertainty about whether our present capital resources will be sufficient to fund our planned operations beyond twelve months from the issuance date of the financial statements included elsewhere in this prospectus and thus has concluded that substantial doubt exists as to our ability to continue as a going concern. Our ability to continue as a going concern is dependent on our ability to execute our business plan and raise capital. If we are unable to raise capital, to continue as a going concern, we would need to modify our operating plans and decrease our spending, which could include delaying, downsizing or ceasing altogether the clinical development of certain of our programs. The financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

Based on our current operating plan, we estimate that our existing cash and cash equivalents as of the date of this prospectus, together with the estimated net proceeds from this offering, will be sufficient to fund our projected operating expenses and capital expenditures into the first quarter of 2028. However, this estimate is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect.

Our future capital requirements will depend on many factors, including:

- the scope, timing, progress, costs and results of discovery, preclinical development, and clinical trials for our current or future product candidates;

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- the number of clinical trials required for regulatory approval of our current or future product candidates, which may differ between the United States and other countries or regions;
- the costs, timing and outcome of regulatory review of any of our current or future product candidates;
- the costs associated with potentially acquiring or licensing additional product candidates, technologies or assets, including the timing and amount of any milestones, royalties or other payments due in connection with our acquisitions and licenses;
- the cost of manufacturing clinical and commercial supplies of our current or future product candidates;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any possible claims by third parties that we are infringing upon their intellectual property rights;
- our ability to establish and maintain possible future strategic collaborations or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution, for any product candidate for which we receive regulatory approval;
- the revenue, if any, received from commercial sales of the product candidate(s) for which we receive regulatory approval;
- expenses to attract, hire and retain skilled personnel;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors for any products that receive regulatory approval;
- our ability to mitigate the impact of adverse macroeconomic conditions or geopolitical events and conflicts, including any health epidemics and their residual effects, bank failures or inflation and increased interest rates, on our preclinical and clinical development or operations;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies.

Until such time, if ever, that we can generate substantial revenue from sales of our product candidates, we expect to finance our cash needs through public or private equity or debt financings or other capital sources, which may include future strategic collaborations and other strategic arrangements with third parties. However, we may not be able to raise additional funds or enter into such other arrangements when needed or on favorable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through future collaboration or licensing arrangements with third parties or other strategic transactions, we may have to relinquish rights to our intellectual property, future revenue streams, research programs, or product candidates or grant licenses on

terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds or enter into such arrangements when needed, we could be forced to delay, limit, reduce or terminate our research and development programs or future commercialization efforts, or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Contractual obligations and commitments

As part of the capital needs to fund our ongoing operations, our material cash requirements include the following contractual obligations.

In June 2024, we entered into a non-cancelable operating lease for office and laboratory space in San Diego, California, with a ten-year initial term through June 2035 (Science Center Lease). The Science Center Lease commenced in June 2025 and includes aggregate monthly rent payments of approximately \$0.3 million, with scheduled annual increases in base rent and rent abatements during an initial period of the term. Additionally, we are obligated to pay real estate taxes, maintenance costs, and other operating expenses allocable to the leased premises, which are variable in nature. We paid a cash security deposit of \$0.9 million, which is refundable at the end of the lease term and is included in other long-term assets in our balance sheet as of March 31, 2026.

As of March 31, 2026, we have future remaining operating lease payments of \$39.2 million relating to leases we have recognized in the balance sheet. These obligations are further described in Note 8 to our audited financial statements and Note 6 to our unaudited condensed financial statements included elsewhere in this prospectus.

In addition, we enter into agreements and purchase orders in the normal course of business with vendors for the provision of goods and services. These agreements may include certain provisions for termination, with notice, which typically consist of payments for services provided or expenses incurred through the date of cancellation. We believe that our non-cancelable obligations under these agreements are not material.

Critical accounting estimates

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States (GAAP). The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, costs, and expenses and the disclosure of contingent assets and liabilities in our financial statements and accompanying notes. We base our estimates on historical experience, known trends and events, and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and judgments on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our financial statements included elsewhere in this prospectus, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Research and development expenses and accrued research and development costs

We are required to estimate our expenses resulting from obligations under contracts with vendors, consultants and CROs, in connection with conducting research and development activities. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows

that do not match the periods over which materials or services are provided under such contracts. We reflect research and development expenses in our financial statements by matching those expenses with the period in which services and efforts are expended. We account for these expenses according to the progress of the preclinical or clinical study as measured by the timing of various aspects of the study or related activities. We determine accrual estimates through review of the underlying contracts along with preparation of financial models taking into account discussions with research, clinical operations and other key personnel, as well as considering the input from our CROs, as to the progress of studies, or other services being conducted.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period.

Stock-based compensation expense

Stock-based compensation expense represents the cost of the grant date fair value of employee, officer, director and non-employee stock options. We estimate the fair value of stock options on the date of grant using the Black-Scholes option pricing model and recognize the expense over the requisite service period of the awards, which is generally the vesting period, on a straight-line basis. We account for forfeitures when they occur and reverse any compensation cost previously recognized for awards for which the requisite service has not been completed, in the period that the award is forfeited.

The Black-Scholes option pricing model uses inputs which are based on highly subjective assumptions and generally require significant judgment. These assumptions include the risk-free interest rate, the expected stock price volatility, the expected term of stock options, the expected dividend yield and the fair value of the underlying common stock on the date of grant.

See Note 6 to our audited financial statements and Note 5 to our unaudited condensed financial statements included elsewhere in this prospectus for more information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options. Certain of such assumptions involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation could be materially different.

Common stock valuation

We are required to estimate the fair value of the common stock underlying our stock-based awards when performing fair value calculations using the Black-Scholes option pricing model. Because our common stock is not currently publicly traded, the fair value of the common stock underlying our stock-based awards has been determined on each grant date by our board of directors or our compensation committee, with input from management, considering our most recently available third-party valuation of common shares. All options to purchase shares of our common stock are intended to be granted with an exercise price per share no less than the fair value per share of our common stock underlying those options on the date of grant, based on the information known to us on the date of grant.

Our determination of the value of our common stock was performed using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants (AICPA), *Audit and Accounting Practice Aid Series: Valuation of Privately Held Company Equity Securities Issued as Compensation* (the AICPA Practice Aid). In addition, our board of directors considered various objective and subjective factors to determine the fair value of our common stock, including:

- the prices at which we sold shares of our convertible preferred stock and the superior rights, preferences and privileges of the convertible preferred stock relative to our common stock at the time of each grant;

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- the progress of our research and development programs;
- our stage of development and our business strategy;
- external market conditions affecting the biotechnology industry and trends within the biotechnology industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our convertible preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering or sale of our company in light of prevailing market conditions; and
- the analysis of IPOs and the valuations and market performance of similar companies in the biotechnology industry.

The AICPA Practice Aid prescribes several valuation approaches for setting the value of an enterprise, such as the cost, income and market approaches, and various methodologies for allocating the value of an enterprise to its common stock. The cost approach establishes the value of an enterprise based on the cost of reproducing or replacing the property less depreciation and functional or economic obsolescence, if present. The income approach establishes the value of an enterprise based on the present value of future cash flows that are reasonably reflective of our future operations, discounting to the present value with an appropriate risk adjusted discount rate or capitalization rate. The market approach is based on the assumption that the value of an asset is equal to the value of a substitute asset with the same characteristics.

In accordance with the AICPA Practice Aid, we considered the various methods for allocating the enterprise value to determine the fair value of our common stock at the valuation date. Under the option pricing method (OPM), shares are valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The value of the common stock is inferred by analyzing these options. The probability weighted expected return method (PWERM) is a scenario-based analysis that estimates the value per share based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to us, as well as the economic and control rights of each share class.

Based on our early stage of development and other relevant factors, for options granted prior to February 11, 2026, we determined that an OPM method was the most appropriate method for allocating our enterprise value to determine the estimated fair value of our common stock. For options granted after February 11, 2026, we determined that a hybrid method that combines both OPM and PWERM was the most appropriate method for allocating our enterprise value to determine the estimated fair value of our common stock. In determining the estimated fair value of our common stock, our board of directors also considered the fact that our stockholders could not freely trade our common stock in the public markets. Accordingly, we applied discounts to reflect the lack of marketability of our common stock based on the weighted-average expected time to liquidity.

There are significant judgments and estimates inherent in the determination of the fair value of our common stock. These judgments and estimates include assumptions regarding our future operating performance, the time to completing a liquidity event and the determination of the appropriate valuation methods. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per share of common stock could have been significantly different.

Once a public trading market for our common stock has been established in connection with the closing of this offering, it will no longer be necessary to estimate the fair value of our common stock in connection with our

accounting for stock option grants and other such awards we may grant, as the fair value of our common stock will be determined based on the quoted market price of our common stock.

Recently issued accounting pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our audited financial statements and unaudited condensed financial statements included elsewhere in this prospectus.

Quantitative and qualitative disclosures about market risks

Interest rate and market risk

We are exposed to market risks in the ordinary course of our business, primarily limited to interest rate fluctuations. Our cash and cash equivalents consist primarily of amounts invested in money market instruments, such as money market funds, treasury bills and securities issued by the U.S. government or its agencies. The primary objective of our investment activities is to preserve principal and liquidity while maximizing income without significantly increasing risk. We do not enter into investments for trading or speculative purposes.

Due to the short-term nature of our investment portfolio, we do not believe that a hypothetical 10% increase or decrease in interest rates during any of the periods presented would have a material effect on our financial statements included elsewhere in this prospectus.

Effects of inflation

Inflation generally affects us by increasing our cost of labor and research and development contract costs. We do not believe inflation has had a material effect on our results of operations during the periods presented in our financial statements included elsewhere in this prospectus.

Emerging growth company and smaller reporting company status

We are an “emerging growth company” as defined in the JOBS Act, and we may remain an emerging growth company for up to five years following the closing of this offering. For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period and, therefore, we are not subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies; however, we may adopt certain new or revised accounting standards early. We would cease to be an emerging growth company upon the earliest to occur of: (i) the last day of the fiscal year in which we have \$1.235 billion or more in annual revenue; (ii) the date on which we first qualify as a large accelerated filer under the rules of the SEC; (iii) the date on

which we have, in any three-year period, issued more than \$1.0 billion in non-convertible debt securities; and (iv) the last day of the fiscal year ending after the fifth anniversary of this offering.

We are also a “smaller reporting company” as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as the market value of our voting and non-voting common stock held by non-affiliates is less than \$250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than \$100.0 million during the most recently completed fiscal year, and the market value of our voting and non-voting common stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter.

Business

Overview

We are a clinical-stage biopharmaceutical company applying our intentional, chemistry-based approach to develop innovative small molecule medicines that address significant unmet medical needs in cancer treatment. With each of our programs, we combine a deep understanding of disease and protein dynamics with our structure-based rational drug design expertise to identify the specific structural liabilities that limit existing therapies or approaches, and then design novel chemical scaffolds to directly address these limitations. Our scientific founder and the team we have assembled have a proven track record of developing innovative small molecule medicines that overcome the limitations of existing therapies, including multiple approved therapies that have delivered transformational patient outcomes.

Our initial development efforts are focused on our two clinical-stage programs: BH-30643, an investigational, non-covalent, macrocyclic, brain active, mutant-selective OMNI-EGFR inhibitor for the treatment of *epidermal growth factor receptor* (EGFR)-mutant non-small cell lung cancer (NSCLC), and BH-30236, an investigational macrocyclic CDC-like kinase (CLK) inhibitor being evaluated first in relapsed or refractory acute myeloid leukemia (R/R AML) and higher-risk myelodysplastic syndromes (HR-MDS). We also have a preclinical-stage product candidate, BH-501284, that leverages a novel chemical scaffold to selectively target and modulate activated KRAS.

Our most advanced product candidate, BH-30643, is an OMNI-EGFR inhibitor being evaluated in SOLARA, a global Phase 1/2 clinical trial in patients with EGFR-mutant NSCLC. While there are commercially available drugs targeting EGFR subtypes, there is a fragmentation of care in EGFR-mutant NSCLC because no drug is effective across all EGFR mutations. Moreover, the durability of response to prior-generation EGFR tyrosine kinase inhibitors (TKIs) has frequently been limited by the emergence of acquired on-target resistance mutations, notably the T790M gatekeeper mutation for first- and second-generation EGFR TKIs and C797S-mediated resistance for third-generation EGFR TKIs, such as osimertinib. BH-30643 is designed to address a broad spectrum of EGFR mutations, including classical mutations, on-target resistance mutations such as C797S and T790M, atypical mutations and exon 20 insertion mutations, with selectivity over wild-type EGFR. The SOLARA Phase 1/2 clinical trial is currently enrolling patients across dose expansion cohorts in both TKI-pretreated and TKI-naïve settings, including a C797S resistance cohort, a population with no currently approved targeted therapy. To date, treatment with BH-30643 has been evaluated for safety, pharmacokinetics and preliminary efficacy in patients with EGFR-mutant NSCLC, including in patients with the C797S resistance mutation across diverse molecular contexts (with or without T790M) in the setting of classical or atypical mutations, and in TKI-naïve patients with classical mutations. We believe the early clinical data observed in this trial support a near-term development path in C797S resistance and establish the foundation for BH-30643's potential against a broad spectrum of EGFR activating mutations. We plan to seek an end-of-Phase 1 meeting with the U.S. Food and Drug Administration (FDA) regarding the recommended Phase 2 dose and a potential accelerated approval pathway for BH-30643 in patients with advanced or metastatic C797S-positive EGFR-mutant NSCLC in the fourth quarter of 2026.

Our second clinical-stage product candidate, BH-30236, is a CLK inhibitor currently being evaluated in an ongoing Phase 1 clinical trial in patients with R/R AML and HR-MDS. BH-30236 represents a novel approach to cancer treatment through the inhibition of CLK to target aberrant alternative mRNA splicing (aberrant alternative splicing), a defining feature implicated in cancer progression and therapeutic resistance across both hematologic malignancies and solid tumors. Our Phase 1 clinical trial is currently enrolling patients in the dose escalation part of the trial and is evaluating BH-30236 as a monotherapy and in combination with the BCL-2 inhibitor venetoclax, the established standard of care therapy for acute myeloid leukemia (AML) patients. To date, BH-30236 has been evaluated for safety, pharmacokinetics and preliminary efficacy across multiple dose

levels as a monotherapy and in combination with venetoclax. We expect to report updated safety and efficacy data from the BH-30236 Phase 1 trial in the first half of 2027.

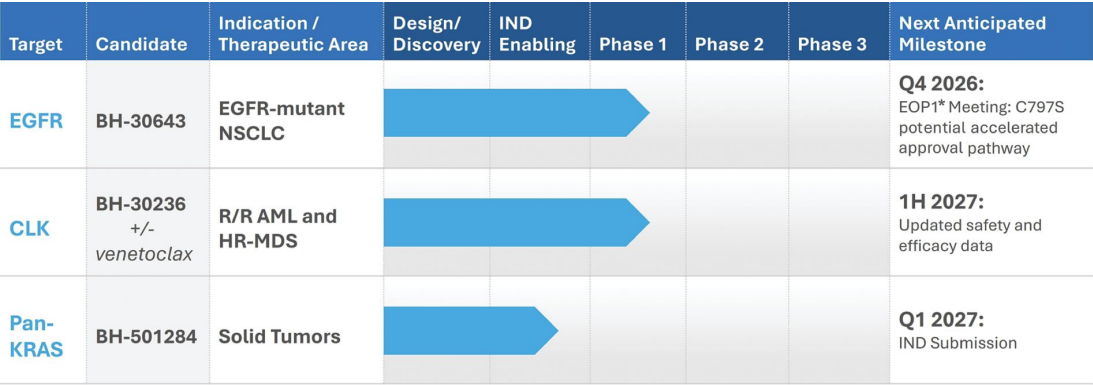
We are also advancing our pan-KRAS program, initially focusing on our preclinical product candidate, BH-501284, which is designed using a novel chemical scaffold to achieve prolonged, potent and selective inhibition of KRAS mutations, but sparing HRAS and NRAS. We believe this molecule, which leverages a newly designed non-covalent scaffold, is unique in its potential to achieve tight and durable binding, a feature described as “pseudo-irreversible” binding. BH-501284 has demonstrated potent cellular pan-KRAS activity, achieved tumor regression at low oral dose levels in multiple KRAS-mutant mouse tumor models and improved oral bioavailability across species. We are currently conducting Investigational New Drug Application (IND) enabling studies of BH-501284 and plan to submit an IND in the first quarter of 2027.

Our ability to develop differentiated small molecules is made possible by our team, led by our scientific founder, President and Chief Executive Officer, J. Jean Cui, Ph.D., who is the lead inventor of three FDA-approved targeted cancer therapies—crizotinib (XALKORI), lorlatinib (LORBRENA) and repotrectinib (AUGTYRO), all of which have achieved significant commercial success and the latter two of which have established the macrocyclic TKI structure as a validated therapeutic design. Our Chief Medical Officer, Geoffrey R. Oxnard, M.D., is a globally recognized clinical and translational cancer investigator focused on molecular drivers of sensitivity and resistance to precision cancer therapies. Dr. Oxnard has played a foundational role in defining the C797S resistance mutation and the application of molecular diagnostics to advance cancer care and drug development.

We believe the combination of Dr. Cui’s proven drug design expertise and Dr. Oxnard’s clinical and scientific leadership in precision oncology, together with our broader executive and management leadership team that has deep experience in drug development, uniquely positions us to execute on our mission to develop innovative small molecule medicines with the potential to overcome the limitations of existing therapies or approaches and address significant unmet medical needs in cancer treatment.

Our pipeline

We are developing a wholly-owned pipeline of two clinical-stage product candidates and one preclinical-stage product candidate, as represented in the figure below.



* EOP1: End-of-Phase 1

BH-30643: OMNI-EGFR inhibitor for the treatment of EGFR-mutant NSCLC

Lung cancer is the leading cause of cancer-related death worldwide. NSCLC accounts for approximately 85% of all lung cancer cases, and, according to GlobalData, approximately 316,000 patients were diagnosed with EGFR-mutant NSCLC across key global markets of the United States, Europe, Japan and China in 2025. Activating mutations in the

EGFR gene represent the most common targetable oncogenic driver in NSCLC and define a clinically and molecularly distinct patient population. A wide variety of EGFR mutations broadly grouped into three categories have been reported: classical mutations (exon 19 deletion and L858R mutation, collectively representing approximately 80% of EGFR mutations), atypical mutations (such as G719X, L861Q and S768I, collectively representing approximately 10% of EGFR mutations) and exon 20 insertion mutations (approximately 10% of EGFR mutations).

Three generations of EGFR TKIs are primarily approved for classical EGFR-mutant NSCLC, with treatment durations averaging less than approximately two years, as resistance typically develops by this point and limits further treatment. Importantly, at the time treatment resistance develops, the EGFR mutations present in NSCLC can evolve further, with the emergence of on-target resistance mutations such as C797S, T790M, L718X and G724X. First and second generation EGFR TKIs have a chemical group extending beyond the T790 residue, referred to as the “back-pocket motif,” and are vulnerable to resistance driven by the T790M gatekeeper mutation; newer TKIs that utilize a similar scaffold inherit this resistance vulnerability. Third generation EGFR TKIs rely on covalent binding for potency and are vulnerable to the C797S resistance mutation which blocks the necessary covalent binding. This C797S mutation is the most common EGFR mutation driving resistance to third generation EGFR-targeted therapy and is detected in approximately 13% of patients at the time of resistance, per several recent publications.

We estimate there are approximately 3,200 NSCLC patients annually in the United States with C797S-driven resistance and considerably more globally. There are currently no approved oral targeted therapies in the United States for patients with C797S-mediated resistance to third generation EGFR TKIs, the current standard of care.

Our most advanced product candidate, BH-30643, is a non-covalent, macrocyclic, brain active, mutant-selective OMNI-EGFR inhibitor for the treatment of EGFR-mutant NSCLC. BH-30643 is designed to address a broad spectrum of EGFR mutations, including classical mutations, on-target resistance mutations such as C797S and T790M, atypical mutations and exon 20 insertion mutations, with selectivity over wild-type EGFR. BH-30643 is being evaluated in SOLARA, a global Phase 1/2, first-in-human clinical trial currently enrolling patients at over 40 sites in 10 countries. Ongoing dose expansion cohorts are enrolling in both TKI-pretreated and TKI-naïve settings, including a C797S resistance cohort. We believe the early clinical data observed in this trial support a near-term development path in C797S resistance and establish the foundation for BH-30643’s potential against a broad spectrum of EGFR activating mutations.

We plan to seek an end-of-Phase 1 meeting with the FDA regarding the recommended Phase 2 dose and a potential accelerated approval pathway for BH-30643 in patients with advanced or metastatic C797S-positive EGFR-mutant NSCLC in the fourth quarter of 2026. We expect to dose the first patient in our anticipated pivotal Phase 2 trial in the first quarter of 2027. We plan to report additional Phase 1 data on durability of response in the C797S population in the first half of 2027, the initial Phase 1 data on the chemotherapy combination cohort in the second half of 2027, and additional Phase 1 data on durability of response in the TKI-naïve cohort for EGFR classical mutations in the second half of 2027.

BH-30236: CLK inhibitor for the treatment of R/R AML and HR-MDS

AML is the most common acute leukemia in adults, with approximately 21,000 new diagnoses and 11,000 deaths annually in the United States. Approximately one-third of AML patients do not have a complete remission or do not respond to frontline venetoclax and azacitidine combination therapy, and the majority of initial responders ultimately develop resistance and progressive disease. There is no currently approved targeted therapy for patients with resistance to venetoclax-based combination therapy in the absence of targetable genetic alterations. Patients with HR-MDS closely mirror AML in clinical course, frontline treatment and unmet need in the relapsed and refractory setting. According to GlobalData, approximately 14,000 patients are diagnosed with HR-MDS annually in the United States.

AML and HR-MDS are, in part, diseases associated with aberrant alternative splicing. While it has been scientifically validated that CLK inhibition modulates aberrant alternative splicing across both hematologic malignancies and solid tumors, prior efforts to target alternative splicing through CLK inhibition have faced challenges clinically and encountered toxicities requiring intermittent dosing. The venetoclax-resistant and refractory segment, for which no approved therapy currently exists for broad application (or usage), represents our initial area of focus for BH-30236.

Our second clinical-stage product candidate, BH-30236, is a CLK inhibitor currently being evaluated in an ongoing Phase 1 first-in-human trial in patients with R/R AML and HR-MDS. Our Phase 1 clinical trial is currently enrolling patients in the dose escalation part of the trial and is evaluating BH-30236 as a monotherapy and in combination with the BCL-2 inhibitor venetoclax, the established standard of care therapy for AML patients. We also plan to explore the antileukemic effect of BH-30236 in additional myeloid malignancies as well as study the safety and antileukemic effect of BH-30236 with venetoclax plus azacitidine for the treatment of AML. We expect to report updated safety and efficacy data from the BH-30236 Phase 1 trial in the first half of 2027.

BH-501284: pan-KRAS inhibitor

KRAS mutations are the most frequent oncogenic driver alterations in human cancer, present in approximately 25% of all malignancies—with particularly high prevalence in pancreatic ductal adenocarcinoma (approximately 90%), colorectal carcinoma (CRC) (approximately 40%) and lung adenocarcinomas (approximately 30%).

While covalent KRAS G12C inhibitors are now approved by the FDA to treat G12C-mutant NSCLC and CRC, these agents address only a single mutant allele and leave patients harboring other frequent oncogenic KRAS mutations, including G12D, G12V, G12S and G12A, without an approved targeted therapy. Investigational KRAS inhibitors leverage several emergent design approaches, including non-covalent Switch-II pocket inhibitors and tricomplex inhibitors. Though tricomplex RAS inhibitors offer broad activity, they face a greater adverse event burden in the clinic. To deliver a clinically meaningful pan-KRAS Switch-II inhibitor, we believe a fresh chemical scaffold is required to achieve both high cell potency and a favorable pharmacology profile, offering an opportunity to achieve a more durable benefit for patients.

We are advancing our preclinical pan-KRAS product candidate, BH-501284, which utilizes a novel Switch-II chemical scaffold designed to provide prolonged, potent and selective inhibition of KRAS, sparing HRAS and NRAS. In preclinical studies, BH-501284 achieved pseudo-irreversible binding characteristics with high binding affinity and a prolonged target residence time exceeding 54 hours, while maintaining high selectivity for KRAS. We are currently conducting IND-enabling studies of BH-501284 and plan to submit an IND in the first quarter of 2027.

Discovery programs

We are also advancing multiple discovery-stage efforts focused on validated and emerging new oncology targets. In addition, we believe our drug discovery approach may also have applicability beyond oncology.

Our team and track record

We were founded by pioneers of small molecule drug design and are led by an executive and management team with deep expertise in oncology drug development and clinical research. We began operations in the summer of 2020, led by our scientific founder, President and Chief Executive Officer, J. Jean Cui, Ph.D. We have assembled a team with broad expertise, which has collectively been involved in the discovery or development of more than a dozen oncology programs and has guided multiple programs from first-in-human studies through FDA approval. Our team is united by a shared conviction that intentional, chemistry-based molecular design can

deliver outcomes that broadly deployed screening-based approaches cannot and facilitates the speed of execution and capital efficiency required to successfully develop and launch new medicines.

Our scientific founder

Our scientific founder, Dr. Cui, is the lead inventor of three FDA-approved targeted cancer therapies—crizotinib (XALKORI), lorlatinib (LORBRENA) and repotrectinib (AUGTYRO)—the latter two of which leverage the macrocyclic small molecule approach that is also utilized in the design of our current clinical-stage candidates. Dr. Cui was elected to the National Academy of Engineering in 2024, one of the highest professional distinctions in engineering, and has received the American Chemical Society Heroes of Chemistry award (2013 and 2021) and the 38th Annual Inventor of the Year award (2011). Notably, lorlatinib, the second of Dr. Cui’s ALK-driven NSCLC medicines to be approved, demonstrated a median progression-free survival (PFS) exceeding 84 months, compared to approximately 10.9 months with crizotinib, a first-generation therapy. Repotrectinib, the lead program at Turning Point Therapeutics, which Dr. Cui co-founded and which was acquired by Bristol-Myers Squibb in 2022, achieved an overall response rate (ORR) of 79% and a median PFS of 35.7 months in TKI-naïve ROS1-positive NSCLC. We believe the same design principles applied to develop these molecules may have the potential to produce a similarly meaningful advancement in EGFR-mutant NSCLC.

Dr. Cui’s FDA-approved medicines

Medicine	Target / Mechanism	Initial Indication	Follow-on Indication
Crizotinib (XALKORI)	ALK / ROS1 / MET TKI <i>1st generation</i>	ALK+ NSCLC	ROS1+ NSCLC
Lorlatinib (LORBRENA)	ALK / ROS1 TKI <i>3rd generation</i>	ALK+ NSCLC after prior TKI	First-line ALK+ NSCLC
Repotrectinib (AUGTYRO)	ROS1 / NTRK TKI <i>2nd generation, macrocyclic</i>	ROS1+ NSCLC with / without prior TKI	NTRK+ solid tumors

Our executive leadership team

Our Chief Medical Officer, Geoffrey R. Oxnard, M.D., is a globally recognized authority on EGFR-mutant NSCLC and the co-author of the first published description of the EGFR C797S resistance mutation—the principal acquired resistance mechanism to third-generation EGFR TKIs such as osimertinib, which BH-30643 is designed to overcome. Prior to joining BlossomHill, Dr. Oxnard served as Vice President, Global Head of Thoracic Cancers at Eli Lilly and Company (formerly Loxo Oncology at Lilly), where he led early- and late-phase clinical development of a broad thoracic oncology portfolio. Before that, he served as Senior Vice President, Head of Clinical Development at Foundation Medicine, where he contributed to the FDA approval of FoundationOne Liquid CDx and oversaw the launch of an emerging circulating tumor DNA monitoring portfolio. Dr. Oxnard is a practicing oncologist who was previously on the faculty of Dana-Farber Cancer Institute and Harvard Medical School for nearly 10 years.

Our Co-Founder and Executive Chairman, Y. Peter Li, Ph.D., MBA, previously co-founded Turning Point Therapeutics and served as its Chairman and Chief Executive Officer leading up to its successful IPO in 2019. Our Chief Financial Officer, Jason Keyes, MBA, brings nearly 25 years of biotechnology finance experience, including roles as Chief Financial Officer at Equillium and Orexigen Therapeutics and prior leadership positions at Amgen and Amylin Pharmaceuticals, as well as having served as director and Audit Committee chairman of multiple publicly-traded oncology therapeutic companies. Our General Counsel, Vincent P. Liptak, JD, Ph.D., MBA, brings over 25 years of legal experience with a focus on intellectual property law, including roles as Life

Sciences Practice Co-Chair at Barnes & Thornburg, where he represented Turning Point Therapeutics as intellectual property counsel and previously served as lead patent counsel for numerous programs at Pfizer.

Since our inception, we have raised over \$257 million in capital from experienced healthcare-focused investors, including our 5% or greater holders Cormorant Asset Management, OrbiMed, Vivo Capital and Janus Henderson Investors. Prospective investors should not rely on the investment decisions of our existing investors, as these investors may have different risk tolerances and purchased their shares in financings that were conducted at a significant discount to the price offered to the public in this offering.

Our strategy

We are committed to building a biopharmaceutical company focused on developing innovative small molecule medicines which address significant unmet medical needs in cancer treatment. Key elements of our strategy include:

- **Advance the clinical development of BH-30643 in C797S-resistant EGFR-mutant NSCLC.** Our near-term priority is to develop BH-30643 for the treatment of C797S-resistant EGFR-mutant NSCLC (with or without T790M) for which there is no currently approved oral targeted therapy. Our Phase 1/2 SOLARA trial is currently enrolling patients across dose expansion cohorts in both TKI-pretreated and TKI-naïve settings, including a C797S resistance cohort that is our near-term development priority. To date in this trial, BH-30643 has been evaluated for safety, pharmacokinetics and preliminary efficacy in patients with EGFR-mutant NSCLC, including with C797S-resistant NSCLC. For additional information, please see the subsection titled “—BH-30643: OMNI-EGFR inhibitor for the treatment of EGFR-mutant NSCLC.” We plan to seek an end-of-Phase 1 meeting with the FDA regarding the recommended Phase 2 dose and a potential accelerated approval pathway for BH-30643 in patients with advanced or metastatic C797S-positive EGFR-mutant NSCLC in the fourth quarter of 2026. We expect to dose the first patient in our anticipated pivotal Phase 2 trial in the first quarter of 2027. We plan to report additional Phase 1 data on durability of response in the C797S population in the first half of 2027.
- **Continue to expand the clinical development of BH-30643 across the full spectrum of EGFR-mutant NSCLC, including earlier lines of therapy.** We believe that our preliminary clinical data in difficult-to-treat on-target resistance mutations, such as C797S, is consistent with our preclinical data and supports BH-30643’s potential against a broad spectrum of EGFR activating mutations. Our current plan is for the Phase 1/2 SOLARA trial to investigate BH-30643 in expansion cohorts across diverse EGFR-mutant populations – including classical, atypical and exon 20 insertions – with the objective of prioritizing late-stage development in populations where emerging clinical results support doing so. We are also evaluating BH-30643 in TKI-naïve cohorts in the SOLARA trial and will use that data to finalize the first-line development approach for BH-30643. In addition to our ongoing monotherapy expansion cohorts, we also plan to evaluate BH-30643 in combination with platinum-based chemotherapy initially for resistance settings, and potentially for use in earlier lines. We plan to report initial Phase 1 data on the chemotherapy combination cohort in the second half of 2027 and additional Phase 1 data on durability of response in the TKI-naïve cohort for EGFR classical mutations in the second half of 2027.
- **Advance the clinical development of BH-30236, our CLK inhibitor, as a novel approach for the treatment of AML and HR-MDS.** We are currently evaluating BH-30236 as a monotherapy and in combination with venetoclax in AML and HR-MDS in our Phase 1 clinical trial and intend to generate preliminary proof-of-concept data to inform further development in the relapsed/refractory and first-line settings. Based on the preliminary anti-leukemic activity observed with BH-30236 plus venetoclax in patients with progression on prior venetoclax-based therapy, we believe CLK inhibition with BH-30236 plus venetoclax may provide meaningful clinical benefit and supports the planned combination with venetoclax plus azacitidine to

enable first-line investigation. Clinical investigation is now expanding to include additional hematologic malignancies and, pending proof of concept, may expand further to include solid tumors. We expect to report updated safety and efficacy data from the BH-30236 Phase 1 trial in the first half of 2027.

- **Advance BH-501284, our pan-KRAS inhibitor, into a first-in-human clinical trial in KRAS-mutant solid tumors.** We intend to evaluate BH-501284 in a Phase 1 clinical trial in patients with KRAS-mutant solid tumors, subject to receipt of regulatory clearance. Our novel pan-KRAS inhibitor, BH-501284, was designed to overcome pharmacokinetic limitations of current KRAS inhibitors in the clinic through durable inhibition of KRAS signaling and has achieved potent preclinical activity against multiple KRAS-mutant forms, which are among the most common oncogenic driver alterations in solid tumors. BH-501284 has demonstrated tumor regression at low oral dose levels in multiple mouse tumor models and good oral bioavailability across species in preclinical studies. We are currently conducting IND-enabling studies of BH-501284 and plan to submit an IND in the first quarter of 2027.
- **Expand and diversify our pipeline through internal discovery efforts.** Our approach has enabled us to rapidly identify differentiated product candidates that have the potential to overcome challenges of existing therapies. We have identified other oncology settings where there continues to be significant unmet need and plan to pursue additional discovery-stage programs leveraging our novel drug design expertise and macrocyclic architecture. In addition, we believe our design approach has potential applicability beyond oncology. We intend to advance new candidates from our internal discovery efforts in a capital-efficient manner.
- **Build the capabilities needed to advance and commercialize our drug candidates.** We intend to leverage the worldwide rights of our broad, strategic intellectual property portfolio across product candidates and preclinical programs to build a fully integrated biopharmaceutical company through which we can pursue the development and potential commercialization of our key product candidates. We may also opportunistically evaluate partnerships and other strategic collaborations that could accelerate development timelines, expand our capabilities or enhance the commercial potential of our programs.

Background and key limitations on prior generations of targeted therapies

Advances in the understanding of genomic alterations that drive tumor initiation, growth and therapeutic resistance, together with increased use of genomic profiling, have transformed cancer drug development. As genomic profiling and molecular characterization have become more widely adopted, cancers are increasingly understood not only by tissue of origin, but also by specific genomic alterations that drive tumor growth and proliferation and, in some cases, emerge over the course of treatment to confer resistance to available therapy. The ability to identify these genomic alterations and match patients to therapies directed against them has given rise to the current era of targeted therapy, in which treatment decisions increasingly are driven by the genomic profile of a patient's cancer, both at diagnosis and following disease progression and resistance to prior therapy. These advances have delivered substantial clinical benefit across multiple tumor types, made targeted therapies integral to the standard of care, and created significant commercial opportunities. In EGFR-mutant NSCLC, our initial key area of focus, the worldwide market of EGFR medicines was estimated to be approximately \$8.0 billion in 2025 and is expected to grow to over \$13.4 billion by 2030.

The history of targeted therapy development demonstrates both the promise and the limitations of prior generations of these medicines. Although many targeted therapies have validated important disease mechanisms and changed the treatment paradigm for patients, validation of a target does not by itself resolve all of the biological and therapeutic challenges associated with that target. Across targeted oncology, prior generations of therapies have often improved outcomes while still leaving important treatment gaps unresolved.

Key limitations of prior generation therapies

Emergence of on-target and off-target resistance mechanisms

A common feature of cancer cells is their ability to gain new mutations to sustain continuous oncogenic signaling and fuel growth and proliferation. Despite the progress achieved with targeted therapies, their clinical benefit is often limited by the emergence of both on-target and off-target resistance mechanisms. On-target resistance in mutation dependent cancers can arise through secondary mutations in the target protein that alter the structural basis of drug binding and reduce inhibitor activity. Off-target resistance may occur through activation of alternative signaling pathways or compensatory mechanisms that enable cancer cells to bypass target inhibition. As a result, patients who initially respond to targeted therapy frequently experience disease progression through predictable resistance mechanisms, limiting the durability of response. For example, the durability of response to prior-generation EGFR TKIs has frequently been limited by the emergence of acquired on-target resistance mutations, notably the T790M gatekeeper mutation for first- and second-generation EGFR TKIs and C797S-mediated resistance for third-generation EGFR TKIs, such as osimertinib. The emergence of these resistance mutations has led to a growing patient population with limited or no options for approved targeted therapy.

Limitations in achieving adequate potency while maintaining selectivity

Many targeted therapies also face inherent challenges in achieving sufficient potency against disease-driving targets while maintaining selectivity over corresponding wild-type proteins, minimizing off-target activity and preserving drug-like properties, including pharmacokinetic characteristics needed to support sustained target coverage. These challenges can constrain both efficacy and tolerability. Inhibition of wild-type proteins in mutation driven cancer or unintended off-target effects may result in toxicities that limit dose intensity or treatment duration, while insufficient potency against the intended mutant targets or suboptimal pharmacokinetic properties may prevent sustained pathway suppression at clinically relevant exposures. Together, these limitations can restrict the therapeutic window and reduce the depth and durability of clinical responses. Targeted therapies purposefully designed to combine high potency against disease-driving mutations with improved wild-type and off-target selectivity and favorable pharmacokinetic properties could increase target coverage to minimize residual disease, potentially leading to more durable responses and opportunities for use in earlier lines of therapy.

Incomplete coverage across molecular drivers of disease

In many settings, prior generations of targeted therapies have not provided a single therapeutic approach capable of addressing a broad spectrum of clinically relevant disease mechanisms. Instead, treatment may remain fragmented across different mutation subtypes, resistance states or biologically defined patient populations. For example, osimertinib has been approved for NSCLC patients with EGFR classical mutations, but not for atypical and exon 20 insertion mutations. The lack of a broadly usable EGFR TKI that can address uncommon and resistant EGFR mutations results in fragmentation of care. Similarly, while covalent KRAS inhibitors have received FDA approval specifically for G12C mutations, the vast majority of KRAS-mutant cancers carry other mutation types—these patient populations remain inadequately served by available targeted therapies. The emergence of multi-KRAS inhibitors offers an opportunity for broader utility across KRAS subtypes, while potentially also addressing KRAS-driven resistance mechanisms to allele-specific KRAS inhibitors.

Advancing beyond high-throughput screening to build on prior insights

We believe that building on prior generations of targeted therapy requires more than incremental modifications to predecessor molecules. Rather, it requires understanding why earlier agents initially succeeded, how they

were limited in their success and whether key liabilities are inherent in the underlying scaffold, their binding mode or a broader design approach. We believe the history of targeted therapy development demonstrates that first-generation therapies often validate a target and establish clinical proof of concept, but do not necessarily fully address the significant unmet need. Instead, we believe they may create or define therapeutic challenges, including resistance, selectivity, tolerability and breadth of patient coverage. We believe this is the result of drug discovery in targeted oncology often relying on high-throughput screening or iterative modification of existing molecular frameworks, which may create or retain structural features associated with these liabilities. As a result, successive generations of targeted therapies may address specific limitations of earlier agents while remaining constrained by the same underlying structural logic. In our view, next-generation targeted therapies should seek not only to achieve clinical activity, but also to address the liabilities that have historically constrained the depth, durability and breadth of benefit.

We believe high-throughput screening is insufficient for developing truly novel chemical scaffolds for drug design. High-throughput screening usually involves identification of a candidate compound followed by iterative modification of predecessor molecules to achieve a threshold profile for clinical development. While this approach has historically produced important medicines, we believe it may also result in compounds that have unintended limitations, including poor drug-like properties, insufficient potency against the intended target or inadequate selectivity. Likewise, we believe a candidate compound derived from a predecessor molecule may achieve potency through a known binding motif while also inheriting liabilities of the predecessor molecule and the broader scaffold class. In our view, certain resistance mechanisms are not random biological accidents; they are structural consequences of binding geometry, often predictable in advance from the scaffold's design. These perspectives guide our chemistry-driven approach to designing novel chemical scaffolds intended to address limitations of prior therapies rather than merely optimizing around predecessor molecules.

Our drug design approach

We believe targeted cancer therapies should be designed from first principles, leveraging a structure-based rational design approach. Our approach encompasses four design components: (1) identification of unmet medical need in defined targets, (2) structural analysis of existing approaches and their limitations, (3) precision drug designs based on deep understanding of target biology and protein structure dynamics and (4) iteration and optimization toward specified performance objectives. This approach, which underlies BH-30643, BH-30236 and BH-501284, produced the two next-generation FDA-approved medicines discovered by our scientific founder, Dr. Cui—lorlatinib (LORBRENA) and repotrectinib (AUGTYRO).

1. Identification of unmet medical need in defined targets

We focus on targets which have clinical proof of concept or well-established disease biology, but where structural or mechanistic liabilities limit the benefit of approved or clinical-stage therapies to patients. Beginning with a validated target allows us to focus our expertise on the question we are best positioned to answer: whether an intentionally designed molecule can deliver a meaningful and durable improvement over what currently exists or achieve approval where others have not succeeded. Equally important, we define at the outset the specific patient population that is underserved—whether due to mutation subtype, acquired resistance or disease in anatomical sites that existing therapies cannot reach—and design compounds to address that population's specific clinical need.

2. Structural analysis of existing approaches and their limitations

After identifying a target of choice, we conduct a comprehensive structural audit of existing medicines and/or clinical candidates in the target class: their binding modes, the scaffold families they represent and the precise

molecular contacts that generate both their potency and their vulnerabilities. We then leverage a deep understanding of target biology and protein dynamics, including the preferred conformation under disease conditions, to establish design principles geared toward overcoming the existing liabilities. This structural analysis allows us to identify not merely that a drug fails or may fail, but also why it fails and how we are going to overcome its limitations—providing key insights into the liabilities intrinsic to an existing chemical scaffold. For example, within EGFR-mutant NSCLC, this analysis reveals that approved EGFR TKIs that use a back-pocket motif inherit T790M vulnerability and those that use the pyrimidine scaffold with covalent binding inherit C797S vulnerability. The analysis informs us to exclude designs based on existing scaffolds and create a potentially transformational new generation scaffold from first principles.

3. Precision drug designs based on deep understanding of target biology and protein structure dynamics

Using the insights we gain from our deep understanding of the biology behind a disease, the chemistry of prior therapies and candidates and the unique protein characteristics of the target, we design molecules with novel chemical structures and develop these into orally available small molecule therapeutic candidates. For programs where the structural biology behind the disease creates the opportunity, we employ three-dimensional macrocyclic scaffolds, a class pioneered by our scientific founder, Dr. Cui, who developed lorlatinib, the first FDA-approved macrocyclic kinase inhibitor. A macrocycle's architecture pre-organizes the molecule's conformation into the target's disease-preferred conformation, enabling a precise contact surface that achieves high binding affinity and conformational selectivity. This architecture is particularly suited to targets for which the disease-relevant protein state is structurally distinct from the normal state. For example, oncogenically mutated kinases preferentially adopt the active, closed conformation whereas wild-type kinases exist predominantly in the inactive, open conformation in the absence of a ligand. The precise three-dimensional macrocyclic architecture of BH-30643 is tuned to selectively engage the mutant EGFR active, closed conformation over the wild-type EGFR inactive, open conformation. The macrocyclic design also rigidifies the molecule to reduce off-target effects.

4. Iterate and optimize toward specified performance objectives

As we employ our first-principles, rational drug design approach, we rigorously iterate until we optimize for a set of essential performance objectives:

- **high potency** as demonstrated by sub-nanomolar cellular inhibitory activity, allowing high target coverage, which we believe is mechanistically required for the depth and duration of response needed to compete at the front of the treatment paradigm rather than solely in later lines;
- **broad inhibition of driver and resistance mechanisms** to address the full spectrum of driver mutations and resistance mutations in tumor subclones to prevent resistance subclones evolving and shortening duration of response;
- **a wide therapeutic window** through selective inhibition of the oncogenic target while minimizing potency against off-target (or wild-type) proteins, thus enabling aggressive dosing without dose-limiting off-target toxicity;
- **deep and durable target engagement** through tight binding, favorable pharmacokinetics and good tolerability that sustain continuous pathway suppression across the dosing interval, preventing the brief pathway reactivation that enables tumor adaptation, and most importantly, minimizing minimal residual disease to achieve long, durable responses; and

- **chemistry scalability and commercial viability** achievable through chemical process manufacturing development and a defensible IP position, as these are considerations which can derail the long-term global impact of otherwise attractive chemical candidates.

Our drug design approach constitutes an integrated process that begins with patient need, proceeds through structural analysis, creates a purpose-built molecular structure and executes toward specified performance objectives. Each of our programs represents the application of this process to a distinct target biology and patient population with significant unmet medical need.

BH-30643: OMNI-EGFR inhibitor

BH-30643 is an investigational, novel, orally bioavailable, non-covalent, macrocyclic, brain active, mutant-selective, OMNI-EGFR inhibitor. In preclinical studies, BH-30643 demonstrated potent inhibitory activity across diverse EGFR mutation categories—classical activating mutations, on-target resistance mutations such as C797S (with and without T790M), atypical mutations and exon 20 insertions—while maintaining marked selectivity over wild-type EGFR. BH-30643 is being evaluated in SOLARA, a global Phase 1/2, first-in-human clinical trial currently enrolling patients across dose expansion cohorts in both TKI-pretreated and TKI-naïve settings, including a C797S resistance cohort. BH-30643 is to our knowledge the first TKI monotherapy to demonstrate meaningful clinical responses in patients with EGFR-mutant NSCLC who have developed the C797S resistance mutation in diverse molecular contexts following treatment with a third-generation EGFR TKI—a population for which no approved oral targeted therapy currently exists. We believe the early clinical data observed in this trial support a near-term development path in C797S resistance and establish the foundation for BH-30643's potential against a broad spectrum of EGFR activating mutations.

We plan to seek an end-of-Phase 1 meeting with the FDA regarding the recommended Phase 2 dose and a potential accelerated approval pathway for BH-30643 in patients with advanced or metastatic C797S-positive EGFR-mutant NSCLC in the fourth quarter of 2026. We expect to dose the first patient in our anticipated pivotal Phase 2 trial in the first quarter of 2027. We plan to report additional Phase 1 data on durability of response in the C797S population in the first half of 2027, the initial Phase 1 data on the chemotherapy combination cohort in the second half of 2027, and additional Phase 1 data on durability of response in the TKI-naïve cohort for EGFR classical mutations in the second half of 2027.

EGFR-mutant NSCLC: disease and treatment landscape

Landscape of EGFR mutations in NSCLC

Lung cancer is the leading cause of cancer-related death worldwide, accounting for an estimated 1.8 million deaths annually. NSCLC accounts for approximately 85% of all lung cancer cases. Activating mutations in the EGFR gene represent the most common targetable oncogenic driver in NSCLC and define a clinically and molecularly distinct patient population.

EGFR activating mutations occur in approximately 10-20% of NSCLC patients of Caucasian ancestry and approximately 40-60% of NSCLC patients of Asian ancestry and are associated with specific clinical characteristics including non-smoking or light-smoking history, female sex and adenocarcinoma histology. According to GlobalData, approximately 316,000 patients were diagnosed with EGFR-mutant NSCLC across key global markets of the United States, Europe, Japan and China in 2025. With the growth of next-generation sequencing of tumor and plasma cell-free DNA, there is a growing appreciation of the diversity of EGFR driver and resistance mutations (*Figure 1*). At diagnosis, the majority of EGFR mutations are considered classical (exon 19 deletion and L858R, collectively representing approximately 80% of EGFR mutations) – a population which has been the target of most pharmaceutical development, including three generations of approved EGFR

inhibitors. A second population is EGFR exon 20 insertions (representing approximately 10% of EGFR mutations), a population which has more recently been targeted for therapeutic development. The remainder of EGFR mutations at diagnosis are considered atypical EGFR mutations, including G719X, L861Q and S768I, which are the most frequent atypical point mutations. The atypical population is less well characterized and is estimated to make up approximately 10% of EGFR-mutant NSCLC. Importantly, at the time of treatment resistance the landscape of EGFR mutations can evolve further, with the emergence of on-target resistance mutations such as C797S, T790M, L718X and G724X. Recent papers have estimated that C797S is the most common EGFR mutation driving resistance to third-generation EGFR-targeted therapy, detected in approximately 13% of patients at time of resistance.

Treatment naïve	Treatment resistance
Exon 19 deletion & L858R Prevalence: ~80% ¹ SOC: TKI combinations	EGFR C797S mutations Prevalence: ~13% ² SOC: Chemo-based
Exon 20 insertions Prevalence: ~10% ¹ SOC: Chemo combinations	MET amplification Prevalence: ~17% ² SOC: Chemo-based
Atypical (including PACC) Prevalence: ~10% ¹ SOC: 2 nd / 3 rd generation TKI	Other / NOS Prevalence: ~70% ² SOC: Chemo-based

Figure 1. EGFR-mutant lung cancer prevalence. 1. Derived from Bandlamudi et al, Cancer Cell, 2026 and Russo et al, JTO, 2026; classical plus atypical grouped with classical per FLAURA label. 2. Derived from Piotrowska et al, Cancer Disc, 2026.

BH-30643 in broader EGFR-mutant NSCLC: classical, atypical, and exon 20 insertion mutations

Background and unmet need

Patients with classical EGFR mutations represent the largest single EGFR-mutant patient population, which we estimate represents approximately 250,000 new patients annually across key global markets of the United States, Europe, Japan and China. Three generations of EGFR inhibitors have been approved for EGFR mutant NSCLC. Osimertinib-based regimens currently are used widely, either as a monotherapy or in combination with chemotherapy. Osimertinib was the first EGFR inhibitor approved by the FDA to treat resistance from 1st generation EGFR inhibitors and received its initial accelerated approval in November 2015 to treat NSCLC patients harboring the EGFR T790M resistance mutation who progressed on or after EGFR TKI therapy.

Osimertinib was initially evaluated as first-line treatment in two treatment-naïve cohorts of the same Phase 1 study. In those cohorts, 60 treatment-naïve patients with EGFR-mutant NSCLC received osimertinib at the 80 mg or 160 mg dose levels (30 patients at each dose), of whom approximately 25% had a history of brain metastases at baseline. Across both dose levels, the reported ORR was 77% and the disease control rate was 97%. By dose, the reported ORR was 67% at 80 mg and 87% at 160 mg, and the reported disease control rate was 93% at 80 mg and 100% at 160 mg. The mean best change in target lesion size was approximately a 48% reduction across doses. Building on these results, the FLAURA trial was able to then demonstrate the superiority of osimertinib over first-generation EGFR TKIs in the first-line setting. The FLAURA2 trial subsequently demonstrated that the addition of platinum-pemetrexed chemotherapy to osimertinib extended PFS further, with a hazard ratio of 0.62 and 57% of patients in the combination arm alive and progression-free

at 24 months compared to 41% for osimertinib monotherapy. More recent trials, such as MARIPOSA, have shown that other first-line combination therapies built off a backbone of a third-generation EGFR TKI can also improve treatment outcomes in the first-line setting. Although the combination therapies based on third generation EGFR inhibitors improved treatment duration, resistance has been shown to typically develop within one to two years. Moreover, intolerance to third-generation EGFR TKIs has shown to be a real clinical problem. For example, osimertinib trials have routinely reported that approximately 11% to 13% of patients discontinue the drug due to adverse events. There is an unmet medical need to develop next generation EGFR inhibitors with better safety and longer treatment duration. BH-30643's preclinical profile—its high potency against classical EGFR mutations, its resistance-proofing against C797S and T790M, its central nervous system (CNS) activity and its wild-type EGFR selectivity—forms the mechanistic basis for investigating whether (1) BH-30643 can be successfully developed for the C797S-resistance population following third-generation EGFR TKI treatment and (2) deeper, more durable responses are achievable with BH-30643 in the first-line setting. If approved, BH-30643 may also be developed to address for patients intolerant to osimertinib. We believe developing BH-30643 as a TKI for C797S-resistance represents our near-term opportunity, while the longer-term opportunity we see for BH-30643 is contingent on clinical data from the TKI-naïve expansion cohorts in SOLARA.

The growing adoption of tumor next-generation sequencing has created increased awareness around less common subtypes of EGFR mutations. Exon 20 insertion mutations account for approximately 10% of oncogenic EGFR mutations, which we estimate represents roughly 31,000 patients annually across key global markets of the United States, Europe, Japan and China in 2025. These insertions are structurally heterogeneous, comprising more than 100 distinct insertion, deletion and point mutations. Exon 20 insertions confer intermediate catalytic activity and structural rigidity at the α C-helix, creating steric resistance to most first- and second-generation TKIs, while maintaining EGFR in an intermediate activation state. The established options—amivantamab (RYBREVANT) with platinum-pemetrexed chemotherapy (first-line, based on PAPILLON: median PFS 11.4 vs. 6.7 months for chemotherapy alone) and amivantamab (RYBREVANT) alone (second-line)—require drug infusion or injection and are associated with meaningful toxicity, including venous thromboembolism, edema and cutaneous toxicity. EGFR TKIs that effectively target exon 20 insertions represent an area of active investigation, but where progress has been halting. Mobocertinib, the first oral agent approved for EGFR exon 20 insertion-positive NSCLC, was voluntarily withdrawn from the U.S. market in 2024 following failure to demonstrate benefit over chemotherapy in the confirmatory Phase 3 EXCLAIM-2 trial. An effective, well-tolerated, oral, brain-active small molecule represents a significant unmet need in this population.

Atypical EGFR mutations, comprising mutations in exons 18–21 other than classical mutations and exon 20 insertions, account for approximately 10% of oncogenic EGFR mutations, which we estimate represents roughly 31,000 patients annually across key global markets of the United States, Europe, Japan and China in 2025. Importantly, these mutations are less well described and can co-exist with other EGFR mutations (including classical mutations), so their prevalence is more difficult to estimate with precision. Atypical mutations present a distinct clinical challenge: they are less sensitive to first- and third-generation EGFR TKIs than classical mutations, and they have been excluded from many major clinical trials. Afatinib, a second-generation TKI, is the only agent with an FDA-approved indication for atypical mutations. The approval was based on retrospective analysis of 32 patients with metastatic NSCLC harboring non-resistant EGFR mutations (S768I, L861Q and/or G719X) other than exon 19 deletions or exon 21 L858R substitutions, with relatively limited clinical activity data captured in the FDA label. Osimertinib has demonstrated activity in small prospective studies (ORR 47-55%; median PFS 8.2–10.5 months) but is not approved for atypical mutations. The population is highly heterogeneous: mutations occur across exons 18–21 at more than 30 residues, frequently as compound mutation combinations and with variable sensitivity to available agents. No therapy has been prospectively validated across the breadth of atypical mutations.

The OMNI-EGFR design of BH-30643—targeting the active, closed conformation shared across all oncogenic EGFR mutation types—is intended to provide clinical activity across a broader set of EGFR-mutant patient populations that are inadequately served by currently approved agents. These broader populations are the subject of ongoing SOLARA expansion cohorts, which are currently in an exploratory stage. We plan to evaluate results from these cohorts to inform subsequent clinical development in additional EGFR-mutant subsets.

History of treatment and the scaffold inheritance problem

The history of EGFR TKI development is substantially the history of scaffold inheritance. Three generations of EGFR TKIs have been approved for EGFR-mutant NSCLC, and all are ATP-competitive inhibitors anchored to the adenine-binding hinge region of the kinase domain. These three generations have emerged from two structural families, and we believe the on-target resistance mechanisms that define the clinical limitations of each generation are a direct consequence of the scaffold choices made during their design.

First and second generations: the anilinoquinazoline scaffold, wild-type inhibition, and the T790M vulnerability

The first generation of approved EGFR inhibitors—gefitinib and erlotinib—were optimized around the anilinoquinazoline chemical scaffold. This scaffold was screened to inhibit wildtype EGFR, and only later found to be potent against mutant EGFR NSCLC following the discovery of EGFR mutations. Inhibition of wild-type EGFR leads to class-characteristic toxicities—diarrhea, rash and stomatitis—that are dose-limiting and prevent the high sustained exposures that may be required for deep, durable target engagement. Second-generation inhibitors, afatinib and dacomitinib, retained the same anilinoquinazoline architecture and added irreversible covalent binding at C797 residue to improve potency, while also adding pan-HER potency that further increased clinical toxicity, with more mucositis and diarrhea. The back-pocket anilino-motif that conferred potency to first- and second-generation TKIs was also the source of their primary resistance liability: the T790M gatekeeper mutation which altered the geometry of the back pocket in a way that interrupted the bonding of this scaffold class and increased catalytic activity of ATP, driving resistance in 40-60% of patients following first- or second-generation TKI treatment.

Third generation: the covalent pyrimidine scaffold and the C797S vulnerability

Osimertinib and other follow-on third-generation EGFR TKIs leverage a covalent pyrimidine-based scaffold discovered through the screening of a collection of covalent molecules with the intent to overcome T790M resistance. These medicines could overcome the T790M mutation while optimizing potency against classical mutations and wild-type selectivity. Osimertinib is a covalent inhibitor that obtains potency through an indolyl group interaction with P-loop and more importantly via an acrylamide-based covalent bond with the cysteine residue at position 797 (C797). Osimertinib is the most widely used first-line therapy for patients with EGFR-mutant NSCLC harboring classical activating mutations. While the covalent pyrimidine-based scaffold of osimertinib solved the T790M resistance problem, it created the next problem – C797S resistance. Pyrimidine-based EGFR inhibitors have been generally designed to form a covalent bond with C797, which enhances target engagement and prolongs residence time. Such covalent binding is a key contributor to their overall potency, as the underlying non-covalent interactions alone provide limited affinity of these molecules relative to the fully-bound state. A scaffold that requires a covalent bond to achieve clinical potency is structurally vulnerable to any mutation that disrupts that bond. C797S—which substitutes serine for cysteine and prevents the covalent bond formation on which osimertinib depends for its potency—is now the primary on-target resistance mechanism to osimertinib, detected in approximately 13% of patients.

The field has not escaped either scaffold family. Prior to designing BH-30643, we reviewed the chemical structures of more than 30 EGFR TKIs, including both approved agents and investigational compounds in clinical or advanced preclinical development, and concluded that the field had remained substantially within

these two structural families (Figure 2). Agents that use a back-pocket motif inherit the T790M vulnerability of first- and second-generation inhibitors; agents that use the pyrimidine scaffold with covalent or near-covalent binding inherit the C797S vulnerability of third-generation inhibitors. Several investigational agents attempt to address both liabilities by appending structural modifications onto existing scaffolds, but these agents do not represent new molecular approaches or have not achieved the required potency and breadth of mutation coverage of EGFR mutations to support broad development.

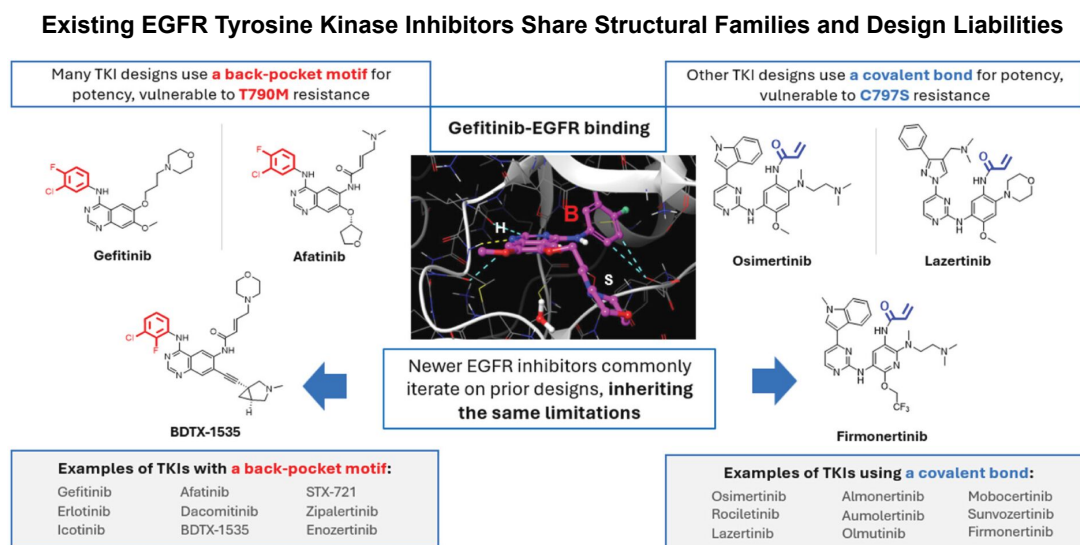


Figure 2. Scaffold inheritance in EGFR TKI development. Structural families and shared design liabilities across approved and investigational EGFR inhibitors.

Our solution: BH-30643

BH-30643 is an investigational mutant-selective, non-covalent, macrocyclic brain active, mutant-selective OMNI-EGFR inhibitor which has demonstrated sub-nanomolar cellular *in vitro* potency against a broad spectrum of EGFR activating mutations, has been well-tolerated and demonstrated favorable pharmacokinetics in our ongoing SOLARA trial, and has confirmed radiographic responses in patients with EGFR-mutant NSCLC, including with C797S-resistant NSCLC (with or without T790M).

Design rationale

BH-30643 was designed to overcome the limitations of currently approved EGFR inhibitors, which were discovered over a decade ago without the current, modern understanding of the structure and protein dynamics of mutant EGFRs.

Targeting the disease-driven active conformation—the mutant OMNI effect

Under normal physiological conditions, wild-type EGFR exists predominantly in an inactive, open conformation with a larger, less-defined ATP-binding pocket. Upon ligand stimulation, wild-type EGFR transitions to the active, closed conformation with a smaller, well-defined ATP-binding pocket to transduce the extracellular signal. The oncogenic activating mutants of EGFR are constitutively active and preferentially adopt the active, closed conformation (Figure 3). Because all oncogenic EGFR mutation types—classical mutations, atypical mutations, exon 20 insertions and acquired resistance mutations—are activating mutations that induce the

protein to adopt the active, closed conformation as the mechanism of constitutive signaling, a molecule designed to engage that conformation selectively should achieve both breadth across the mutation space and selectivity over wild-type EGFR in a single, mechanistically integrated way. We believe targeting the active, closed conformation unlocks the potential for OMNI-EGFR activity while maintaining wild-type sparing tolerability.

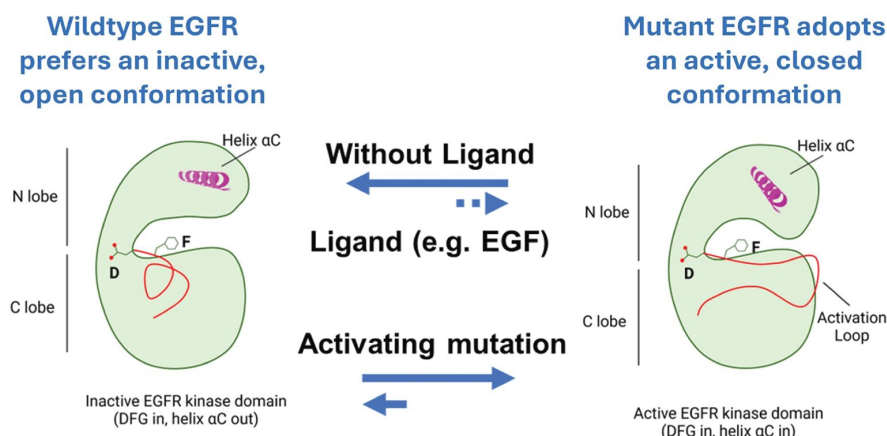


Figure 3. EGFR kinase domain conformations. Wild-type EGFR favors the inactive, open conformation; activating mutations lock the kinase in the active, closed conformation targeted by BH-30643.

Eliminating the T790M and C797S vulnerabilities—non-covalent binding

BH-30643 leverages an entirely novel macrocyclic scaffold in an effort to uniquely address both T790M and C797S resistance. Because BH-30643 is not reliant on a back-pocket motif to achieve potency, the T790M mutation—which blocks the binding of first- and second-generation EGFR inhibitors—does not diminish BH-30643’s observed binding affinity. Further, BH-30643’s binding is not driven by covalent attachment and thus, the C797S mutation—which destroys the covalent chemistry by which osimertinib depends—does not reduce BH-30643’s potential therapeutic strength. Our design approach is not an incremental modification of an existing scaffold, but rather represents a newly designed EGFR scaffold that eliminates the structural vulnerability that disables all prior-generation EGFR TKIs in the C797S-resistant population.

Macrocyclic architecture—conformational precision, potency and selectivity

BH-30643 was invented based on a carefully designed 15-member pyrazolopyridine macrocyclic architecture (Figure 4), which was chosen based on the unique size of EGFR ATP adenine hinge area to achieve the conformational precision required to distinguish the active, closed conformation of mutant EGFR from the inactive, open conformation of wild-type EGFR with high affinity and selectivity. The use of a macrocyclic scaffold in approved kinase inhibitors—including lorlatinib and repotrectinib, both designed by our scientific

founder, Dr. Cui—has demonstrated that this structural approach can achieve exceptional potency, selectivity and pharmacokinetic properties in clinical practice.

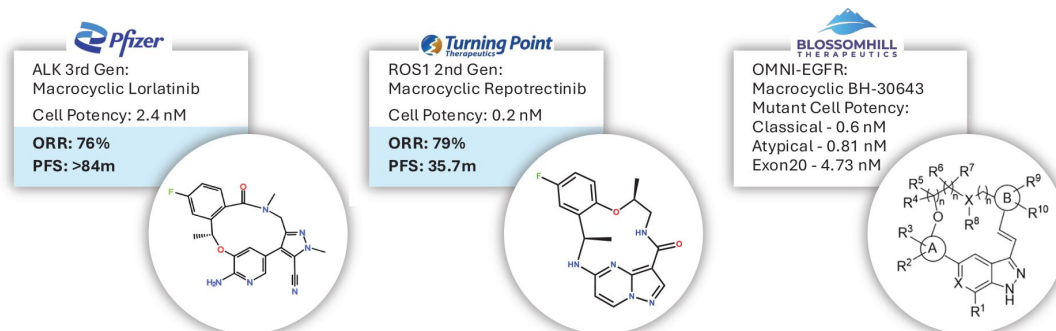


Figure 4. Approved macrocyclic TKIs and BH-30643 macrocyclic scaffold.

Together, these three design principles constitute the OMNI-EGFR approach: a single molecule with the structural basis to address classical, atypical, exon 20 insertion, and resistance mutations, including C797S (with or without T790M), in a unified mechanistic framework.

Background: the C797S resistance problem

There are currently no approved targeted therapies for EGFR-mutant NSCLC patients with C797S-mediated resistance to third-generation EGFR TKIs. We estimate that more than 16,000 patients annually develop C797S-mediated resistance across key global markets of the United States, Europe, Japan and China, including approximately 3,200 in the United States and approximately 2,200 in Japan, a number projected to grow substantially as global first-line use of third-generation EGFR TKIs such as osimertinib expands.

Targeting resistance is a well-established path for targeted therapy development in lung cancer. Osimertinib was the first EGFR inhibitor designed to treat resistance from 1st generation EGFR inhibitors, and received its initial accelerated approval in November 2015 to treat NSCLC patients harboring the EGFR T790M resistance mutation who progressed on or after EGFR TKI therapy. Building on these results and supported by early Phase 1 data suggesting activity in treatment-naïve patients, the FLAURA trial was able to then demonstrate the superiority of osimertinib over first-generation EGFR TKIs in the first-line setting. The FLAURA2 trial subsequently demonstrated that the addition of platinum-pemetrexed chemotherapy to osimertinib extended PFS further, with a hazard ratio of 0.62 and 57% of patients in the combination arm alive and progression-free at 24 months compared to 41% for osimertinib monotherapy. More recent trials, such as MARIPOSA, have shown that other first-line combination therapies built off a backbone of a third-generation EGFR TKI can also improve treatment outcomes in the first-line setting.

Despite these advances, resistance has invariably developed. The primary on-target resistance mechanism to osimertinib and other third-generation covalent EGFR TKIs is the C797S mutation, which substitutes serine for cysteine at position 797 of the EGFR kinase domain. Because osimertinib and other third-generation covalent EGFR TKIs depend on forming a covalent bond with the cysteine at C797 to achieve their clinical potency, the serine substitution—which prevents the covalent bond from forming—effectively eliminates the primary source of osimertinib's binding affinity. Recent reports suggest that C797S accounts for approximately 13% of acquired resistance following first-line osimertinib use, and it can also emerge in later-line settings. C797S may occur with T790M (the triple mutant combination) in patients who received sequential first- or second-generation followed by third-generation TKI therapy, creating a compound mutation against which, to our knowledge, no covalent inhibitor has retained activity.

The EGFR C797S mutation was first described more than a decade ago, but no targeted therapies have been able to demonstrate meaningful responses. The only regimen to receive full approval following third-generation EGFR TKI resistance has been chemotherapy plus amivantamab (RYBREVANT), an EGFR-MET bispecific antibody, based on the MARIPOSA-2 Phase 3 clinical trial. While the MARIPOSA-2 trial was positive for PFS, showing a median PFS of 6.3 months for amivantamab (RYBREVANT) plus chemotherapy vs 4.2 months for chemotherapy ($p < 0.001$), the toxicity profile is burdensome and there has been no report of overall survival improvement. Moreover, a retrospective subset analysis of MARIPOSA-2 patients with secondary EGFR mutations (including C797S) in circulating tumor DNA at baseline demonstrated no meaningful PFS improvement with the addition of amivantamab (RYBREVANT) (median 5.7 months vs. 5.0 months)—biologically consistent with the expectation that the addition of an EGFR-MET bispecific antibody to chemotherapy would not overcome C797S-mediated on-target kinase resistance with meaningful benefit over chemotherapy alone. Accordingly, platinum-based chemotherapy remains the predominant systemic option for C797S-resistant patients.

More recent therapeutic development has focused on antibody-drug conjugates, including the accelerated approval of dato-DxD, which achieved an ORR of 42.7% and a median PFS of 5.8 months in patients following treatment with EGFR TKI and chemotherapy. Given the considerable toxicity burden of investigational antibody-drug conjugates (ADC) agents and treatment inconvenience from infusion, there remains a significant need for an oral targeted therapy with a favorable safety profile. The lack of progress in the development of treatments for C797S-resistant EGFR-mutant NSCLC has left this patient population with limited treatment options. Furthermore, given both osimertinib monotherapy and osimertinib-based combinations are now established first-line standards of care, the global exposure to osimertinib—and consequently the incidence of C797S resistance—is expected to continue to grow. We believe that the significant and growing patient population with C797S resistance could be meaningfully addressed by BH-30643.

Why BH-30643 specifically addresses C797S resistance

We believe the non-covalent design of BH-30643—described above—is directly and specifically consequential for the C797S-resistant population. Osimertinib's potency against EGFR depends on its acrylamide warhead forming a covalent bond with the cysteine at position 797. Without that bond, the underlying pyrimidine scaffold has insufficient intrinsic binding affinity to inhibit the EGFR kinase at clinically achievable concentrations. When C797S occurs, the serine substitution—which prevents the covalent bond from forming—effectively eliminates the primary source of osimertinib's binding affinity.

BH-30643 was designed to avoid this vulnerability. By targeting the active, closed conformation of mutant EGFRs through non-covalent interactions that do not depend on a single protein residue for potency, BH-30643's binding affinity is structurally unaffected by the C797S substitution. In addition, the triple mutants—ex19del/T790M/C797S or L858R/T790M/C797S—against which both first/second-generation agents (blocked by T790M) and third-generation agents (blocked by C797S) are inactive, have appeared addressable by BH-30643 in preclinical models. This is the mechanistic foundation for BH-30643's near-term development program.

Preclinical activity

Preclinical activity across EGFR mutations

In preclinical studies, we believe the cell activity of BH-30643 observed against EGFR classical, atypical, exon 20 insertion and C797S/T790M resistance mutations, and selectivity observed against wild-type EGFR (Figure 5), validate our molecular design and support the evaluation of BH-30643 across EGFR mutations in NSCLC patients.

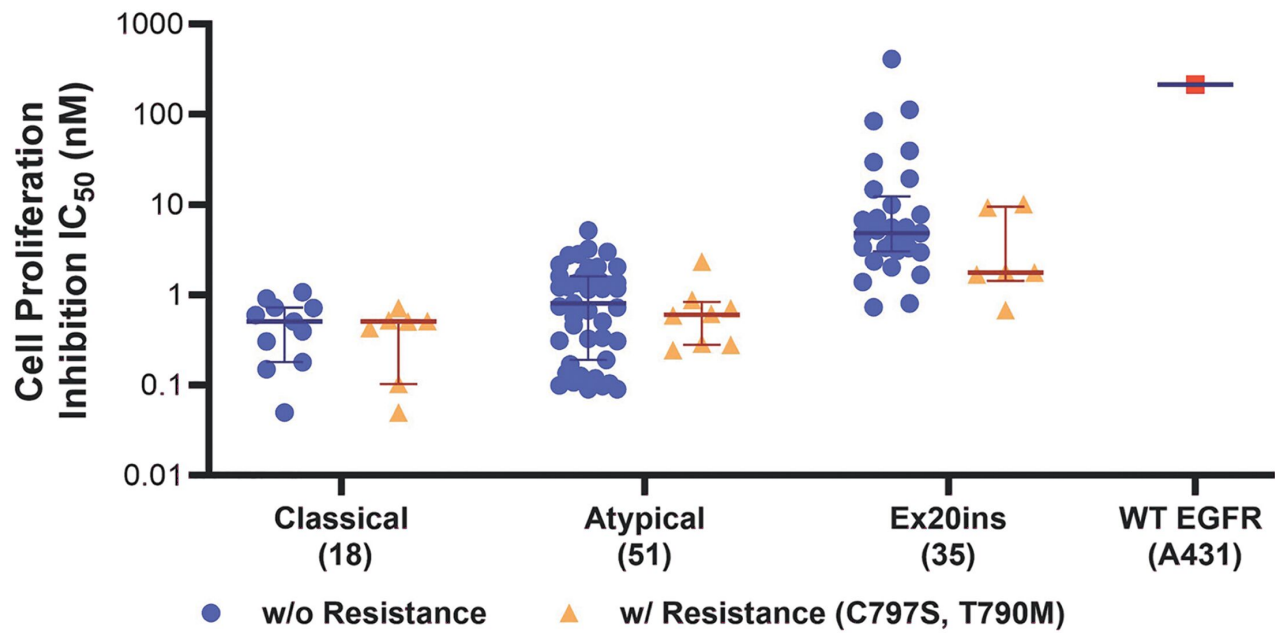


Figure 5. BH-30643 cellular potency across EGFR mutation subtypes. IC₅₀ values across representative classical, atypical, and exon 20 insertion cell lines, with and without C797S/T790M resistance mutations.

Classical mutations in the OMNI context: substantial potency and potential first-line differentiation

In cell proliferation assays across eleven primary cancer and engineered Ba/F3 cell lines carrying classical EGFR mutations (exon 19 deletion or L858R), BH-30643 demonstrated IC₅₀ values of 0.05 to 1.07 nM. This level of cellular potency forms the mechanistic basis for our hypothesis that deeper, more durable tumor suppression may be achievable in the treatment-naïve setting. BH-30643 demonstrated robust antitumor activity in a PC9 cell-derived xenograft (CDX) mouse tumor model with the EGFR exon 19 deletion and an H1975 cell-derived xenograft (CDX) model with an L858R/T790M compound mutation (Figure 6). We believe the OMNI-EGFR design

-will cause any C797S resistance emerging following first-line treatment to remain susceptible to continued BH-30643 activity—a potential durability advantage informing our longer-term first-line investigation.

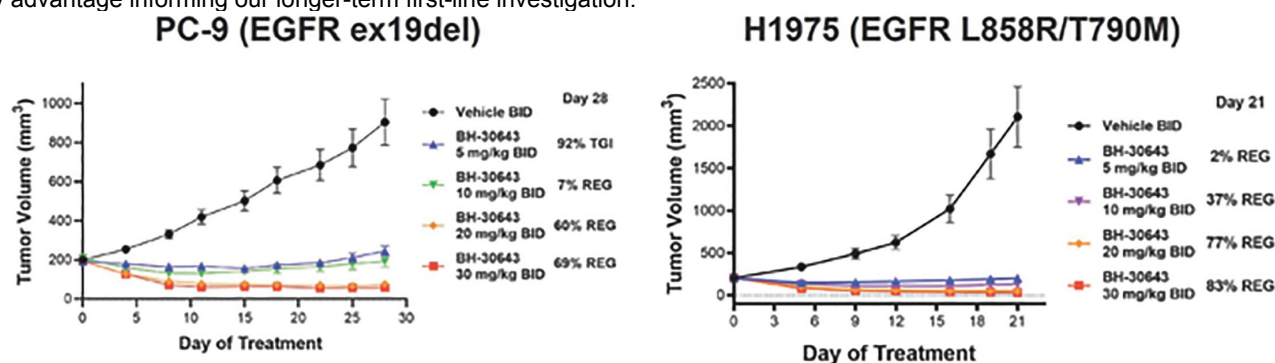


Figure 6. In Vivo Activity of BH-30643 in Classical EGFR Mutation Models. Right: H1975 (L858R/T790M) CDX tumor model; Left: PC-9 (ex19del) CDX tumor model. All doses orally administered.

Atypical mutations

In cell proliferation assays across 51 engineered Ba/F3 cell lines carrying single or compound atypical EGFR mutations, BH-30643 exhibited potent inhibitory activity with a median IC₅₀ of 0.81 nM. Mutations evaluated covered residues G719, S768, L861, E709, L747, V834, L833, V769 tested as single mutations and as compound mutations with classical, with other atypical variants, and with T790M, C797S or T790M and C797S.

Exon 20 insertions

In cell proliferation assays across 35 engineered Ba/F3 cell lines carrying EGFR exon 20 insertion mutations, BH-30643 inhibited cell growth with a median IC₅₀ of 4.61 nM. BH-30643 demonstrated preferential activity against insertions located in the C-terminal of the α C-helix (median IC₅₀ 1.68 nM, N=3) and the near loop following the α C-helix (median IC₅₀ 4.03 nM, N=18) compared to far-loop insertions (median IC₅₀ 39.7 nM, N=7). Potency was maintained in the presence of C797S, T790M or C797S and T790M resistance mutations compound with near-loop exon 20 insertions (median IC₅₀ 1.78 nM, N=6).

HER2 kinase domain mutations

In cell proliferation assays across 35 Ba/F3 cell lines, BH-30643 demonstrated a median IC₅₀ of 8.13 nM in cell lines harboring HER2 exon 20 insertion or tyrosine kinase domain mutations versus 57.7 nM for wild-type HER2. BH-30643 was less potent against WT HER2 and retained potency in Ba/F3 cell lines harboring HER2 mutations compound with T798M/I or C805S acquired resistance mutations.

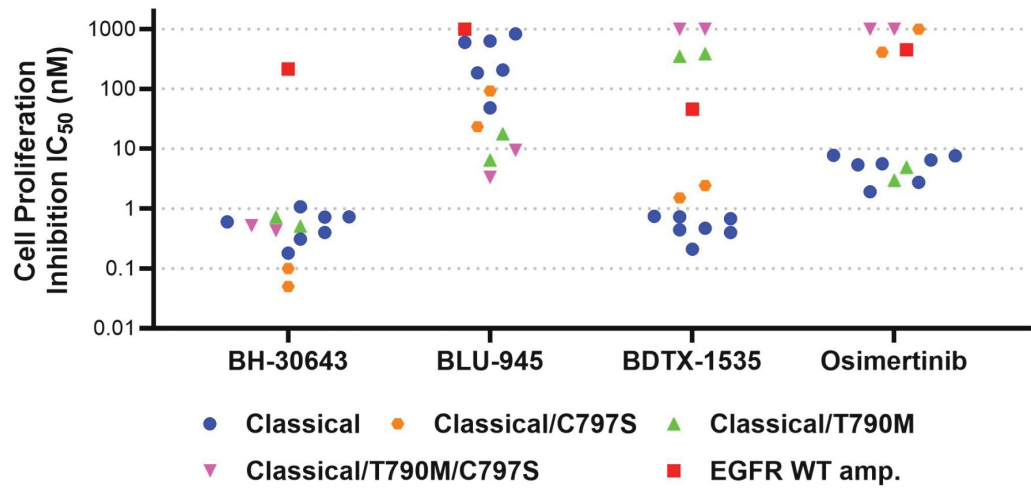
Preclinical activity: C797S focus

In preclinical studies, BH-30643 demonstrated potent inhibitory activity against classical EGFR mutations and their C797S resistance variants, including the triple mutant combinations (classical/T790M/C797S) that define the near-term development opportunity.

Classical mutations and retained potency with C797S and T790M

In cell proliferation assays across seven primary cancer and engineered Ba/F3 cell lines carrying classical EGFR mutations, BH-30643 was studied and compared to osimertinib and other EGFR TKIs investigated to target

EGFR resistance mutations (Figure 7). BH-30643 demonstrated IC₅₀ values of 0.18 to 1.07 nM, compared to 1.92 nM to 7.77 nM for osimertinib in the same cell lines. Consistent with this proliferation activity, BH-30643 potently inhibited EGFR phosphorylation in primary cancer cell lines carrying classical mutations (ex19del: IC₅₀ 0.69 nM in PC-9 cells; L858R: IC₅₀ 0.26 nM in 11-18 cells). BH-30643 retained potency in the presence of T790M and C797S resistance mutations: IC₅₀ values in six cell lines carrying compound classical/resistance mutations ranged from 0.05 to 0.71 nM, including the triple mutant combinations L858R/T790M/C797S (IC₅₀ 0.54 nM) and ex19del/T790M/C797S (IC₅₀ 0.43 nM), against which osimertinib had IC₅₀ values greater than 1,000 nM. Other EGFR TKIs targeting C797S, including BLU-945, have demonstrated activity across C797S-containing genotypes (e.g., classical/C797S IC₅₀ values of 23.3 and 91.9 nM and classical/T790M/C797S IC₅₀ values of 3.33 and 9.40 nM), but show reduced potency against classical EGFR mutations (IC₅₀ values of 47.9 -832 nM). Similarly, BDTX-1535 has demonstrated potent activity against classical/C797S (IC₅₀ values of 1.52 and 2.44 nM) but exhibits reduced activity against classical/T790M mutations (IC₅₀ >350 nM).



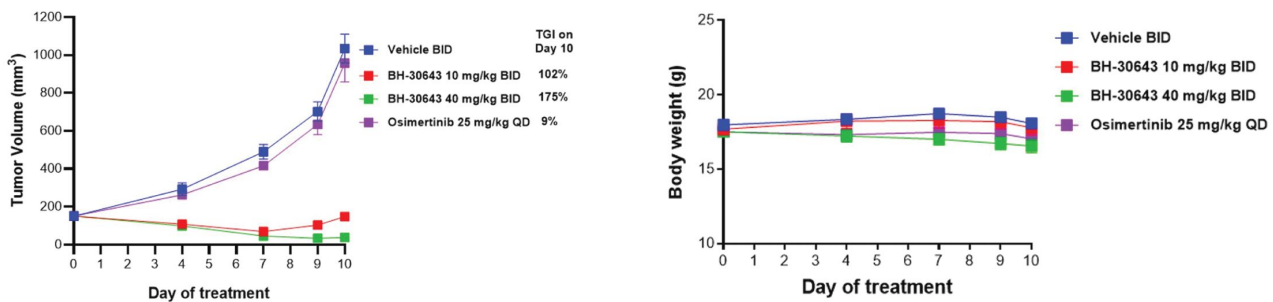
Note: Classical: L858R and ex19del; Any IC₅₀ value > 1000 nM was plotted as 1000 nM.

Figure 7. Cellular potency of BH-30643 vs. selected EGFR TKIs. Cell proliferation IC₅₀ (nM) for driver mutations, C797S and/or T790M compounds and wild-type EGFR (A431 cells).

Triple mutant in vivo: tumor regression where osimertinib showed no activity

In mouse tumor models bearing EGFR triple mutants—a patient-derived xenograft (PDX) model harboring ex19del/T790M/C797S and a CDX model harboring L858R/T790M/C797S—oral administration of BH-30643 induced deep, dose-dependent tumor regression (Figure 8). Osimertinib showed no antitumor activity in either model. We believe these preclinical findings are encouraging for the potential of BH-30643’s non-covalent mechanism to translate to clinical benefit in the C797S-resistant population.

Activity of BH-30643 in the Ba/F3 EGFR L858R/T790M/C797S CDX Tumor Model in SCID/beige Mice



Activity of BH-30643 in the LD-0025-200717 PDX Tumor Model Harboring EGFR ex19del/T790M/C797S Mutations in Nu/Nu Mice

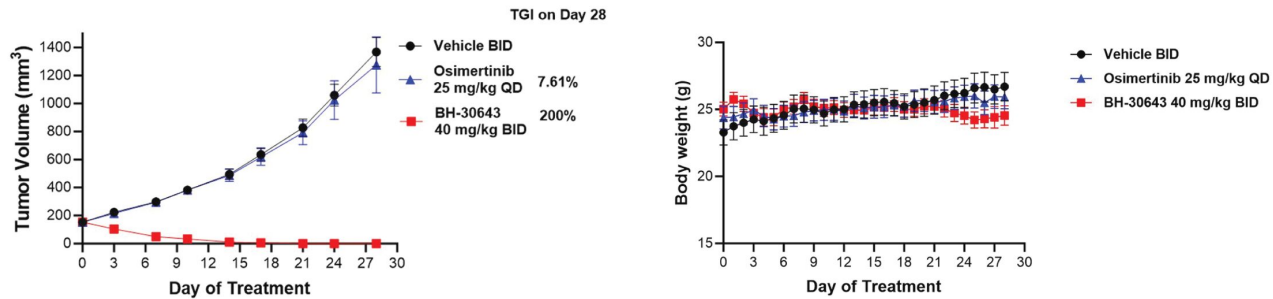


Figure 8. In vivo activity of BH-30643 in triple-mutant CDX and PDX models. Top: Ba/F3 EGFR L858R/T790M/C797S CDX model; Bottom: LD1-0025-200717 PDX model harboring EGFR ex19del/T790M/C797S. Osimertinib 25 mg/kg once-daily (QD) shown for comparison on all charts.

Sub-nanomolar cellular potency as a first-line differentiator

The first-line classical mutation market has recently seen improving benchmarks from osimertinib-based combination regimens, raising the threshold for monotherapy competition. We believe the next generation of first-line agents is likely to be defined by the depth and durability of initial tumor response, and that molecules with sub-nanomolar cellular IC50 values against classical EGFR mutations in preclinical assays—BH-30643 has demonstrated IC50 values of 0.18 nM to 1.07 nM against classical mutations compared to 1.92 nM to 7.77 nM for osimertinib in the same cell lines—may achieve longer PFS by more completely suppressing the initial tumor clone, especially when higher clinical exposure is also achieved. In a preclinical colony formation assay (CFA) analysis comparing BH-30643 versus osimertinib in an EGFR L858R-mutant model, the depth and durability of response were more profound with BH-30643, especially under the challenge of ligand EGF which served as a

potential resistance mechanism (Figure 9). We believe this data supports the potential for BH-30643 to offer a more prolonged impact in the first-line setting.

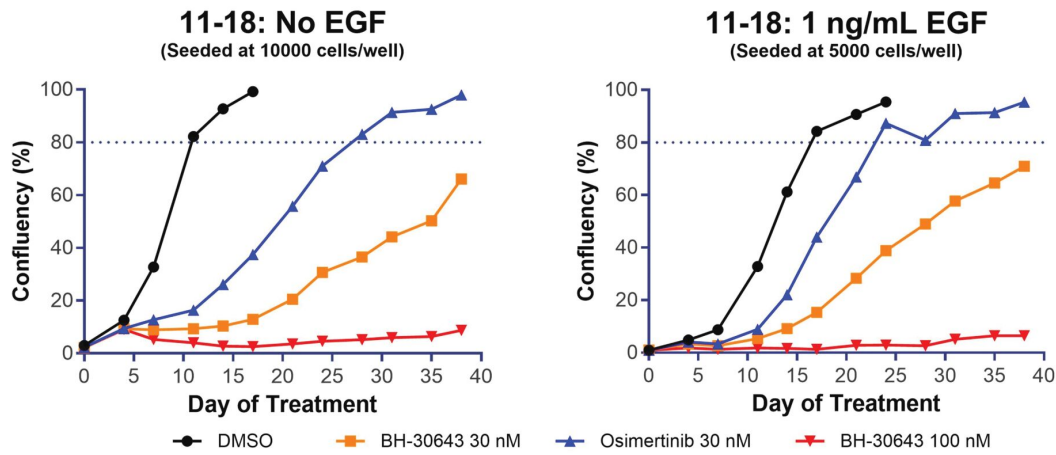


Figure 9. Preclinical colony formation assay (CFA) analysis comparing BH-30643 versus osimertinib in an EGFR L858R-mutant model (11-18)

Brain Penetration and CNS activity

In primate studies, the ratio of unbound CSF to free plasma concentrations for BH-30643 was approximately 27% at clinically relevant steady state trough exposure level, comparable to that reported in human data for other CNS-active EGFR TKIs such as osimertinib. Given the high prevalence of CNS metastases in EGFR-mutant NSCLC, activity against brain metastases is a key requirement for an EGFR TKI. In an intracranial xenograft model, HCC827-luc tumor cells carrying an EGFR ex19del mutation were implanted intracranially and tumor growth was monitored by bioluminescent imaging (Figures 10, 11). Oral administration of BH-30643 at 10 mg/kg twice-daily (BID) induced a profound reduction in intracranial tumor burden, demonstrating CNS activity at therapeutically relevant concentrations.

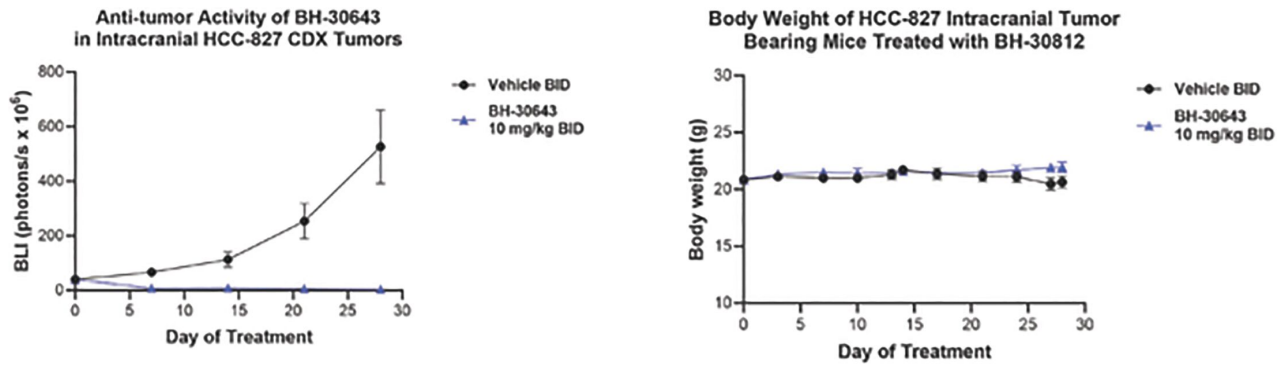


Figure 10. CNS activity of BH-30643 in intracranial HCC-827 (ex19del) CDX model. Left: Bioluminescence signal (BLI) over time; Right: Body weight. BH-30643 10 mg/kg BID vs. vehicle control.

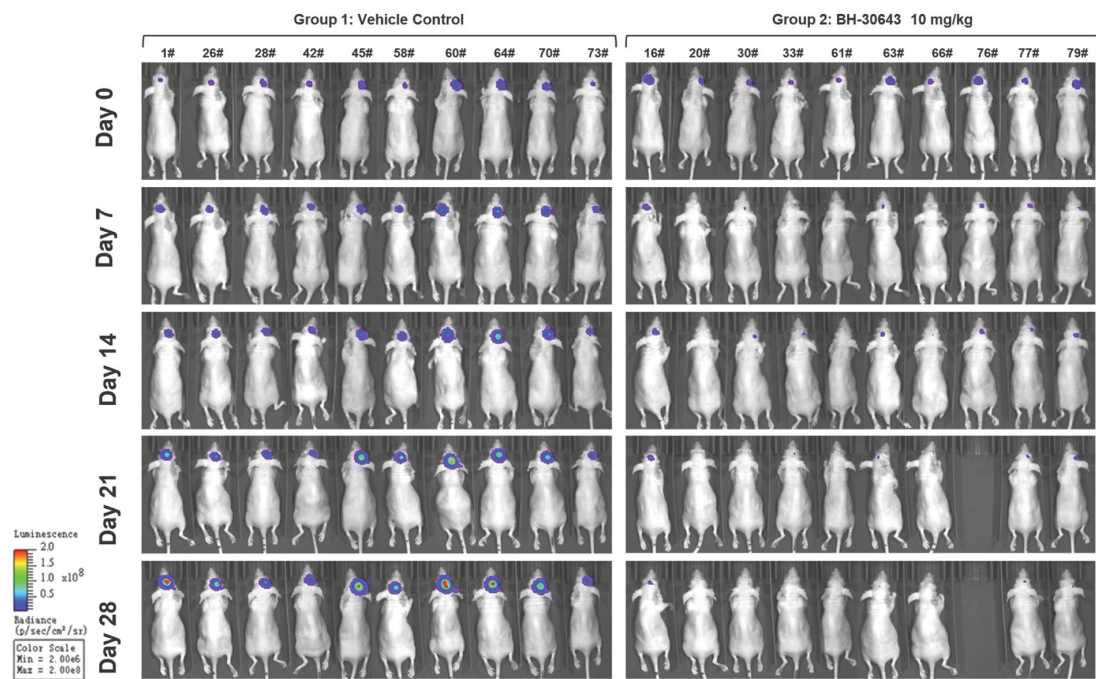


Figure 11. Bioluminescence imaging of intracranial HCC-827 (ex19del) CDX tumors. Vehicle control (Group 1, left) vs. BH-30643 10 mg/kg BID (Group 2, right) over 28 days. Signal reflects intracranial tumor burden.

PK/PD: pharmacodynamic target coverage against the triple mutant

In pharmacokinetic and pharmacodynamic studies using the Ba/F3 EGFR L858R/T790M/C797S CDX tumor model, BH-30643 inhibited phospho-EGFR in a dose- and concentration-dependent manner, establishing a free plasma 90% of target inhibition (EC₉₀) of 1.79 nM for 90% inhibition of mutant EGFR phosphorylation (Figure 12), that is

equivalent to a total human plasma concentration of 67 ng/mL. These parameters provided the pharmacological rationale for dose levels selected in SOLARA and the clinical exposure benchmarks against which BH-30643’s human pharmacokinetics are evaluated.

PK/PD Relationship of BH-30643 in Ba/F3 EGFR L858R/T790M/C797S CDX Tumors Following 2-day Treatment

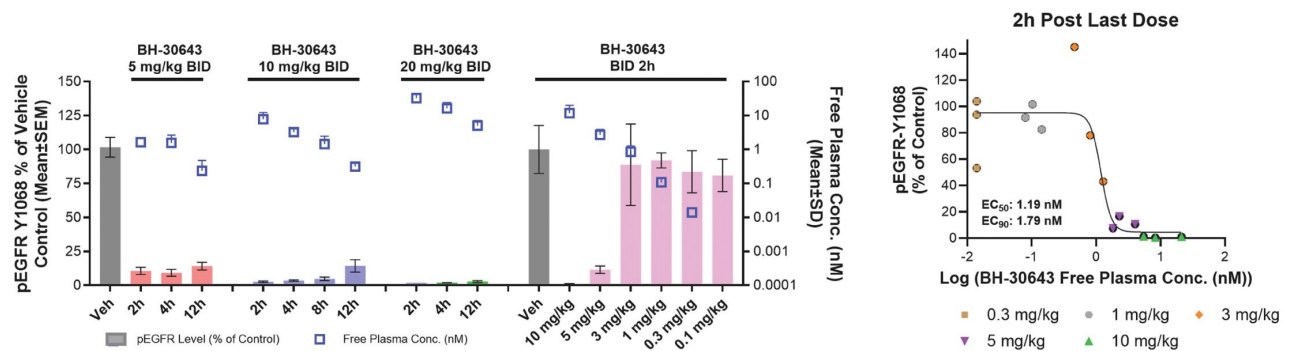


Figure 12. PK/PD relationship: pEGFR inhibition vs. free plasma concentration. Ba/F3 EGFR L858R/T790M/C797S CDX tumor model. Free plasma EC₅₀ = 1.19 nM; EC₉₀ = 1.79 nM.

Wild-type EGFR selectivity.

In cell proliferation assays, BH-30643 exhibited substantially reduced activity in A431 cells harboring wild-type EGFR amplification (IC₅₀ ~ 217 nM), compared to 0.05–1.07 nM for classical mutations in the same assay format. BH-30643 did not inhibit proliferation of normal human fibroblast BJ cells (IC₅₀ 5,220 nM) or parental Ba/F3 cells (IC₅₀ 4,450 nM), demonstrating specificity for mutant EGFR-driven proliferation.

Kinase selectivity.

In a selectivity screen against 372 wild-type human kinases (Figure 13), BH-30643 inhibited greater than 90% of enzymatic kinase activity at 100 nM for only four kinases in addition to EGFR and HER2: TNIK, MINK, HGK and LRRK2.

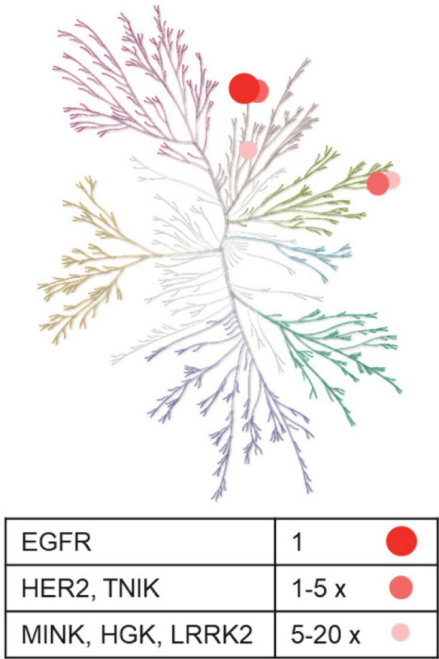


Figure 13. Kinase selectivity profile of BH-30643. BH-30643 inhibits only four additional kinases (TNIK, MINK, HGK, LRRK2) beyond EGFR and HER2 in a screen of 372 wild-type human kinases.

BH-30643: Development Plans

Our development strategy for BH-30643 is first focused on the EGFR TKI resistant population, followed by evidence generation to support our expanded development strategies as described below.

C797S monotherapy development strategy

Our near-term development priority for BH-30643 is to advance through Phase 1 dose expansion, establish a recommended Phase 2 dose (RP2D), and subsequently conduct a pivotal Phase 2 trial in C797S-positive resistance for a potential single arm accelerated approval. The current Phase 1 C797S expansion cohort (Cohort A) is intended to inform the design of our anticipated pivotal Phase 2 trial which can generate potentially registration-enabling data, with ORR as the planned primary endpoint and DOR/PFS as secondary endpoints, subject to discussion and alignment with FDA.

Evidence generation to support broader development in EGFR-mutant NSCLC

We believe the market for EGFR-targeted therapies is evolving rapidly driven by the combination of an EGFR inhibitor backbone with different treatment modalities, such as chemotherapy, ADC or novel biologics. The improvement of the EGFR inhibitor backbone is fundamental for the success of the combination therapies. We

believe the profile of BH-30643 has the potential to be an improved EGFR inhibitor backbone. Osimertinib, the current standard of care for first-line treatment of NSCLC patients with classical mutations, reported sales of over \$7 billion in 2025. We believe BH-30643 has the potential to make an impact for patients that are resistant to or that cannot tolerate osimertinib, as well as in settings where osimertinib is a current standard of care.

- **Preclinical potency and clinical exposure levels.** We believe BH-30643's OMNI-EGFR design rationale, preclinical potency results and clinical exposure level provide a mechanistic basis for investigating BH-30643 in the first-line classical mutation setting. Our preliminary clinical evidence has demonstrated plasma concentrations of BH-30643 exceeding that of published osimertinib plasma exposure data, and our preclinical results show BH-30643 demonstrated IC50 values of 0.18 to 1.07 nM against classical mutations compared to 1.92 to 7.77 nM for osimertinib in the same cell lines. As established in targeted therapy development, later generation TKIs that are more potent against both primary and resistance mutations (e.g., osimertinib, lorlatinib, and repotrectinib) often provide longer and more durable treatment outcomes when used in the first-line setting. We believe the development of BH-30643 in the first-line setting represents a longer-term opportunity—the design and pursuit of any clinical development for first-line classical mutations would be informed by results from the TKI-naïve expansion cohorts in SOLARA, regulatory alignment, and capital allocation decisions. We do not have randomized clinical data in TKI-naïve patients, and we expect that any decision to pursue a global registrational program in the first-line setting, either as a monotherapy or combination therapy, would be made in a data-driven manner.
- **OMNI-EGFR coverage as a strategic advantage.** As comprehensive genomic profiling becomes standard practice in the frontline setting, we believe clinicians and payers may increasingly favor agents that are active across the full spectrum of EGFR mutations—not only classical mutations but also atypical variants, exon 20 insertions and resistance mutations that emerge during treatment. We believe BH-30643's OMNI-EGFR design, which is intended to address classical, atypical, exon 20 insertion and C797S resistance mutations with or without T790M within a single molecule, could address this need potentially with longer duration of treatment. We will continue generating clinical data in Phase 1 expansion TKI-naïve cohorts for classical, atypical and exon 20 insertion mutations to inform future development in these populations, either as a monotherapy or a combination therapy. The specific trial design, patient selection criteria, endpoints and regulatory strategy for any such programs is expected to be determined based on expansion cohort data and discussions with the FDA.
- **Target selectivity derived from macrocyclic design as a therapeutic window determinant.** We believe tolerability at high clinical exposures to be a key competitive requirement for any agent seeking to demonstrate superior efficacy over osimertinib in the first-line setting. Wild-type EGFR inhibition has historically been dose-limiting for earlier-generation agents, constraining the exposures achievable in clinical practice. BH-30643's observed selectivity over wild-type EGFR—which in preclinical assays supported a potential therapeutic window of approximately 200- to 1,000-fold over classical mutation potency—is designed to enable the high, sustained clinical exposures required for deep and durable target suppression. Moreover, BH-30643's macrocyclic non-covalent design also has enabled it to avoid the idiopathic toxicities observed with osimertinib, including rare pneumonitis (1%) and no cardiac effects. Osimertinib's covalent binding also causes frequent cytopenias through off-target inhibition of JAK3 and BTK; we believe the absence of burdensome cytopenias observed with BH-30643 in our SOLARA trial supports its potential for combination with cytotoxic regimens including chemotherapy and emerging ADCs. We plan to establish the potential safety of BH-30643 as a combination partner in our chemotherapy combination cohort in the SOLARA trial.

BH-30643: Clinical Development (the SOLARA trial)

Trial design

BH-30643 is being evaluated in SOLARA, a Phase 1/2, open-label, multicenter, first-in-human trial evaluating the safety, tolerability, pharmacokinetics and antitumor activity of BH-30643 as monotherapy or in combination with carboplatin and pemetrexed in adults with locally advanced or metastatic NSCLC harboring EGFR and/or HER2 mutations. The trial began enrollment in January 2025 in the United States and currently has over 40 active sites across 10 countries, including the United States, Australia, Canada, Hong Kong, Japan, Malaysia, Singapore, Taiwan, Thailand and South Korea.

The Phase 1 portion of the trial consists of three parts. Phase 1, Part 1 (Dose Escalation/Backfill) uses a Bayesian Optimal Interval (BOIN) design to evaluate safety, tolerability, pharmacokinetics and preliminary antitumor activity across escalating dose levels and to identify Recommended Dose(s) for Expansion (RDEs). Phase 1, Part 2 (Dose Expansion/Optimization) evaluates the RDEs across molecularly defined expansion cohorts to identify a Recommended Phase 2 Dose (RP2D). Phase 1, Part 3 (Combination) is evaluating BH-30643 in combination with carboplatin and pemetrexed at selected RDEs. Dose-limiting toxicities (DLTs) are evaluated during the first cycle of treatment. Efficacy is evaluated by Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 criteria per investigator assessment. Serial plasma circulating tumor DNA (ctDNA) samples are collected at baseline and on treatment.

The SOLARA trial currently includes multiple expansion cohorts intended to further characterize the safety, PK and antitumor activity of BH-30643, including patients previously treated with EGFR-targeted therapies as well as patients who are targeted therapy naive. The first expansion cohort is focused on the enrollment of patients with C797S-resistance and supports the near-term development focus; the remaining cohorts are exploratory at this stage and will inform the future development of BH-30643. Each cohort is planned to enroll approximately 20-40 patients per dose level. A transition to Phase 2 development is then planned in select populations based on emerging expansion cohort data.

Patient population: Dose Escalation and Backfill

The preliminary clinical findings from Dose Escalation and Backfill were presented at the American Society of Clinical Oncology (ASCO) 2026 Annual Meeting using a March 2, 2026 data cut, with further efficacy follow-up through an April 29, 2026 data cut. As of the March 2, 2026 safety data cut, 82 patients had enrolled into the SOLARA dose escalation and backfill cohorts of whom 31 remained on therapy (Figure 14). Seven dose levels evaluated ranged from 10 mg BID to 80 mg BID and 80 mg QD. Patients were heavily pretreated, with a median of three prior lines of systemic therapy (range 1-12) and 66% having a history of brain metastases at baseline.

Driver mutation subtypes at enrollment included EGFR classical mutations in 54 patients, exon 20 insertions in 16 patients, atypical or other mutations in 10 patients and HER2 mutations in two patients.

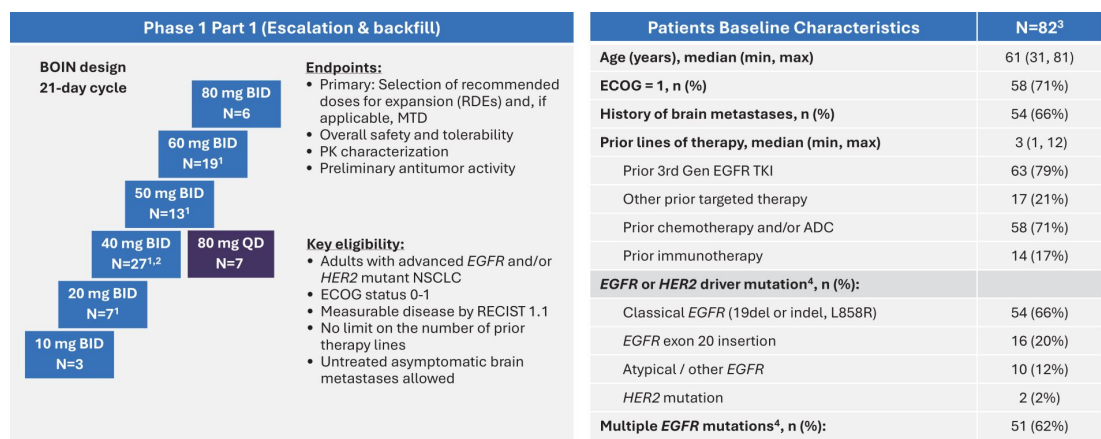


Figure 14: Dose escalation and backfill cohorts enrolled a heavily pretreated and heterogenous NSCLC population. Left: ¹Backfill cohorts enrolled at potentially efficacious doses based on PK and/or preclinical anti-tumor activity; ²Includes patients enrolled into pilot food effect sub study at 40mg BID. Right: ³All data as of the March 2, 2026 data cut, with efficacy follow-up through the April 29, 2026 data cut; ⁴Includes historical and baseline molecular results.

Pharmacokinetics

Pharmacokinetics was assessed in the dose escalation and backfill cohorts, with results available for 64 patients as of the March 2, 2026 ASCO cutoff. BH-30643 has been absorbed with a median time to maximum concentration of two to four hours across all dose levels in dose escalation and backfill cohorts. Systemic exposure (C_{max} and AUC) increased with dose across the evaluated range. At steady state, the geometric mean plasma trough concentration (C₁₂) at 40 mg BID was 205 ng/mL, exceeding the total human plasma exposure of 67 ng/mL required for EC₉₀ against phosphorylation of EGFR L858R/C797S/T790M mutation derived from a free EC₉₀ of 1.79 nM (0.93 ng/mL) in a mouse PK/PD study. The plasma exposures of BH-30643 at ≥ 40 mg BID

exceeded the steady-state plasma exposures of osimertinib and other contemporary EGFR TKIs at their respective clinical doses (Figure 16). The elimination half-life of BH-30643 was approximately 12 hours at steady state.

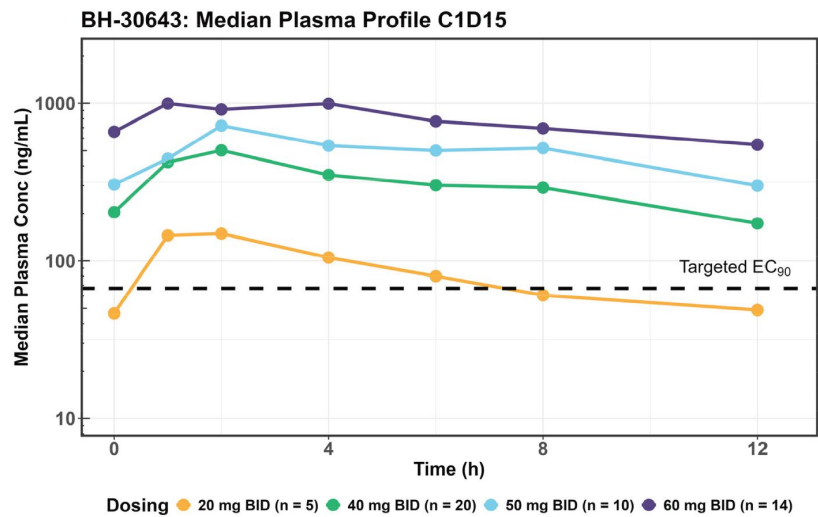


Figure 15. BH-30643 median plasma profile at steady state (C1D15). Median plasma concentrations at 20 mg BID, 40 mg BID, 50 mg BID, and 60 mg BID versus targeted EC_{90} (dashed line); EC_{90} = 67 ng/mL of total human plasma concentration derived from a free EC_{90} of 1.79 nM, representing the concentration required for 90% inhibition of mutant EGFR phosphorylation in the L858R/T790M/C797S CDX tumor model). Geometric mean trough concentration (C_{12}) at 40 mg BID = 205 ng/mL (approximately 3x EC_{90}). Exposures at ≥ 40 mg BID well exceeded the EC_{90} .

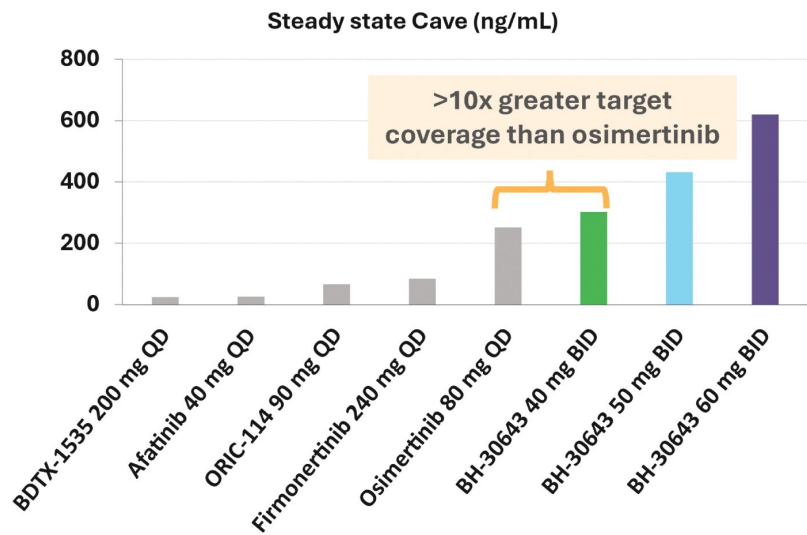


Figure 16. The plasma exposures of BH-30643 at ≥ 40 mg BID exceeded exposure levels of many contemporary EGFR TKIs. Note: The clinical exposure data for contemporary EGFR TKIs are from publications and the comparisons presented above are based on cross-study comparisons and are not based on any head-to-head

clinical trials. Differences exist between trial designs, patient characteristics and other factors and caution should be exercised in drawing any conclusions from a comparison of the data across studies as cross study comparisons are inherently limited and such data may not be directly comparable.

Safety and tolerability

As of the March 2, 2026 data cut, BH-30643 was generally well-tolerated across all evaluated dose levels in dose escalation and backfill (N=82), with a median duration of treatment of 3.0 months. Treatment-related adverse events (TRAEs) occurred in 71 of 82 patients (87%) and were predominantly Grade 1 or 2. The most frequently reported TRAEs (occurring in 10% or more of patients) were diarrhea (37%), rash (37%), bilirubin increased (35%), stomatitis (18%), fatigue (17%), dry skin (12%), nausea (12%) and paronychia (10%). Grade 2 or higher EGFR wild-type-related TRAEs were reported in 27% of patients, more commonly at doses of 60 mg BID and above. Grade 3 TRAEs were observed in 16 of 82 patients (20%), most commonly bilirubin elevation (11 of 16 Grade 3 TRAEs). Three dose-limiting toxicities (DLTs) were reported: one Grade 3 mucositis and one bilirubin increase at 80 mg BID, and one Grade 3 mucositis at 60 mg BID. TRAEs led to dose reduction in 13 patients (16%, predominantly bilirubin increase) and to discontinuation in one patient (1.2%). Two Grade 4 AEs were reported as possibly related, one of which (Grade 4 hyponatremia) was later changed to unlikely related. One patient reported possibly related Grade 4 alanine aminotransferase (ALT) elevation in the absence of bilirubin elevation; this patient enrolled after treatment with an immune checkpoint inhibitor, and ALT elevation resolved with steroids and interruption of BH-30643. No Grade 5 TRAEs were observed.

Safety Population (N=82)	TRAE				TEAE	
	Any Gr	Gr 1	Gr 2	Gr 3*	Any Gr	Gr 3+
Any AE, n (%)	71 (87)	34 (41)	21 (26)	16 (20)	80 (98)	33 (40)
EGFR wildtype-related AEs						
Diarrhea	30 (37)	22 (27)	8 (10)	0	35 (43)	0
Rash	30 (37)	20 (24)	7 (9)	3 (4)	34 (41)	3 (4)
Stomatitis	15 (18)	6 (7)	7 (9)	2 (2)	16 (20)	2 (2)
Dry skin	10 (12)	9 (11)	1 (1)	0	14 (17)	0
Paronychia	8 (10)	2 (2)	5 (6)	1 (1)	11 (13)	1 (1)
Additional TRAEs reported in ≥ 10% of patients						
Bilirubin increased	29 (35)	7 (9)	11 (13)	11 (13)	31 (38)	11 (13)
Fatigue	14 (17)	10 (12)	3 (4)	1 (1)	18 (22)	2 (2)
Nausea	10 (12)	4 (5)	6 (7)	0	14 (17)	0

* The one Grade 4 TRAE was one case of ALT elevation, observed following recent immune-checkpoint inhibitor therapy, and recovered with dose interruption and steroids; no Grade 5 TRAE were reported. Median duration of treatment was 3.0 months.

Figure 17. BH-30643 treatment-related adverse events observed in the dose escalation and backfill safety population (N=82).

Bilirubin elevation was observed in 29 patients (35%) and we believe is attributable to inhibition of the UGT1A1 enzyme and the hepatic transporter OATP1B1 by BH-30643, not to hepatocellular injury or wild-type EGFR inhibition. The nonclinical studies indicate that BH-30643 is not a substrate of UGT1A1 but is a potent inhibitor of UGT1A1 activity in both recombinant enzyme and human liver microsome systems. Bilirubin elevation has been predominantly unconjugated and asymptomatic and has generally been observed early in treatment, consistent

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with exposure-dependent UGT1A1 inhibition. The resulting hyperbilirubinemia has been pharmacologically analogous to Gilbert syndrome —asymptomatic, unconjugated and not associated with transaminase elevation, anemia or clinical liver dysfunction. Cases of bilirubin elevation were generally isolated (no aspartate aminotransferase (AST)/ALT elevation), low grade and reversible upon dose interruption or reduction; bilirubin has normalized rapidly following dose interruption without additional therapeutic intervention. Treatment-emergent ALT or AST elevations were observed in 12 patients (15%), including two Grade 3 events and one Grade 4 event. No cases met criteria for Hy's law.

A comprehensive pharmacovigilance review of the broader safety dataset of 196 patients treated with BH-30643, as of May 12, 2026, suggests that idiosyncratic toxicity of BH-30643 was infrequent with pneumonitis (possibly related) reported in two patients (1.0%, one Grade 3 and one Grade 4) and no clinically meaningful QTc prolongation or other treatment-related cardiac conditions observed. Treatment-related Grade ≥ 3 ALT elevations were reported in 14 patients (7.1%, two Grade 4) and AST elevations were reported in 9 patients (4.6%, all Grade 3), with no cases meeting Hy's law criteria. No other Grade 4 TRAEs were reported, and no Grade 5 TRAEs were reported. All grade treatment-emergent neutropenia was observed in 7.1% and thrombocytopenia in 10.2% of patients. All cause TEAEs reported in $>10\%$ of participants are shown in Figure 18, including the profile at the 3 dose levels taken forward for expansion investigation. Following the May 12, 2026 data cut and as of July 31, 2026, two additional cases with Grade 4 transaminitis were reported. The first, reported as an SAE, presented with asymptomatic Grade 4 ALT and Grade 4 AST and occurred without concurrent bilirubin elevation, in the setting of concurrent pravastatin and doxycycline; treatment was interrupted and LFTs improved. The second, not reported as an SAE, presented with asymptomatic Grade 4 ALT and Grade 3 AST and occurred with Grade 2 bilirubin elevation (50% unconjugated) in the setting of known liver metastases; treatment was interrupted and LFTs improved. A third case in a patient with baseline bilirubin elevation (83% unconjugated) presented with Grade 3 transaminitis concurrent with Grade 4 bilirubin (93% unconjugated). Treatment in this patient was discontinued, pending additional monitoring and work-up.

TEAEs, Starting Dose and Grade	All doses (N = 196)		40 mg BID (N = 85)		50 mg BID (N=60)		60 mg BID (N = 28)	
N (%), by preferred term	All Grade	Grade 3+	All Grade	Grade 3+	All Grade	Grade 3+	All Grade	Grade 3+
Any TEAEs	189 (96.4)	75 (38.3)	84 (98.8)	32 (37.6)	57 (95.0)	18 (30.0)	25 (89.3)	12 (42.9)
Rash ¹	93 (47.4)	6 (3.1)	42 (49.4)	3 (3.5)	25 (41.7)	0	15 (53.6)	1 (3.6)
Bilirubin Elevation ²	93 (47.4)	21 (10.7)	43 (50.6)	7 (8.2)	29 (48.3)	4 (6.7)	11 (39.3)	4 (14.3)
Diarrhea	87 (44.4)	4 (2.0)	41 (48.2)	0	21 (35.0)	2 (3.3)	14 (50.0)	1 (3.6)
Dry skin	45 (23.0)	0	22 (25.9)	0	14 (23.3)	0	8 (28.6)	0
Stomatitis ³	45 (23.0)	4 (2.0)	19 (22.4)	1 (1.2)	12 (20.0)	0	8 (28.6)	2 (7.1)
Aspartate aminotransferase increased	38 (19.4)	9 (4.6)	22 (25.9)	6 (7.1)	9 (15.0)	2 (3.3)	2 (7.1)	0
Fatigue	38 (19.4)	3 (1.5)	19 (22.4)	2 (2.4)	8 (13.3)	0	6 (21.4)	0
Alanine aminotransferase increased	37 (18.9)	17 (8.7)	22 (25.9)	10 (11.8)	10 (16.7)	4 (6.7)	1 (3.6)	0
Nausea	30 (15.3)	1 (0.5)	17 (20.0)	1 (1.2)	3 (5.0)	0	5 (17.9)	0
Paronychia	29 (14.8)	1 (0.5)	17 (20.0)	0	5 (8.3)	0	3 (10.7)	1 (3.6)
Decreased appetite	26 (13.3)	2 (1.0)	10 (11.8)	2 (2.4)	6 (10.0)	0	5 (17.9)	0
Anaemia	25 (12.8)	6 (3.1)	13 (15.3)	4 (4.7)	4 (6.7)	0	3 (10.7)	1 (3.6)
Headache	25 (12.8)	1 (0.5)	12 (14.1)	1 (1.2)	5 (8.3)	0	6 (21.4)	0
Vomiting	23 (11.7)	0	10 (11.8)	0	4 (6.7)	0	7 (25.0)	0
Constipation	21 (10.7)	0	11 (12.9)	0	4 (6.7)	0	5 (17.9)	0
Cough	20 (10.2)	0	9 (10.6)	0	3 (5.0)	0	3 (10.7)	0

1 Rash is a grouping term and includes PTs of Rash, Rash maculo-papular, Dermatitis acneiform, Dermatitis contact, and Dermatitis.

- 2
- Bilirubin elevation: Grouped term includes PTs of Blood bilirubin increased and Hyperbilirubinaemia.
- 3
- Stomatitis includes: Stomatitis, Mucosal Inflammation.

Figure 18: Summary of treatment-emergent adverse events (TEAE) reported in >10% of participants as of the May 12, 2026 safety data cut (N=196), with a median exposure of 2.8 months. TEAE profile for the dose levels selected for expansion investigation is shown, noting that median exposure is longer for 40 mg BID (4.7 months) as compared to 50 mg BID (2.1 months) or 60mg BID (1.9 months).

Preliminary clinical activity: Dose Escalation and Backfill

As of the March 2, 2026 data cut, 82 patients had been enrolled in the dose escalation and backfill cohorts across all evaluated dose levels. Of the 82 patients enrolled in this heavily pretreated population, 31 patients (38%) remained on therapy as of the April 29, 2026 efficacy cutoff, with the longest ongoing treatment duration exceeding 13 months.

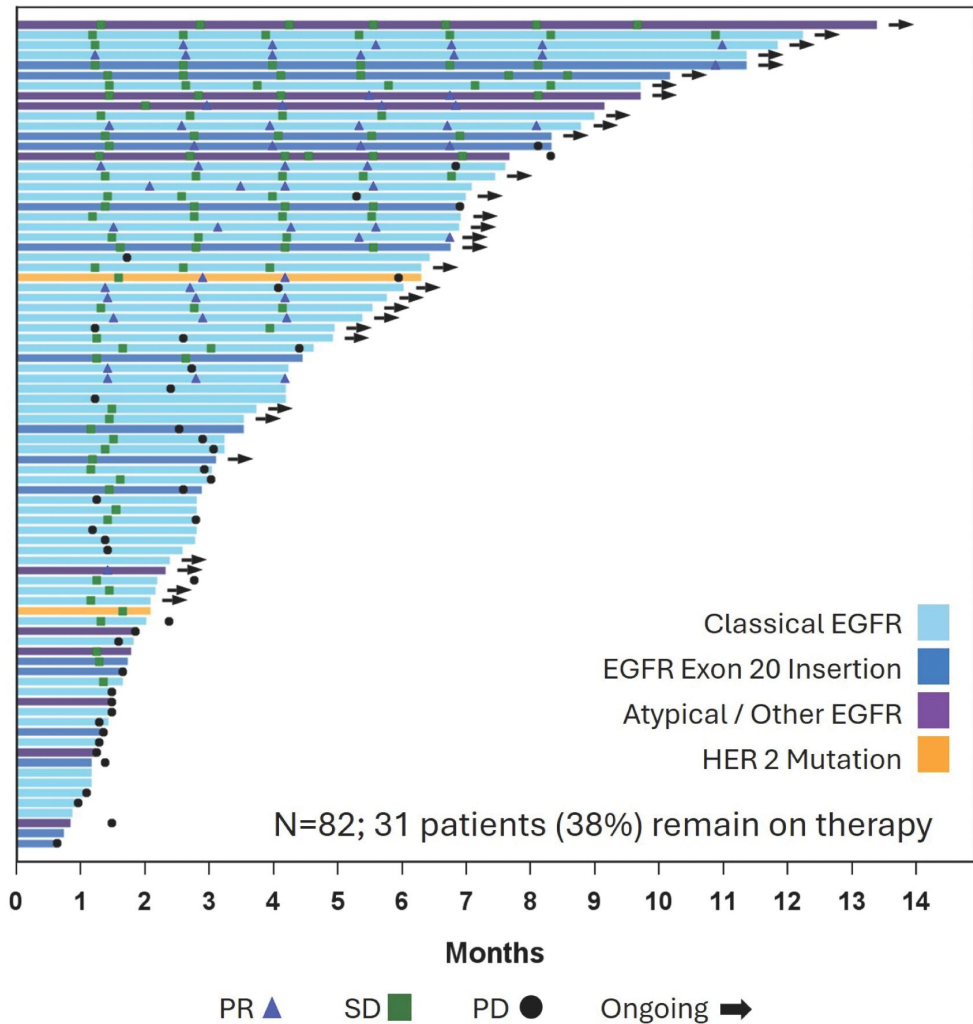


Figure 19. Responses (confirmed or ongoing) and prolonged stable disease observed in the dose escalation and backfill safety population (N=82).

Among the 77 patients in this population who had at least one post-baseline imaging assessment, antitumor activity was observed across diverse EGFR genotypes and was enriched in patients with multiple (or compound) EGFR mutations, informing our initial development focus on tumors harboring C797S resistance mutations. Confirmed or ongoing partial responses were observed in greater than 20% of evaluable patients in this unselected, heavily pretreated population, including patients with EGFR classical, atypical, and exon 20 insertion mutations.

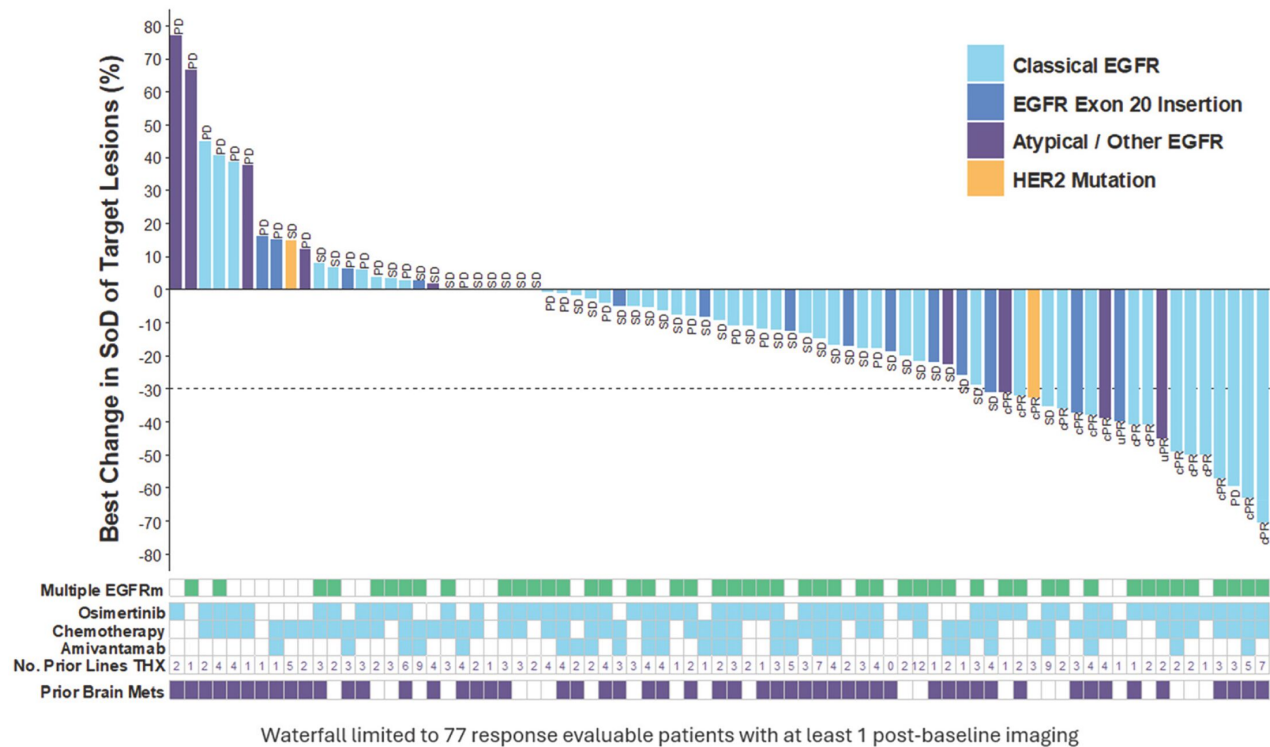


Figure 20. Best percent change from baseline in target lesion size for the dose escalation and backfill cohorts (N=77) with at least one (1) post-baseline imaging, illustrating responses across patients with diverse EGFR genotypes.

Representative case examples from the dose escalation and backfill cohorts illustrate clinical activity across diverse EGFR genotypes. A patient with EGFR exon 19 deletion and C797S resistance achieved a confirmed partial response following prior treatment with osimertinib, amivantamab and immunotherapy, with treatment ongoing after nearly a year. A patient with an atypical EGFR mutation achieved a confirmed partial response despite prior therapy with three different EGFR TKIs. A patient with an EGFR exon 20 insertion mutation

previously treated with multiple lines of chemotherapy achieved a confirmed partial response, including reduction of a large brain metastasis, in the absence of radiation or steroids.

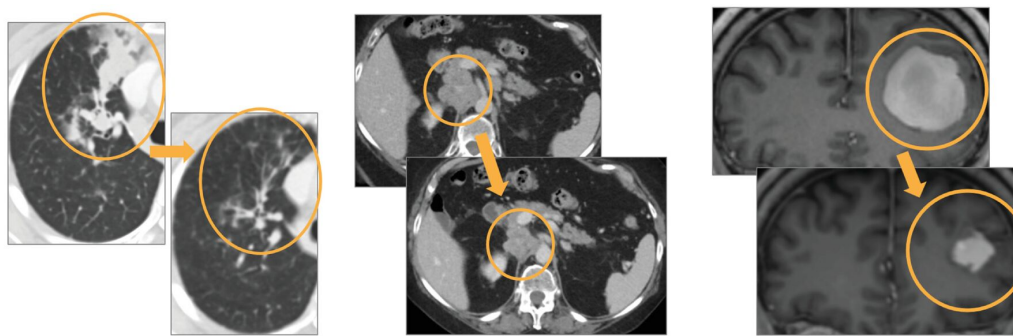


Figure 21. Representative case examples from the dose escalation and backfill cohorts illustrating clinical responses: 44 year-old female, enrolled at 40mg BID, with EGFR exon 19 deletion & C797S detected after prior osimertinib, amivantamab and immunotherapy and >11 months on treatment (left); 68 year-old female enrolled at 80mg QD, with EGFR L861Q previously treated with chemotherapy, erlotinib, osimertinib, mobocertinib and nine (9) months on treatment (center); 51 year-old male enrolled at 80mg BID, with EGFR exon 20 insertion with three (3) prior lines of chemotherapy with no brain radiation or steroids and eight (8) months on treatment (right).

Preliminary clinical activity: C797S resistance

As described previously, the Phase 1 Part 1 dose escalation / backfill experience included a number of patients with multiple EGFR mutations such as concurrent C797S and T790M who had a response to BH-30643 after prior TKI treatment. To characterize this signal further, expansion enrollment was initiated studying on-target resistance mutations such as C797S. The combined experience across escalation / backfill and early expansion represents the clinical activity against C797S that supports the near-term development plans.

To study whether BH-30643 can achieve effective inhibition of resistant clones, serial liquid biopsy analysis was performed using circulating tumor DNA (ctDNA) sequencing at baseline and after 3-6 weeks on therapy. Central plasma next-generation sequencing identified 27 patients across the dose escalation and expansion cohorts with C797S, T790M or both detected at baseline. Clearance of C797S in circulating tumor DNA was observed in 19 of 22 patients with detectable C797S at baseline (86%), and clearance of T790M was observed in 9 of 14 patients with detectable T790M at baseline (64%). Nine patients had concurrent C797S and T790M, of whom five

demonstrated clearance of both resistance mutations. Clearance of C797S and T790M was observed across diverse EGFR driver backgrounds, including exon 19 deletions or indels, L858R, atypical G719X and exon 20 insertions.

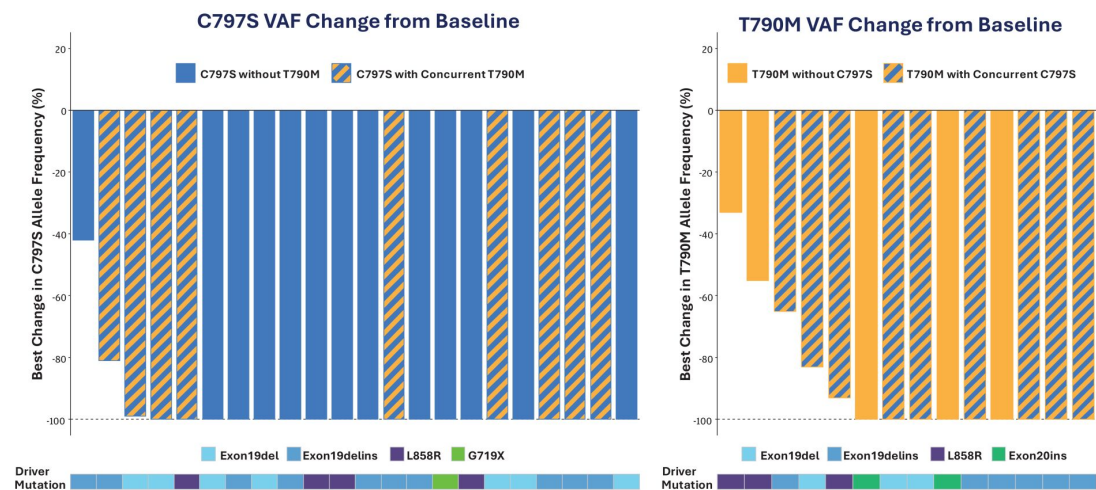


Figure 22. C797S and T790M ctDNA clearance in the context of diverse EGFR driver mutations including exon 19 del or indel, L858R, G719X and exon 20 ins.

Efficacy was studied in the C797S target population including 44 patients from dose escalation/backfill and expansion cohorts as of an updated May 20, 2026 efficacy cutoff (Figure 23). This analysis excludes patients with concurrent driver alterations or who previously received a TKI specifically targeting C797S. The median follow-up is 4.2 months as of the data cut; 32 of 44 participants (73%) remain on therapy at the time of analysis with the longest on therapy for approximately 12.5 months. 34 patients were evaluable for response with at least one post-baseline tumor assessment across the dose escalation/backfill and expansion cohorts (Figure 24). Partial responses (including 14 confirmed responses and two (2) unconfirmed responses ongoing at time of analysis) were observed in 53% of patients without prior chemotherapy (8/15) and 42% of patients with prior chemotherapy (8/19). Partial responses were observed both with and without concurrent T790M and both with and without a prior history of brain metastases, and were observed in the context of diverse EGFR driver mutations: exon 19 deletion and indel, L858R, and atypical G719X and E709K. This response profile continues to evolve with ongoing follow-up; as of the May 20, 2026 data cut, two (2) patients were ongoing on treatment with only a single follow-up scan available and two (2) patients with stable disease had developed a partial

response which was pending confirmation (uPR). These data remain preliminary and are subject to change as additional patients are enrolled and follow-up matures.

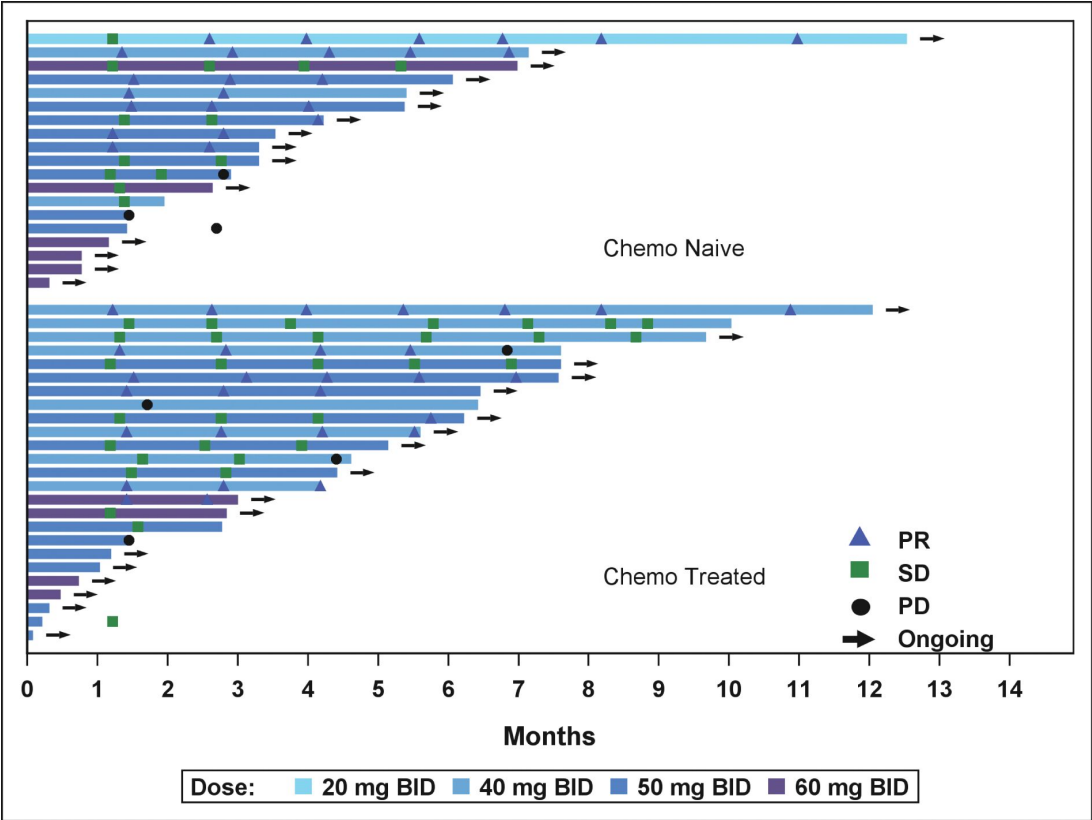


Figure 23. Swimmer plot showing 44 patients from the target C797S population as of the May 20, 2026 efficacy data cut, which excludes patients with concurrent driver alterations or who previously received a TKI specifically targeting C797S. 32 patients (73%) remain on therapy at time of analysis, with two patients over 12 months on therapy.

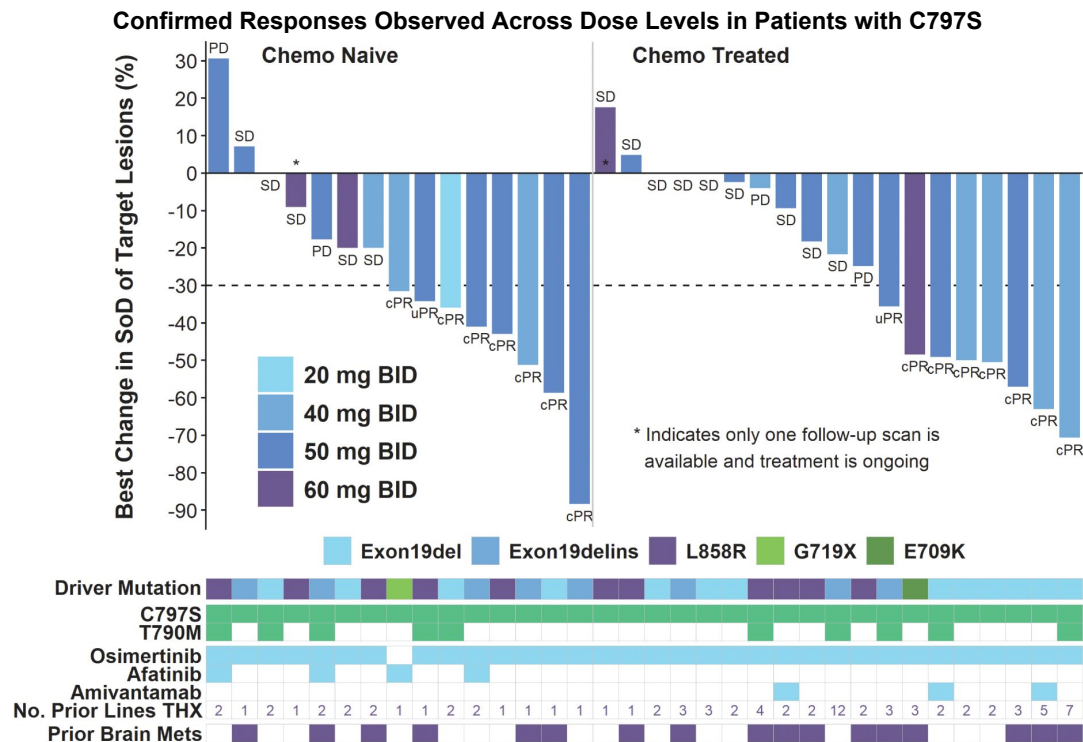


Figure 24. Waterfall plot showing 34 patients from the target C797S population who were response evaluable across escalation/backfill and expansion cohorts as of the May 20, 2026 efficacy data cut. Overall response rate (including confirmed responses or unconfirmed responses which were ongoing) was 53% (8/15) in chemo naive patients and 42% (8/19) in chemo pretreated patients, with a median of 4.2 months of follow-up.

Preliminary clinical activity: TKI Naive with EGFR Classical Mutations

We are also evaluating BH-30643 in a dose expansion cohort of patients with advanced classical EGFR-mutant NSCLC who have not received prior EGFR TKI therapy. As of the May 20, 2026 efficacy data cut, 27 patients in this TKI-naive cohort had undergone at least one post-baseline tumor assessment with four having only one post treatment scan (Figure 25). This cohort was enriched for patients with higher-risk disease features, including 48% with a history of brain metastases and 30% with exon 19 deletion/insertions or other higher-risk genotypes such as H870R. With a median follow-up of approximately 4.2 months, 21 of 27 patients (78%) achieved a partial response (16 confirmed, 5 unconfirmed with three having only one follow-up scan and two from SD and ongoing), and all evaluable patients experienced a reduction in target lesion size, with a median best reduction of approximately 43%. Among patients with paired circulating tumor DNA assessments, 11 of 13 (85%) showed complete clearance of detectable EGFR mutations after three to six weeks and the two remaining

patients showed greater than 98% reduction. These data remain preliminary and are subject to change as additional patients are enrolled and follow-up matures.

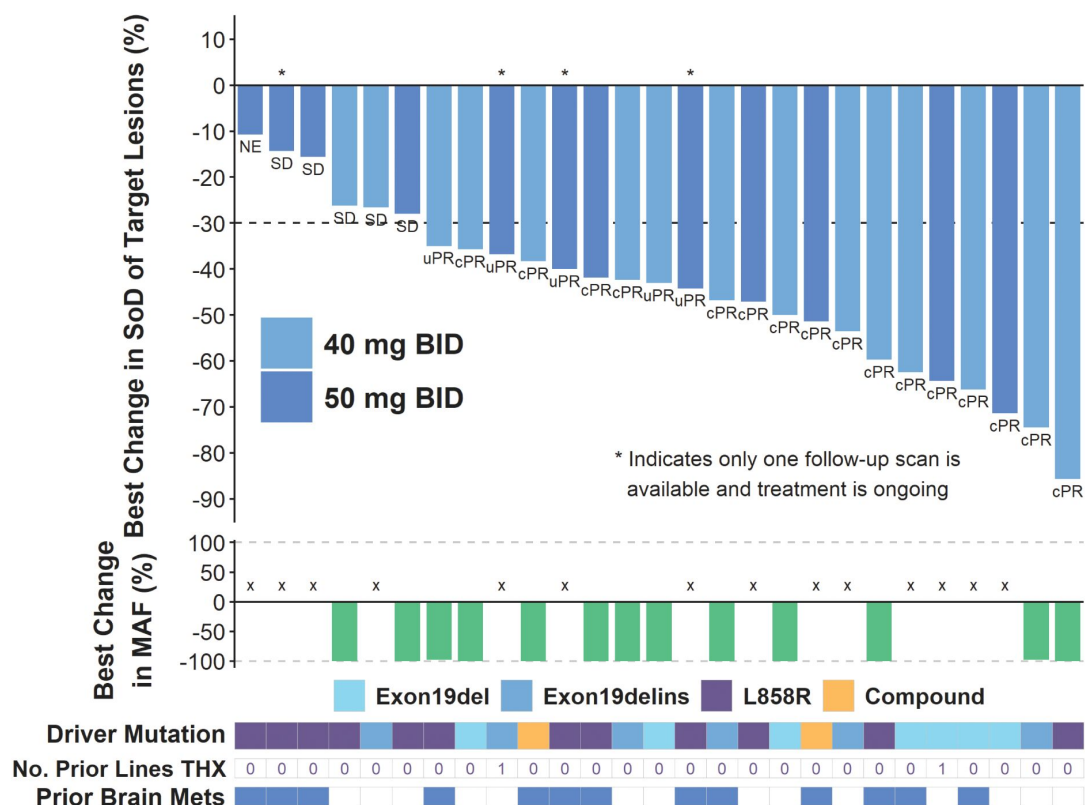


Figure 25. Waterfall plot showing 27 TKI naïve patients from the expansion cohort with classical EGFR mutations who were response evaluable as of the May 20, 2026 efficacy data cut. Overall response rate (including confirmed responses or unconfirmed responses which were ongoing) was 78% with a median of 4.2 months of follow-up.

Representative case examples from this cohort include a patient with EGFR L858R treatment-naïve disease treated at 40 mg BID who achieved a confirmed partial response with an approximately 86% reduction in target lesion size, and a patient with EGFR exon 19 deletion and H870R treatment-naïve disease presenting with multiple brain metastases, treated at 40 mg BID, who achieved both a systemic and a CNS partial response in the absence of radiation or steroids. Both responses were ongoing as of the May 20, 2026 efficacy data cut.

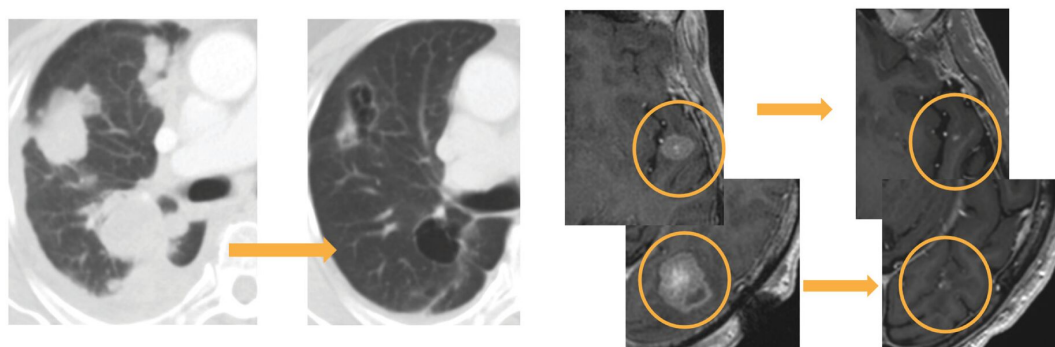


Figure 26. Representative case examples from the classical TKI-naïve dose expansion cohort: L858R treatment naïve patient, treated at 40 mg BID, with treatment ongoing and partial response confirmed on second scan (~86%) (left); exon19del & H870R treatment naïve patient, presented with multiple brain mets, treated at 40mg BID with systemic and CNS PR, in the absence of radiation / steroids, with therapy ongoing (right).

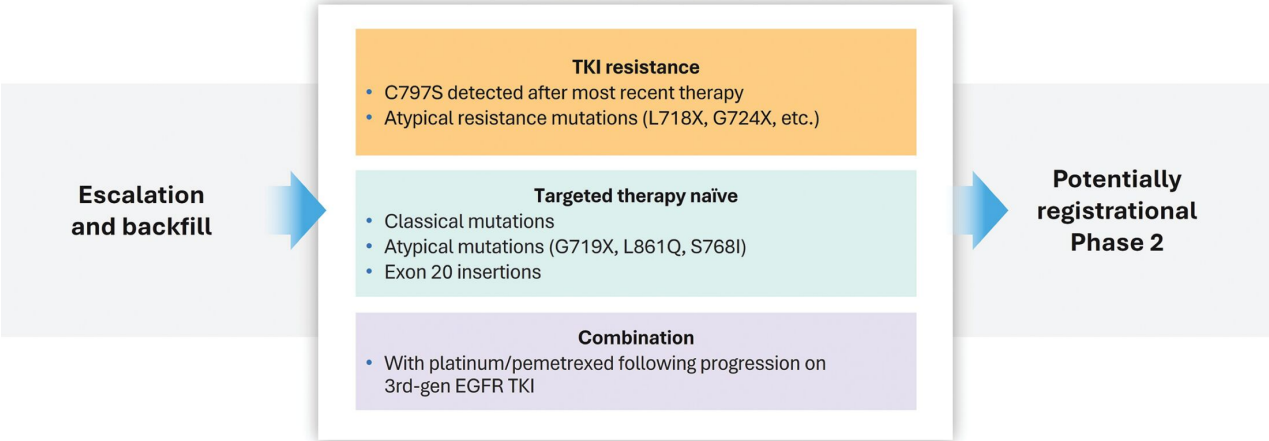
Ongoing expansion investigation

Enrollment is also ongoing in multiple dose expansion cohorts to inform selection of RP2D, including for patients with resistance mutations as well as targeted therapy naïve patients with EGFR classical, atypical or exon 20 insertion mutations. Data from these cohorts are at an early stage, and we expect to provide additional information regarding clinical activity in these populations as the cohorts mature. The protocol also now includes

the addition of a chemotherapy combination cohort to characterize the safety and preliminary antitumor activity of BH-30643 plus platinum / pemetrexed in patients following progression on a 3rd-generation EGFR TKI.

SOLARA Expansion Cohorts: Now Enrolling Across Multiple Dose Levels

Expansion cohorts to inform Phase 2/3 development:



Each cohort may study multiple doses

Figure 27. SOLARA trial design. Following dose escalation / backfill, molecularly defined expansion cohorts and combination cohorts are designed to further characterize the clinical profile in TKI-pretreated and TKI-naïve patient populations, support the transition to Phase 2 and inform broader development plans.

BH-30236: our CLK inhibitor

BH-30236 is an investigational orally bioavailable, macrocyclic inhibitor of the CDC-like kinase family. At clinically relevant concentrations, BH-30236 has also been shown in preclinical studies to inhibit DYRK1A, DYRK1B, DYRK2, PIM3 and FLT3. BH-30236 is currently in clinical development for the treatment of AML and HR-MDS. BH-30236 is designed to modulate aberrant alternative splicing in cancerous tissue, targeting the same aberrant splicing machinery that drives AML and HR-MDS disease biology and that cancer cells exploit to develop resistance to venetoclax, FLT3 inhibitors and chemotherapy.

We are evaluating BH-30236 in a Phase 1/1b multicenter, open-label, first-in-human dose escalation and expansion trial in adults with R/R AML and HR-MDS. The FDA has granted orphan drug designation to BH-30236 for the treatment of AML. As of the April 10, 2026 safety data cut, BH-30236 was well-tolerated across multiple monotherapy dose levels and in combination with the BCL-2 inhibitor venetoclax, with preliminary antileukemic activity observed in both settings. We expect to report updated safety and efficacy data from the BH-30236 Phase 1 trial in the first half of 2027.

Disease and treatment landscape

AML and HR-MDS: disease, epidemiology, and unmet need

AML is the most common acute leukemia in adults, with approximately 21,000 new diagnoses and 11,000 deaths annually in the United States. The median age at AML diagnosis is approximately 68 years, and the disease disproportionately affects older patients who may be unable to tolerate intensive induction chemotherapy. Despite

therapeutic advances over the past decade, the prognosis for patients with relapsed or refractory AML remains poor: median overall survival without allogeneic hematopoietic cell transplantation (allo-HCT) is less than three months, and allo-HCT, while potentially curative, is available to only a minority of patients given the age and fitness of the affected population. Myelodysplastic syndromes (MDS) are clonal hematopoietic disorders characterized by ineffective hematopoiesis, peripheral blood cytopenias and variable risk of transformation to AML. According to GlobalData, approximately 14,000 patients are diagnosed with HR-MDS annually in the United States, with a median age at diagnosis of approximately 77 years. Patients with HR-MDS closely mirror AML in clinical course, frontline treatment, and unmet need in the relapsed and refractory setting. For patients with HR-MDS who progress following hypomethylating agent therapy, median overall survival is approximately five to six months.

Together, AML and HR-MDS represent approximately 35,000 new diagnoses annually in the United States. The venetoclax-resistant and refractory segment, for which no approved therapy currently exists for broad application (or usage), represents the initial area of focus for BH-30236. The global AML therapeutics market is estimated to exceed \$3 billion and is projected to grow substantially over the coming decade, driven by aging demographics, the established role of venetoclax-based regimens in frontline therapy and the consequent emergence of venetoclax-resistant disease as a growing and largely unaddressed clinical segment. We estimate that approximately 10,000 to 15,000 AML patients in the United States annually have disease that is resistant to or has relapsed following venetoclax-based therapy. The HR-MDS market represents a parallel opportunity of comparable scale: according to GlobalData, approximately 14,000 patients are diagnosed with HR-MDS annually in the United States, the majority of whom will likely ultimately require therapy beyond frontline hypomethylating agents (HMAs), and for whom no approved targeted option currently exists following HMA failure.

Splicing as disease driver and resistance enabler

AML and HR-MDS are, in part, diseases of aberrant splicing. Aberrant splicing is common in cancer and can influence many hallmarks of cancer including the apoptosis pathway and the DNA damage repair pathway. In myeloid malignancies, spliceosome gene mutations—in genes including SF3B1, SRSF2 (as defined below) and U2AF1—are among the most common recurrent genetic events, present in up to 25% of AML cases and up to 85% of MDS. Even in patients without somatic spliceosome mutations, genome-wide aberrant alternative splicing led by oncogenic signaling has been documented in AML: approximately one-third of genes show differential splicing patterns compared with normal myeloid precursors. These aberrant splicing events are not incidental—they drive leukemic proliferation, impair differentiation and promote evasion of apoptosis from the outset of disease.

Alternative splicing enables a single gene to produce multiple forms of a protein, called isoforms. Cancer cells can exploit this mechanism by generating protein isoforms that drive uncontrolled growth, and when alternative splicing becomes dysregulated it can contribute to disease progression and therapeutic resistance. Upregulation and mutation of serine/arginine-rich splicing factors (SRSFs) have been reported in hematologic malignancies and solid tumors. By way of example, dysregulated alternative splicing can result in increased

expression of pro-growth oncoproteins such as MET, or decreased expression of pro-apoptotic regulators such as p53, contributing to tumor progression and resistance to therapy.

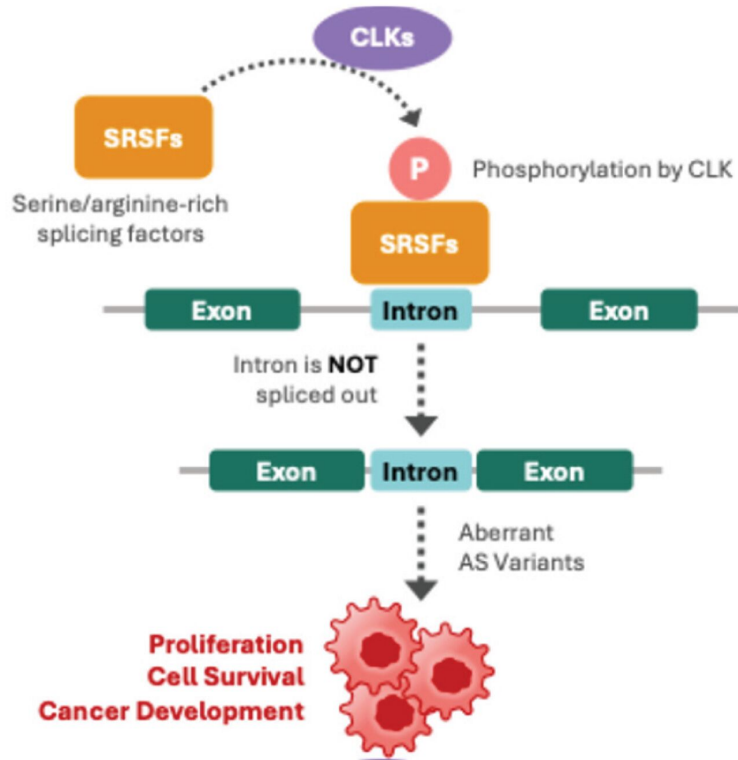


Figure 28. CLK–SRSF axis in cancers: mechanism of aberrant alternative splicing and treatment resistance.

The molecular machinery responsible for this aberrant splicing includes the CLK–SRSF axis (Figure 28). The CDC-like kinase family comprises nuclear serine/threonine kinases—CLK1, CLK2, CLK3 and CLK4—that phosphorylate SRSF proteins, which regulate spliceosome assembly, exon recognition and splice site selection. Overexpression of SRSFs and dysregulated CLK activity drives SRSF hyperphosphorylation, producing the genome-wide splicing alterations that characterize myeloid malignancy. The same CLK–SRSF machinery that contributes to disease at diagnosis is the mechanism that cancer cells exploit to develop resistance to standard-of-care therapy, venetoclax—making CLK inhibition an approach with the potential to address both the underlying disease biology and the primary mechanisms of therapeutic failure simultaneously.

Current standard of care and limitations

For patients with AML who are older or otherwise ineligible for intensive induction chemotherapy—a large and growing proportion of the patient population given aging demographics—the combination of venetoclax and azacitidine has become the established standard of care. In the VIALE-A trial, a Phase 3, randomized, double-blind study evaluating the combination of venetoclax and azacitidine, this combination demonstrated a composite complete remission rate of 66.4% and a median overall survival of 14.7 months versus 9.6 months for azacitidine alone, establishing the regimen as a meaningful advancement over prior therapy in this population. For patients with HR-MDS, hypomethylating agents represent standard of care, with ORR of

approximately 20-30%. In addition, venetoclax-based combinations are increasingly used in HR-MDS in a manner parallel to their application in AML.

Despite these advances, the durability of venetoclax-based therapy is limited. For example, approximately one-third of AML patients do not have a complete remission or do not respond to frontline venetoclax and azacitidine combination therapy, and the majority of initial responders ultimately develop resistance and progressive disease. Resistance to venetoclax-based combination therapy arises through multiple interconnected mechanisms: upregulation of the anti-apoptotic proteins MCL-1 and BCL2A1, which share structural features with BCL-2 but are not inhibited by venetoclax; expansion of monocytic leukemic clones with intrinsic BCL-2 independence; and activation of the FLT3 and RAS/MAPK signaling pathways that bypass BCL-2 dependency. What unifies these mechanisms is that each is enabled or maintained through aberrant alternative splicing—making the CLK–SRSF axis not merely one pathway among many, but the upstream regulator that governs resistance across all of these routes simultaneously. Direct BCL-2 inhibition with venetoclax cannot address these upstream splicing-mediated resistance mechanisms, which explains both the high rate of primary non-response and development of acquired resistance over time.

Prior CLK inhibitors: a validated mechanism with an unresolved tolerability problem

The therapeutic rationale for CLK inhibition in AML has been established by prior clinical programs. CLK inhibitors cirtuvivint (SM08502) and rogocekib (CTX-712) have reached clinical development in solid tumors with rogocekib also in R/R AML and HR-MDS. Both have demonstrated preliminary proof-of-concept that CLK inhibition can produce clinical antitumor effect—but both programs have prioritized intermittent dosing rather than daily dosing, primarily due to tolerability limitations.

Cirtuvivint is an investigational potent CLK inhibitor that demonstrated antiproliferative activity across a broad range of tumor models. In a Phase 1 clinical trial in patients with advanced solid tumors, gastrointestinal toxicities required intermittent dosing (5 days on, 2 days off), limiting the feasibility of continuous splicing suppression and constraining the program's combination potential. Rogocekib reported an ORR of 42.9% in a Phase 1 clinical trial of 14 patients with R/R AML and HR-MDS in Japan, the majority of whom had received prior azacitidine-based therapy including venetoclax, providing clinical validation of CLK inhibition as an active mechanism in this setting. Activity trended higher in patients with splicing factor mutations (SRSF2, U2AF1) than in those without, though responses were observed in both groups. However, diarrhea and cytopenias have limited rogocekib to a twice-weekly intermittent dosing schedule.

These experiences illustrate what we believe is a fundamental challenge for the class: sustained SRSF phosphorylation suppression—the mechanism by which CLK inhibition remodels BCL-2 family isoform expression and sensitizes leukemic cells to venetoclax—requires maintained drug exposure that intermittent schedules may be unable to provide. We specifically designed BH-30236 with the objective of targeting aberrant alternative mRNA splicing in cancers in a manner suitable for daily oral dosing without the tolerability challenges that limited prior molecules.

Our solution: BH-30236

BH-30236 is an investigational, novel, macrocyclic, non-covalent CLK inhibitor which has been well-tolerated with continuous daily dosing across multiple monotherapy dose levels and in combination with the BCL-2 inhibitor venetoclax, with preliminary antileukemic activity observed in both settings. Aberrant SRSF activity, which can be modulated by CLK, can be a driver of the underlying disease biology of AML and HR-MDS when resistance develops to venetoclax and other therapies. BH-30236 targets CLK upstream of multiple resistance pathways—not by addressing one resistance mechanism after it develops, but by suppressing the splicing machinery that enables resistance to begin.

Design rationale

BH-30236 was designed to achieve high potency against the primary disease-relevant kinase targets while maintaining a tolerability profile consistent with continuous once-daily dosing. The macrocyclic scaffold was chosen to impose the conformational rigidity required to achieve selective binding across the CLK/DYRK/PIM/FLT3 kinase cluster while minimizing the off-target interactions that drove the tolerability challenges encountered with prior CLK inhibitors.

Continuous once-daily dosing is a core design objective for BH-30236, given that the BCL-2 family remodeling that underlies venetoclax sensitization, specifically, the reduction of MCL-1, BCL2A1 and BCL-2 expression through SRSF suppression and nonsense-mediated mRNA decay, is a transcriptional and splicing-level effect that requires sustained CLK inhibition to maintain. We believe the intermittent dosing schedules that have been evaluated for cirtuvivint and rogocekib are likely to permit recovery of SRSF phosphorylation and BCL-2 family anti-apoptotic protein expression during off-drug intervals. This interrupted inhibition undermines the durability of splicing remodeling and limits the potential for synergistic interaction with venetoclax. BH-30236 was designed to address this limitation.

As a multi-kinase CLK inhibitor, BH-30236 was also designed to inhibit other disease-relevant targets at clinically relevant concentrations. In preclinical studies, BH-30236 has also been shown to inhibit DYRK1A, DYRK1B, DYRK2, PIM3 and FLT3, with all primary targets inhibited at sub-nanomolar concentrations in enzymatic kinase assays. At cellular anti-phosphorylation assays, BH-30236 inhibited the phosphorylation of DYRK substrate TAU protein and PIM substrate 4EBP1 with IC₅₀s of approximately 50 nM and approximately 80 nM. BH-30236 potently inhibited the phosphorylation of FLT3 with an IC₅₀ of 0.2 nM as shown in the table. DYRK family is close to CLK family and plays roles in alternative splicing. PIM3 regulates the proliferation, survival and chemotaxis of AML cell lines and FLT3 mutations occur in up to 35% of AML. We believe co-inhibition of DYRK, FLT3 and PIM3 may provide additive antileukemic effects. The primary therapeutic rationale for BH-30236 is CLK-mediated splicing remodeling and venetoclax sensitization; the multikinase profile is a supporting characteristic of the compound's design.

BH-30236	CLK1	CLK2	CLK3	CLK4	DYRK1A	DYRK1B	DYRK2	PIM3	FLT3_ITD
Enzyme Kinase IC ₅₀ (nM)	0.13	0.16	5.9	0.45	0.11	0.15	0.56	0.12	0.54
Cell Phosphorylation IC ₅₀ (nM)	pSRSF4 (Kasumi-1 cells)				pTAU (SH-SY5Y cells)			p4EBP1 (MM1S cells)	pFLT3 (MV-4-11 cells)
	25.3				~50			~80	0.2

Figure 29. Enzymatic and phosphorylation assay profile of BH-30236 demonstrating multi-kinase activity across CLKs 1-4, DYRK1A, DYRK1B, DYRK2, PIM3 and FLT3.

Key differentiation versus other CLK inhibitors

Although no head-to-head clinical studies have been conducted, BH-30236 demonstrated low nanomolar enzymatic potency against CLK family kinases in our preclinical studies, comparable to cirtuvivint (SM08502) and rogocekib (CTX-712). In head-to-head cellular assays, BH-30236 demonstrated more potent inhibition of SRSF phosphorylation comparable to rogocekib or cirtuvivint (Figure 30).

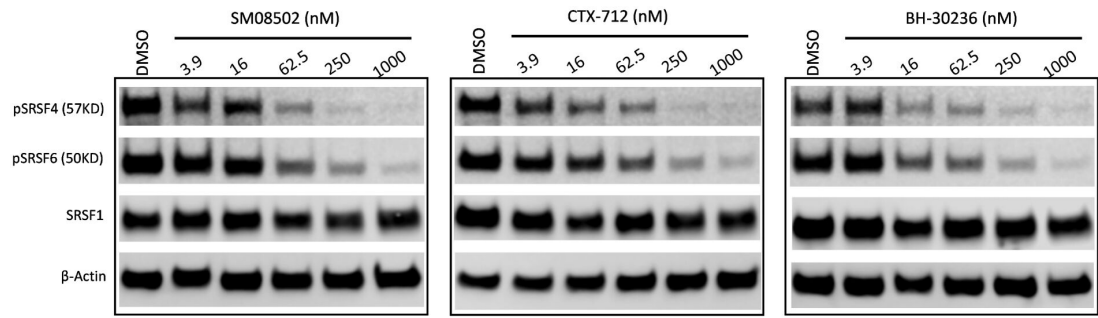


Figure 30. Inhibition of phosphorylation of SRSFs in KASUMI-1 cells.

Preclinical studies and data

Biochemical and cellular potency

BH-30236 demonstrated sub-nanomolar enzymatic potency against CLK1, CLK2 and CLK4, and also potently inhibited PIM3, DYRK1A, DYRK1B, DYRK2 and FLT3 at sub-nanomolar concentrations in enzymatic kinase assays. In cellular anti-phosphorylation assays, BH-30236 inhibited the phosphorylation of DYRK substrate TAU protein and PIM substrate 4EBP1 with IC₅₀s of approximately 50 nM and approximately 80 nM. BH-30236 potently inhibited the phosphorylation of FLT3 with an IC₅₀ of 0.2 nM.

Antiproliferative activity

In antiproliferative assays across a panel of 116 hematologic and solid tumor cell lines and three normal cell lines, BH-30236 demonstrated broad antiproliferative activity, with notably greater potency in hematologic malignancy lines than in solid tumor lines or normal cells, reflecting activity concentrated in disease-relevant cell types (Figure 31).

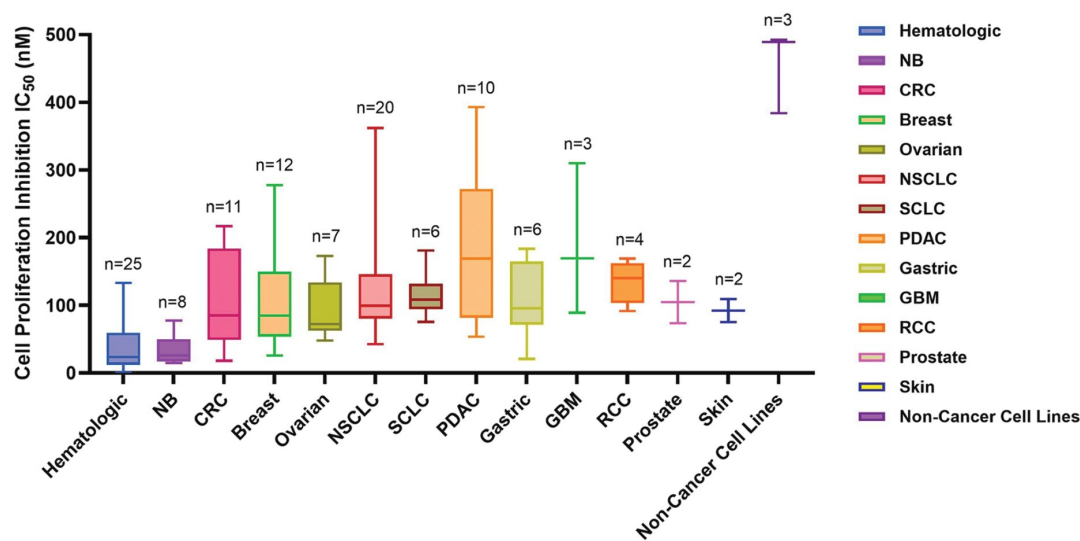
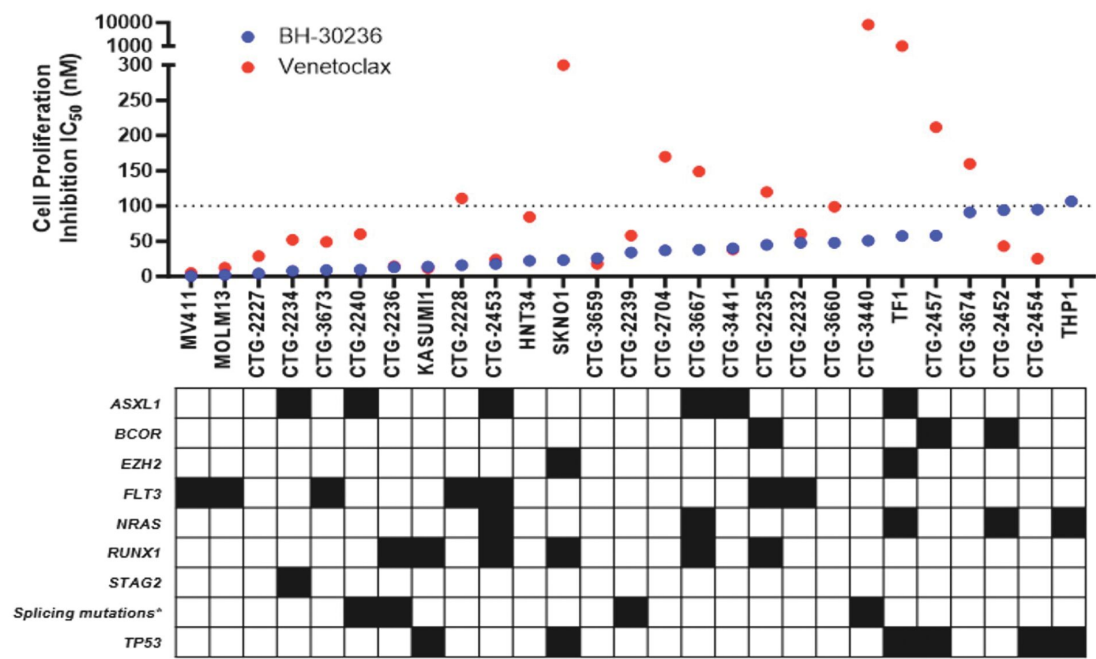


Figure 31. Antiproliferative activity of BH-30236 in a panel of 116 hematologic and solid tumor cell lines and three normal cell lines.

In patient-derived AML cell models and primary AML cell line models, BH-30236 demonstrated greater antiproliferative potency than venetoclax in 22 out of 27 models tested, including models harboring splicing factor mutations commonly encountered in AML and HR-MDS (Figure 32). We believe this observed mutation-agnostic activity pattern supports the potential for BH-30236 to be active across a broad, biomarker-unselected AML patient population—a characteristic we believe distinguishes BH-30236 from rogocekib, for which reported clinical activity has appeared enriched in patients with splicing factor mutations.



* Mutations include SF3B1, SRSF2, and U2AF1

Figure 32. BH-30236 vs. venetoclax antiproliferative activity in patient-derived AML cell models (n=27; CTG assay) and primary cell lines.

Mechanism of action: SRSF suppression and BCL-2 family remodeling

In our preclinical studies, we characterized the mechanism by which BH-30236 sensitizes leukemic cells to venetoclax through RNA sequencing of patient-derived AML cell models and targeted protein analyses in established AML cell lines. We observed that BH-30236 dose-dependently downregulated SRSF family members at both the mRNA and protein levels through nonsense-mediated mRNA decay (NMD) driven by poison exon splicing—a self-reinforcing mechanism by which CLK inhibition reduces SRSF expression, which in turn further diminishes aberrant alternative splicing activity. BH-30236 also suppressed DNA damage repair gene expression through alternative splicing-induced NMD.

The downstream functional consequence most directly relevant to the venetoclax combination is a coordinated remodeling of BCL-2 family expression. BH-30236 dose-dependently reduced mRNA expression of MCL1, BCL2 and BCL2A1—three anti-apoptotic proteins each independently implicated as a primary mediator of venetoclax resistance—while simultaneously increasing expression of the pro-apoptotic BCLxS isoform in leukemic cell lines (Figure 33). This simultaneous suppression of all three primary venetoclax resistance effectors through a single

upstream mechanism is the molecular basis for the venetoclax synergy demonstrated in subsequent combination studies.

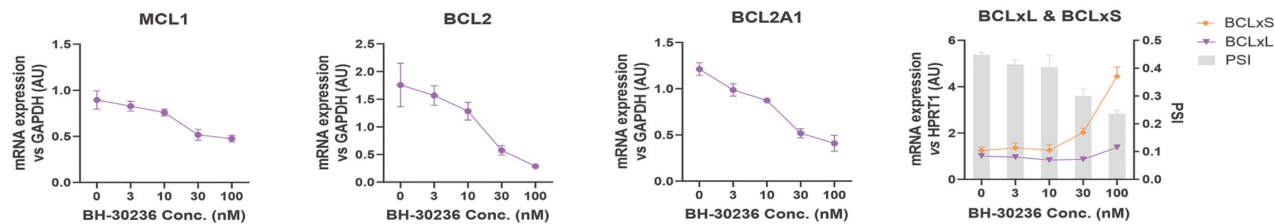


Figure 33. BCL-2 family mRNA expression in AML cell lines following BH-30236 treatment (Kasumi-1 cells shown). MCL1, BCL2, and BCL2A1 mRNA levels decreased dose-dependently; pro-apoptotic BCLxS increased.

BH-30236 additionally downregulated FLT3 expression through NMD in AML cell lines. This potential mechanism of FLT3 suppression is mechanistically distinct from direct FLT3 kinase inhibition: because BH-30236 not only inhibited FLT3 autophosphorylation, but also eliminated FLT3 transcript, it is not subject to the secondary kinase domain mutations that confer resistance to approved FLT3 inhibitors. This property may be of clinical relevance in patients who have relapsed following FLT3 inhibitor-containing regimens.

Venetoclax combination: preclinical rationale and evidence

The scientific rationale for combining BH-30236 with venetoclax follows directly from the BCL-2 family remodeling characterized in the mechanism of action studies. Venetoclax inhibits BCL-2 directly, but resistance emerges primarily through upregulation of MCL-1 and BCL2A1—BCL-2 homologs that venetoclax does not inhibit. By suppressing MCL-1, BCL2A1 and BCL-2 expression through upstream splicing remodeling, BH-30236 is designed to remove the anti-apoptotic proteins that allow leukemic cells to survive venetoclax pressure. We believe the combination therefore represents a mechanistic convergence: one agent blocking BCL-2 at the protein level, the other eliminating the alternative survival proteins at the transcriptional and splicing level through non-overlapping and mutually reinforcing mechanisms.

We observed that BH-30236 demonstrated equal potency in venetoclax-resistant and cytarabine-resistant cell lines relative to their parental counterparts, suggesting that the mechanisms driving resistance to these two major therapeutic classes do not confer cross-resistance to BH-30236 (Figure 34). This finding is consistent with

BH-30236 acting upstream of the resistance effectors to which both agents have already failed and supports its evaluation in patients with prior venetoclax or cytarabine exposure.

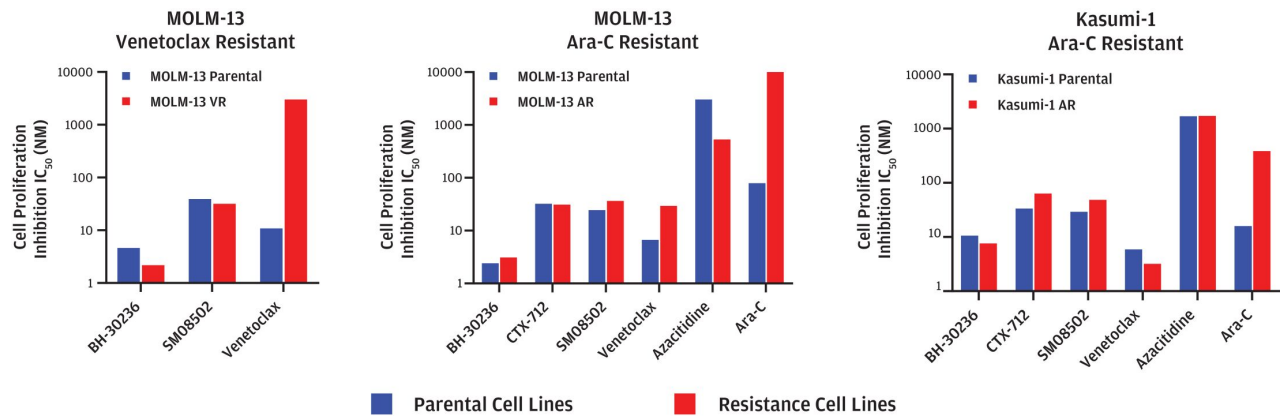


Figure 34. BH-30236 activity in venetoclax-resistant (VR) and cytarabine-resistant (Ara-C-R) cell lines versus parental counterparts.

In vitro combination studies demonstrated synergistic activity for BH-30236 and venetoclax across a broad panel of AML, diffuse large B-cell lymphoma and mantle cell lymphoma cell lines, including models harboring FLT3, TP53 and NRAS mutations. Bliss synergy scores (quantified as the difference between the observed effect of a drug combination and the expected effect, calculated as if the drugs act independently) (Figure 35) suggest that the combination was synergistic—not merely additive—across multiple hematologic tumor types and across the major molecular subtypes of AML most commonly encountered in the venetoclax-resistant population.

Cell Line Name	Cancer Type	Proliferation Inhibition IC ₅₀ (nM)		Synergy Score ¹	Mutation Status
		BH-30236	Venetoclax		
MOLM-13	AML	0.62	1.36	11.0	FLT3-ITD, KMT2A fusion
MV-4-11	AML	0.70	8.88	3.93	FLT3-ITD, KMT2A, AFF1
HNT34	AML	14.6	17.4	19.8	BCR-ABL1
KASUMI-1	AML	26.4	12.4	12.1	RUNX1 fusion, KIT, RAD21, TP53
THP1	AML	55.6	826	18.8	CSNK2A1-DDX39B, KMT2A-MLLT3, NRAS, TP53
SKNO1	AML	120	149	21.6	RUNX1-fusion, KIT, TP53
HL60	AML	244	10.0	17.5	NRAS Q61L, TP53, CDKN2A, cMyc-Ampl.
KG1	AML	279	96.4	25.4	FGFR1 fusion, NRAS, TP53
HG3	CLL	86.1	>1000	17.6	NA
MEC1	CLL	164	>1000	12.9	R3HCC1L-HTRA1, TP53
JeKo1	MCL	39.5	>3000	26.4	CDKN2A, TP53
MINO	MCL	65.9	10.0	11.1	CDKN2A, NRAS, TP53
MOLM-1	CML	158	163	16.4	BCR-ABL1
SUPB15	B-ALL	53.3	1.20	10.1	BCR-ABL1
Jurkat E6.1	TLL	127	>3000	7.67	BAX, FBXW7, INPP5D, MSH2, MSH6, SYK, TP53
TOLEDO	DLBCL	19.3	21.5	20.5	KRAS, TP53

¹ Synergy score was calculated as highest average Bliss or HSA score of a 3x3 field matrix. Scores <-10 indicates antagonistic effects, scores from -10 to 10 indicates additive effects, scores > 10 indicates synergistic effects.

Figure 35. BH-30236 + venetoclax *in vitro* synergy across hematologic cell line panel (AML, DLBCL, MCL). Bliss synergy scores >10 indicate synergy. * Highest average Bliss score across 3x3 field matrix.

In vivo antitumor activity

In venetoclax-resistant AML mouse tumor models, the combination of BH-30236 and venetoclax achieved substantial antitumor activity—substantially exceeding the activity of either agent alone—at BH-30236 doses within the range currently under evaluation in the Phase 1 clinical trial. Complete tumor regression was achieved in resistant models (Figure 36), with tumors remaining absent following cessation of both agents, demonstrating that the combination can overcome single-agent resistance at clinically achievable exposures. Consistent combination activity was observed across molecularly distinct AML models representing both FLT3-mutant and FLT3 wild-type AML, supporting the view that the venetoclax synergy of BH-30236 is not restricted to a specific oncogenic driver.

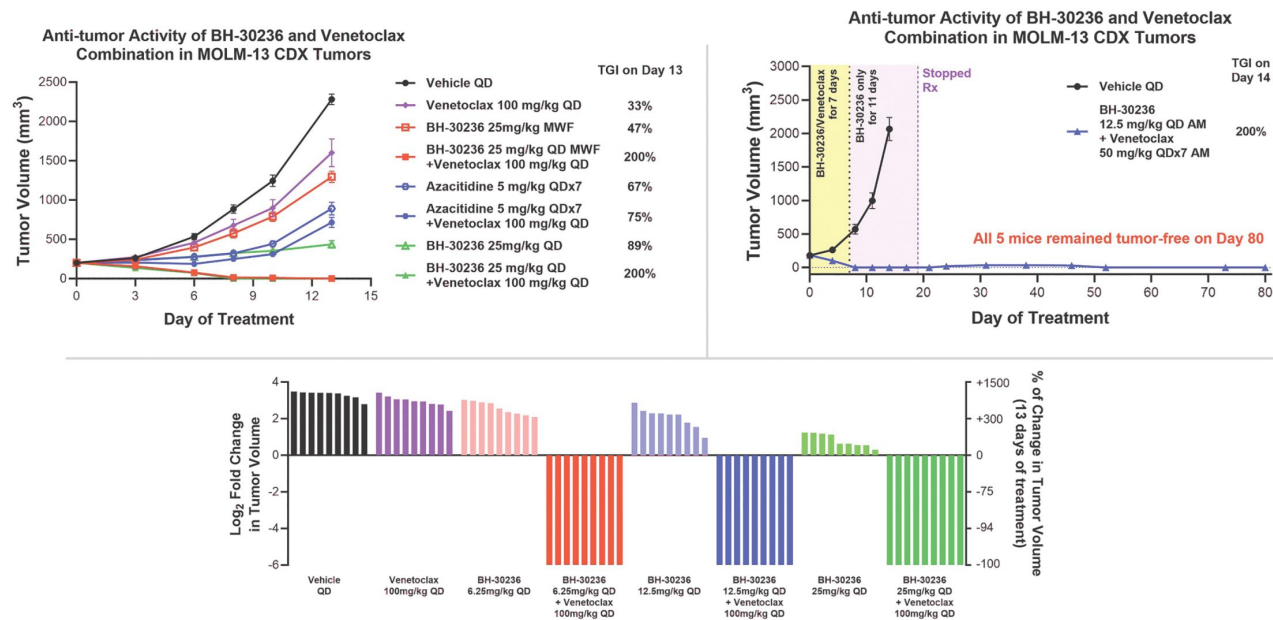


Figure 36. BH-30236 + venetoclax in MOLM-13 (FLT3-ITD, venetoclax-resistant) CDX model. Combination achieves 200% tumor growth inhibition (TGI) vs. 33% venetoclax alone; complete regression with no regrowth post-cessation.

Given BH-30236 has FLT3 inhibitory activity in addition to CLK inhibition, we investigated the mechanism of anti-leukemic effect in a FLT3-driven model. In mouse xenograft studies of FLT3-ITD mutant AML, we observed that BH-30236 administered as a single agent achieved complete and durable tumor regression (Figure 37), with no tumor regrowth observed for at least 30 days following cessation of dosing. The durability of effect exceeded that of a FLT3 inhibitor alone and mirrored the effect of a different CLK inhibitor, but with less toxicity. Evidence of reduced CD123 RNA expression on therapy suggests durability seen may reflect NMD-mediated elimination of FLT3 transcript, which may produce more sustained suppression of FLT3 signaling

than reversible kinase inhibition—consistent with the absence of tumor regrowth upon treatment discontinuation in a model where approved FLT3 inhibitors demonstrate rapid regrowth upon cessation.

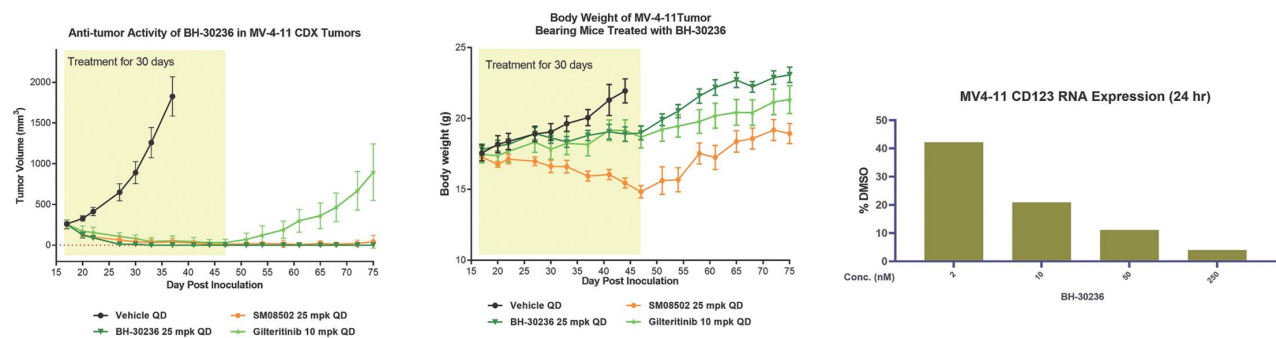


Figure 37. BH-30236 single-agent activity in MV-4-11 (FLT3-ITD) xenograft model. 25 mg/kg QD; complete regression with no regrowth 30 days post-cessation.

Clinical development

Trial design and enrollment status

We are evaluating BH-30236 in a Phase 1/1b, multicenter, open-label, first-in-human dose escalation and expansion trial in adults with R/R AML or HR-MDS. The trial employs a Bayesian Optimal Interval (BOIN) design for dose escalation and is structured in multiple parts, including monotherapy and combination dose escalation, followed by expansion cohorts to establish the RP2D.

We are now enrolling the monotherapy dose escalation/backfill portion of the trial evaluating the safety, tolerability, pharmacokinetics and pharmacodynamics of BH-30236 as a single agent in up to 50 participants, with the primary objectives of characterizing the dose-limiting toxicities and identifying the maximum tolerated dose and RDE. As of the April 10, 2026 safety data cut, 30 participants had been enrolled in the Phase 1 monotherapy dose escalation (AML n=23; HR-MDS n=7) across dose levels from 5 mg to 120 mg once daily. Monotherapy participants had a median age of 70 years (range 23 to 85), a median of 2 prior lines of therapy, and a median treatment duration of 1.1 months (range 0.3 to 10.1 months). Of the patients enrolled, 26 of 30 (87%) had received prior venetoclax-based therapy.

Concurrently, we are evaluating BH-30236 in combination with venetoclax at a target dose of 400 mg once daily in the combination dose escalation portion of the trial in up to 48 participants, with the primary objective of identifying the recommended Phase 2 dose for the combination. As of the cutoff date, 18 participants had been enrolled in Phase 1, Part 2 combination dose escalation (AML n=14; HR-MDS n=4) at BH-30236 dose levels of 20 mg, 30 mg, 60 mg and 90 mg once daily in combination with venetoclax. Combination arm participants had a median age of 73 years (range 27 to 85), a median of 2 prior lines of therapy, and a median treatment duration of 1.1 months (range 0.5 to 3.6 months). Of the patients enrolled, 16 of 18 (89%) had received prior venetoclax-based therapy.

Additional dose escalation investigations are planned to include monotherapy in other hematologic malignancies (e.g. MPNs) as well as triplet combination with azacitidine and venetoclax. Future Phase 1b expansion cohorts are then planned to enroll participants in monotherapy and combination cohorts (including in newly diagnosed unfit AML) to further evaluate safety and antileukemic activity and to generate preliminary efficacy data to support Phase 2 design.

Pharmacokinetics

Pharmacokinetic exposure of BH-30236 monotherapy increased with dose (Figure 38), with no accumulation observed with continuous once-daily dosing. In the combination dose escalation, no apparent pharmacokinetic drug interaction was observed between BH-30236 and venetoclax.

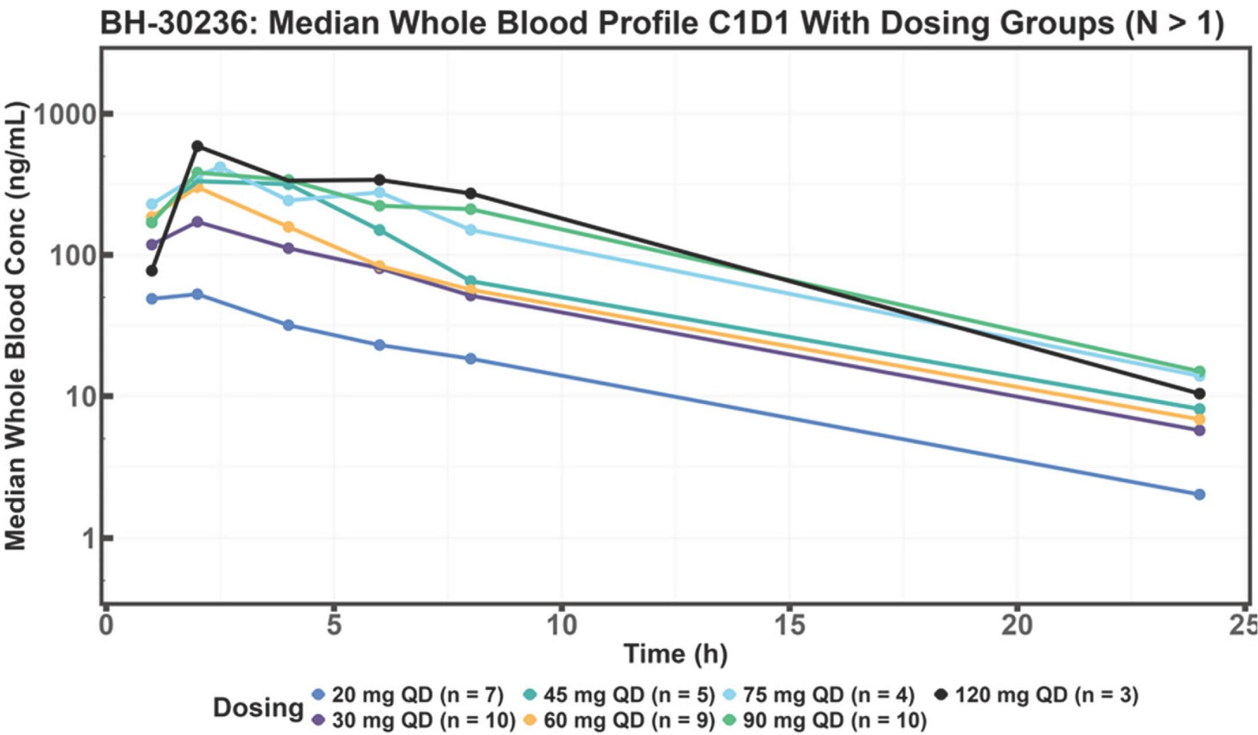


Figure 38. BH-30236 median single dose whole blood exposure profile at C1D1, including patients dosed in both monotherapy and combination therapy cohorts. Median whole blood concentrations increased with increasing dose.

Safety and tolerability

As of the April 10, 2026 data cut, BH-30236 has been generally well tolerated as a continuous once-daily dose, with manageable gastrointestinal toxicities as the most frequent TRAEs. Across all patients dosed (monotherapy or combination), three had events consistent with differentiation syndrome. All events were Grade 2 and resolved with corticosteroid treatment with and without dose interruption. Dose reductions due to TRAEs occurred in two (2) out of 48 (4.2%) patients with discontinuations due to TRAEs in one (1) of 48 (2.1%) patients.

As a monotherapy, BH-30236 has been generally well-tolerated at continuous once-daily doses through 90 mg. As of the data cut, one DLT of Grade 3 diarrhea was observed at 120 mg once daily. TRAEs were reported in 18 of 30 monotherapy participants (60.0%), half of which were Grade 2 or lower. The most frequently reported TRAEs (occurring in 10% or more of participants) were diarrhea, nausea and vomiting; the only Grade 3 or higher TRAE occurring in 10% or more of participants was diarrhea (Figure 39). Two cases of possible differentiation syndrome were observed; both were managed with corticosteroids without dose interruption. No clinically significant cardiac effects or QTc prolongation has been observed.

In the venetoclax combination arm, TRAEs were reported in 10 of 18 participants (55.6%). Combination tolerability was similar to monotherapy with more frequent cytopenias consistent with a venetoclax-based regimen. The most frequently reported TRAEs (occurring in 10% or more of combination participants) were diarrhea, nausea, vomiting, decreased neutrophil count, decreased platelet count and decreased white blood cell count (Figure 39). No DLTs were observed with BH-30236 in combination with venetoclax.

Safety Analysis Set (N=48)	Monotherapy (N=30)		Venetoclax Combination (N=18)	
	All Grades	Grade ≥3	All Grades	Grade ≥3
Any BH-30236 Related AEs	18 (60.0)	9 (30.0)	10 (55.6)	9 (50.0)
Dose Limiting Toxicities (DLTs)	1 Grade 3 diarrhea		0	
Gastrointestinal				
Diarrhea	10 (33.3)	5 (16.7)	5 (27.8)	2 (11.1)
Nausea	9 (30.0)	0	6 (33.3)	0
Vomiting	4 (13.3)	0	4 (22.2)	0
Hematologic				
Neutrophil count decreased	2 (6.7)	1 (3.3)	5 (27.8)	5 (27.8)
Platelet count decreased	2 (6.7)	2 (6.7)	5 (27.8)	4 (22.2)
Anemia	2 (6.7)	2 (6.7)	4 (22.2)	4 (22.2)

Figure 39. Treatment-related adverse events observed in patients receiving BH-30236 as monotherapy or in combination with venetoclax as of the April 10, 2026 data cut.

Treatment-emergent serious adverse events (SAEs) reported for BH-30236 were generally consistent with the high morbidity of AML and HR-MDS profiles: 36 of 48 treated participants (75.0%) experienced at least one SAE, including 23 of 30 (76.7%) with BH-30236 monotherapy and 13 of 18 (72.2%) with BH-30236 plus venetoclax. Overall, SAEs assessed as at least possibly related to BH-30236 were reported in nine of 48 participants (18.8%), comprising five of 30 (16.7%) in monotherapy and four of 18 (22.2%) in combination therapy. These related SAEs were infrequent and generally consistent with the emerging safety results described in Figure 39, including diarrhea, cytopenia-associated complications such as febrile neutropenia or infection, and differentiation syndrome and related manifestations. In monotherapy, one AML participant had SAEs of Grade 3 hypotension and Grade 3 sinus tachycardia assessed by the investigator as possibly related, although we assessed these SAEs as unlikely related in the context of extensive medical history, significant comorbidities and concomitant infections. In the combination therapy arm, one AML participant experienced SAE of Grade 3 fatigue assessed as possibly related to both BH-30236 and venetoclax in the setting of a concurrent SAE of Grade 2 bacteremia assessed as unlikely related to BH-30236 and related to venetoclax.

Preliminary clinical activity

A preliminary assessment of anti-leukemic activity was performed as of the May 20, 2026 data cut. In the Phase 1 monotherapy dose escalation, marrow blast count reductions of 50% or greater were observed in six (6) of 21 participants (28.6%) with post-baseline bone marrow assessment (Figure 40), including one participant with HR-MDS treated at 60 mg once daily who achieved a sustained blast count reduction with treatment ongoing for more than a year (Cycle 13+). In total, two (2) of six (6) patients with pretreated HR-MDS treated with BH-30236 monotherapy experienced complete response (33%): one patient achieved a CR after the first cycle of treatment,

and a second patient achieved a measurable residual disease (MRD) negative complete remission with limited count recovery (CRL) and discontinued treatment to undergo allogeneic stem cell transplant (HSCT).

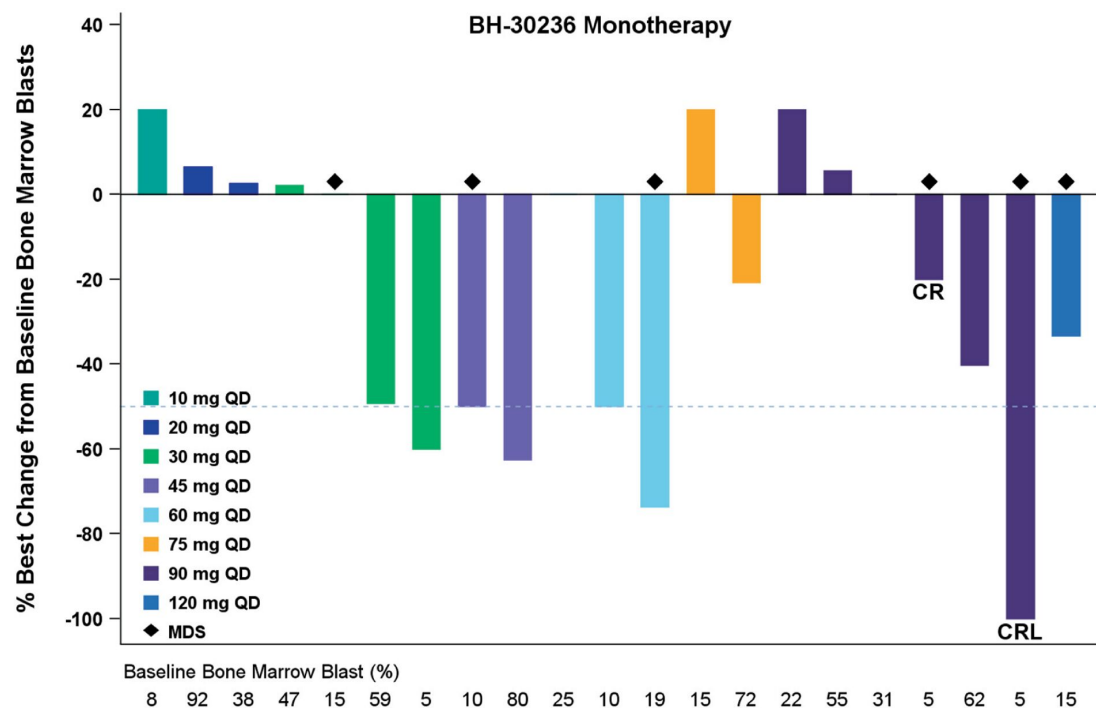


Figure 40. BH-30236 monotherapy anti-leukemic activity for evaluable participants at all dose levels. CR: complete remission; CRL: complete remission with limited hematologic recovery.

Dose	Demographics / Disease	Baseline Mutations	Prior Therapy	Key Blood and Marrow Parameters (pre → post)	Objective Response
60 mg QD	81 y/o M Relapsed HR-MDS	ASXL1 DDX41 ETV6, SETBP1 SRSF2 PAX5	1. Azacitidine + SL-172154/ Azacitidine → CR	BM blasts: 19% → 5% ANC: 0.30 → 1.35 PLTs: 25 → 28	NR as overall response; Continuing on treatment in Cycle 13+
90 mg QD	66 y/o M Relapsed HR-MDS	ASXL1 NF1 SETBP1 SRSF2	1. Azacitidine + venetoclax → CR 2. Allogeneic hematopoietic stem cell transplant → CR	BM blasts: 5% → 0% ANC: 0.16 → 1.31 PLTs: 20 → 24	CR_L (MRD –) D/C for allogeneic HSCT
90 mg QD	67 y/o F Refractory HR-MDS	TP53	1. Azacitidine + venetoclax → PR	BM blasts: 5% → 4% ANC: 0.85 → 4.42 PLTs: 194 → 113	CR after 1 cycle of treatment

Figure 41. Case examples of individual patient outcomes for three patients treated with BH-30236 monotherapy. NR: non-response; CR: complete response; CRL: complete remission with limited hematologic recovery; MRD: minimal residual disease; HSCT: hematopoietic stem cell transplantation.

In the Phase 1, Part 2 combination dose escalation, among 15 evaluable participants with post-baseline bone marrow assessments, marrow blast count reductions of 50% or greater were observed in 8 of 15 evaluable participants (53.3%) and overall response rate in 11 patients with R/R AML was 36% (4/11) (Figure 42). One

participant with AML whose disease was refractory to all prior therapy, including venetoclax, achieved a measurable residual disease (MRD)-negative complete remission (CR) and subsequently proceeded to HSCT. A second participant with disease refractory to venetoclax therapy also achieved a sustained CR and is continuing therapy awaiting HSCT (Figure 43). A third patient with HR-MDS with disease progression after HMA therapy achieved a CRL and is continuing on treatment. While these results are subject to change as additional participants are enrolled and follow-up matures, we believe these early findings in a heavily venetoclax-pretreated population are consistent with the preclinical mechanistic evidence and provide initial clinical support for BH-30236-mediated venetoclax sensitization.

Venetoclax Combo: Anti-leukemic Activity Observed in Ven Pre-treated Patients Across Dose Levels

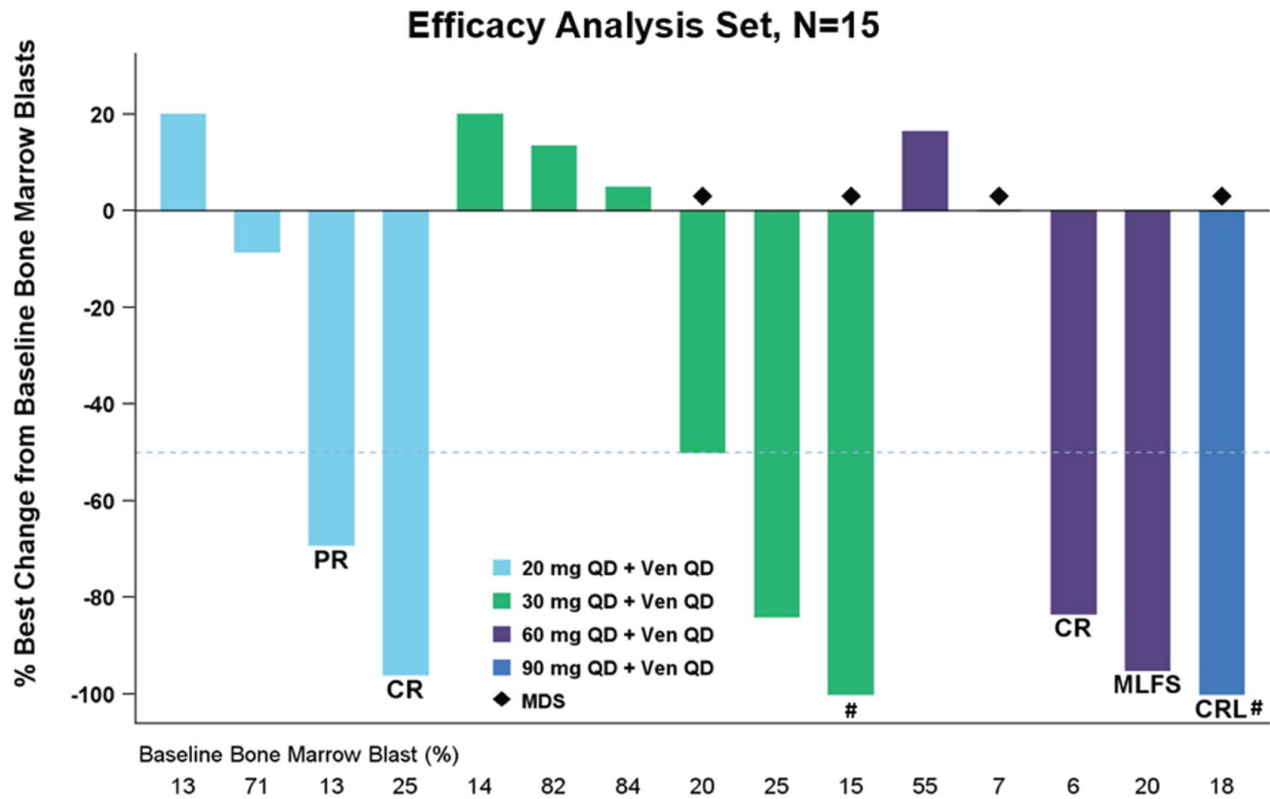


Figure 42. BH-30236 plus venetoclax combination anti-leukemic activity in patients with prior venetoclax exposure. PR: partial response; CR: complete remission; CRL: complete remission with limited hematologic recovery; MLFS: morphologic leukemia-free state; #: venetoclax naive.

Dose	Demographics / Disease	Baseline Mutations	Prior Therapy	Key Blood and Marrow Parameters (pre → post)	Objective Response
20 mg QD	60 y/o M AML 2° to HR-MDS	DDX41 SETD2	1. Azacitidine for MDS 2. 7+3 chemo → NR 3. High dose cytarabine → NR 4. FLAG-idarubicin + venetoclax → NR	BM blasts: 25% → 1% ANC: 0.86 → 5.86 PLTs: 59 → 158	CR (MRD-) D/C for allogeneic HSCT
60 mg QD	78 y/o M R/R AML	DNMT3A RAD21 RUNX1 SF3B1 TET2	1. Decitabine + venetoclax → CR 2. Cladribine + low dose cytarabine + venetoclax → PR	BM blasts: 6% → 1% ANC: 1.26 → 2.35 PLTs: 227 → 158	CR Treatment ongoing; Awaiting allogeneic HSCT; Loss of RUNX1 & SF3B1 mutations in bone marrow
90 mg QD	79 y/o M Venetoclax-naïve relapsed HR-MDS	ETV6, EZH2	1. Inqovi → NR	BM blasts: 18% → 2% ANC: 1.00 → 1.50 PLTs: 18 → 53	CR_L (MRD -) Treatment ongoing

All data as of 10 April 2026 data cut, with efficacy follow-up through 20 May 2026 data cut.

Figure 43. Individual patient outcomes for three patients treated with BH-30236 plus venetoclax combination. NR: non-response; CR: complete remission; CRL: complete remission with limited hematologic recovery; MRD: minimal residual disease; HSCT: hematopoietic stem cell transplantation.

Development plan

Our development strategy for BH-30236 is organized around investigating monotherapy in HR-MDS and potential venetoclax synergy in AML and HR-MDS as well as initiating investigation in additional hematologic malignancies.

- **Development path for R/R AML and HR-MDS.** Our near-term priority is to complete monotherapy and combination dose escalation, select the dose levels for expansion, and advance BH-30236 monotherapy and combination with venetoclax into Phase 1b dose expansion cohorts. We anticipate that ORR and biomarker data from the Phase 1b expansion would support discussions with the FDA regarding further development paths in R/R AML and HR-MDS, including the RP2D, trial design and primary endpoints.
- **Hematologic malignancies beyond AML and HR-MDS.** We believe the preclinical data demonstrate the potential for BH-30236 activity across a range of hematologic malignancy and solid tumor models. We plan to submit a protocol amendment, pursuant to which we plan to evaluate BH-30236 in additional myeloid malignancies such as myeloproliferative neoplasms (MPN). Pending proof-of-concept, we would plan to further develop BH-30236 in hematologic malignancies and/or solid tumor cohorts based on emerging clinical and translational data.

BH-501284: pan-KRAS inhibitor

BH-501284 is an investigational, orally bioavailable pan-KRAS inhibitor, which utilizes a novel Switch-II chemical scaffold in an effort to achieve prolonged, potent and selective inhibition of KRAS mutations, sparing HRAS and NRAS. We believe this molecule, which uses a non-covalent scaffold, is unique in achieving tight and durable binding, a feature described as “pseudo-irreversible” binding. In preclinical studies, BH-501284 has demonstrated high potency across KRAS-mutant cell lines, prolonged target binding exceeding 54 hours, and consistent deep responses in mouse tumor CDX models at low and clinically relevant doses. We are currently conducting IND-enabling studies of BH-501284 and plan to submit an IND in the first quarter of 2027.

Background and unmet need

KRAS mutations are the most frequent oncogenic driver alterations in human cancer, present in approximately 25% of all malignancies—with particularly high prevalence in pancreatic ductal adenocarcinoma (PDAC) (approximately 90%), CRC (approximately 40%), and NSCLC (approximately 30%)—and the most common alterations occur at codon 12, including G12C, G12D, G12V, G12S and G12A. Though we believe the approval of covalent KRAS G12C inhibitors validated the allosteric Switch-II pocket as a tractable site for small molecule intervention, these agents address only a single mutant allele and leave patients harboring G12D, G12V, G12S, G12A and other KRAS alterations without an approved targeted therapy. While tricomplex pan-RAS inhibitors have recently demonstrated meaningful clinical activity, the parallel inhibition of HRAS and NRAS in addition to KRAS can result in a narrow therapeutic window limiting efficacy. While there is hope that non-covalent Switch-II pocket inhibitors could offer a better therapeutic window, the inhibitors under investigation, evolving as a class from MRTX1133 (a molecule no longer in development), have generally required a higher molecular weight to achieve potency leading to suboptimal oral bioavailability (Figure 44). The recent progress in KRAS inhibitor development is fundamentally motivating, but there remains a significant need for a fresh approach—a new chemical scaffold which can allow potent and durable pan-KRAS inhibition in an oral targeted therapy with a favorable therapeutic window.

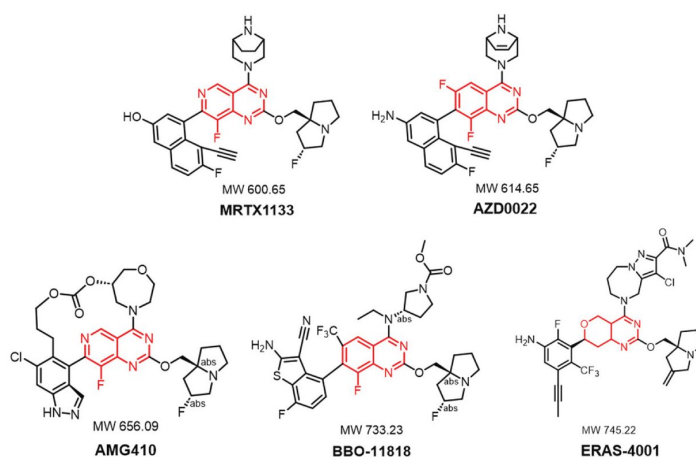


Figure 44. Representative examples of KRAS inhibitors that share structural similarities with the MRTX1133 scaffold.

Many non-covalent KRAS inhibitors in the clinic have iterated on the MRTX1133 chemical scaffold, potentially inheriting ADME/PK and/or potency liabilities.

Our solution: BH-501284

BH-501284 is designed as a pseudo-irreversible, HRAS and NRAS sparing, orally bioavailable pan-KRAS inhibitor targeting the allosteric Switch-II pocket using a novel chemical scaffold which has demonstrated favorable cell potency against KRAS G12V/D/C and other KRAS mutations and good preclinical oral bioavailability and tolerability in multiple species.

Design rationale

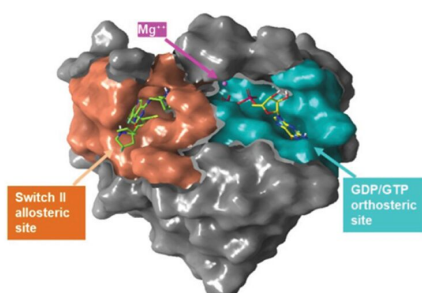
BH-501284 was designed as a non-covalent inhibitor to have the prolonged blocking of KRAS signaling, equivalent to covalent inhibitors, bolstered by prolonged residence time and high binding affinity for mutant

KRAS proteins. The novel chemical scaffold was designed to target Switch-II and induce KRAS conformational change. As with our other programs, this molecule was designed after a detailed review of contemporary KRAS inhibitors, and represents years of iterative, creative chemical evolution to achieve differentiated properties. A key feature of the new chemical scaffold is the strong IP position of this molecule, made possible through its differentiated design.

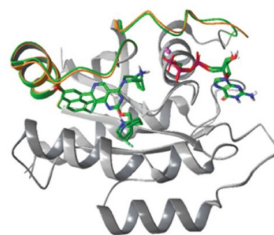
Pan-KRAS Switch-II inhibition with pseudo-irreversible binding

The allosteric pocket near the Switch-II loop, known as the Switch-II pocket, is an inducible pocket that was first discovered by developers of covalent KRAS G12C inhibitors. The allosteric Switch-II pocket exists in both KRAS GTP (on) or GDP (off) states. The allosteric Switch-II inhibitors induce GTP-bound KRAS and GDP-bound KRAS into a similar conformation that is more rigid and no longer flexible enough for interaction with different effectors, leading to blocking downstream signaling (Figure 45).

The induced Switch II allosteric pocket is available in both GTP-bound (on) and GDP-bound (off) KRAS



A Switch-II inhibitor can achieve dual state binding ("On" / "Off") through an induced and rigidified KRAS conformation that disables effector interaction



Overlap of MRTX1133 bound KRAS G12D in GDP "off" state (PDB:7RPZ) with GTP "on" state (PDB:7T47)

Figure 45. Molecular surface model of KRAS protein Switch II pocket and GDP/GTP allosteric site (left) and molecular ribbon model of MRTX1133 within the KRAS G12D Switch-II binding pocket in the "On" and "Off" state (right).

Our approach was to design a novel Switch-II inhibitor scaffold strongly inducing KRAS conformational change that leads to high binding affinity and a long residence time, a binding mode we refer to as pseudo-irreversible, to effectively block KRAS interactions with effectors, resulting in our product candidate BH-501284. Modeling of BH-501284 demonstrated deep binding in the Switch-II pocket enabling the prolonged pseudo-irreversible binding (Figure 46).

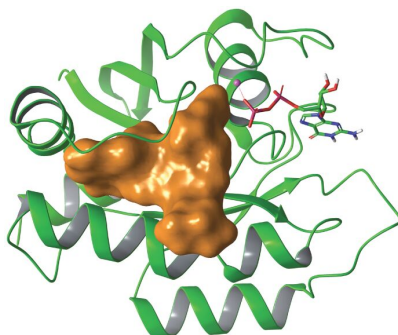


Figure 46. Molecular surface of BH-501284 modeled within the KRAS G12D Switch-II binding pocket.

Preclinical studies and data

Pan-KRAS cellular potency

In enzymatic assays, BH-501284 potently inhibited SOS1-mediated KRAS nucleotide exchange across a broad panel of codon 12 alleles, with sub-nanomolar IC₅₀ values, and demonstrated substantially reduced activity against HRAS and NRAS. In cellular anti-ERK phosphorylation assays and 2D cell viability assays across a panel of KRAS-mutant cancer cell lines (Figure 47 and 48), BH-501284 demonstrated low nanomolar potency against the most clinically prevalent KRAS mutations, including G12V, G12C, G12D and amplified KRAS, with high selectivity for KRAS over HRAS- and NRAS mutant cell lines. Median IC₅₀ in cell viability assays was 0.73 nM for G12V, 2.8 nM for G12D and 0.62 nM for G12C.

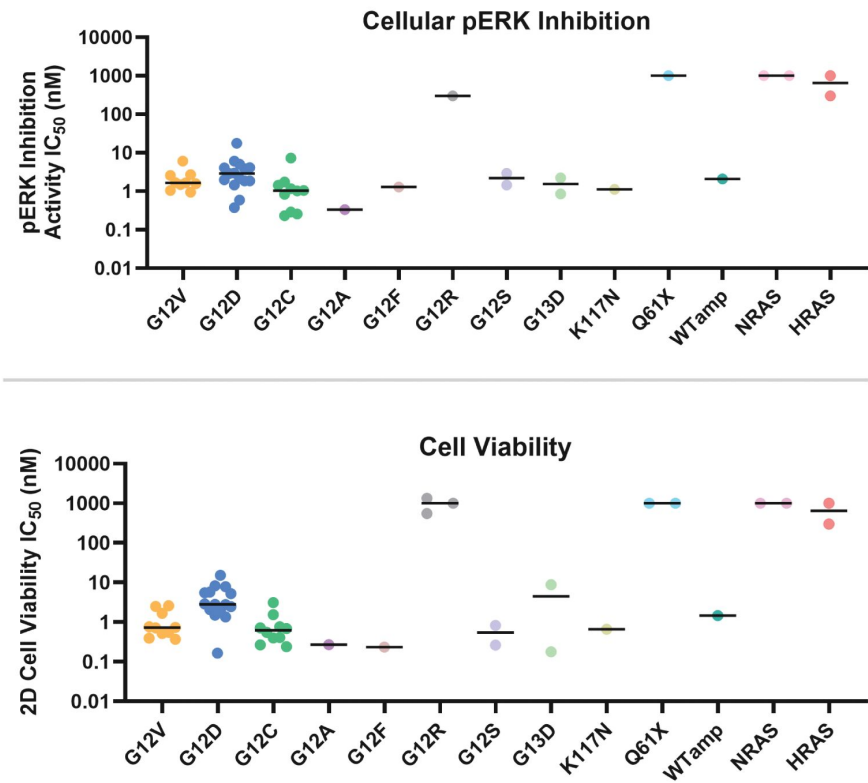


Figure 47. BH-501284 cellular potency across KRAS-mutant cancer cell lines. Note: Any IC₅₀ value >300 nM, or >1000 nM was plotted as 300 nM, or 1000 nM, respectively.

Median cell viability IC ₅₀ 0.81 nM in 41 KRAS G12/G13 mutant cells excluding KRAS G12R		
RAS Mutation	Median IC ₅₀ (nM)	
	pERK (N)	Cell Viability (N)
KRAS G12V	1.66 (9)	0.73 (10)
KRAS G12D	2.91 (15)	2.80 (15)
KRAS G12C	1.03 (10)	0.62 (10)
KRAS G12A	0.33 (1)	0.27 (1)
KRAS G12F	1.30 (1)	0.23 (1)
KRAS G12R	>300 (1)	>1000 (3)
KRAS G12S	2.20 (2)	0.55 (2)
KRAS G13D	1.54 (2)	4.49 (2)
KRAS K117N	1.12 (1)	0.66 (1)
KRAS Q61X	>1000 (1)	>1000 (2)
KRAS WT ^{amp}	2.09 (1)	1.48 (1)
NRAS ^{Mut}	>1000 (2)	>1000 (2)
HRAS ^{Mut}	>650 (2)	> 650 (2)

N: Number of KRAS mutant cell lines evaluated

Figure 48. Median cell viability IC₅₀ 0.81 nM in 41 KRAS G12/G13 mutant cells excluding KRAS G12R.

In comparative cell proliferation studies, BH-501284 demonstrated cellular potency comparable to the pan-RAS tricomplex inhibitor daraxonrasib and greater cellular potency than the non-covalent pan-KRAS Switch-II inhibitor AMG410 (Figure 49). Whereas daraxonrasib inhibited proliferation of both KRAS-mutant and KRAS-wild-type cells as well as in HRAS and NRAS wild-type cells, BH-501284 inhibited only KRAS-mutant or KRAS-amplified cells and exhibited substantially reduced activity against HRAS- and NRAS-wild-type cells and in the normal colon epithelial cell line CCD841CoN. We believe this profile reflects BH- 501284’s selectivity for mutant and amplified KRAS, distinguishing its mechanism from that of pan-RAS tricomplex inhibitors that engage all wild-type RAS isoforms.

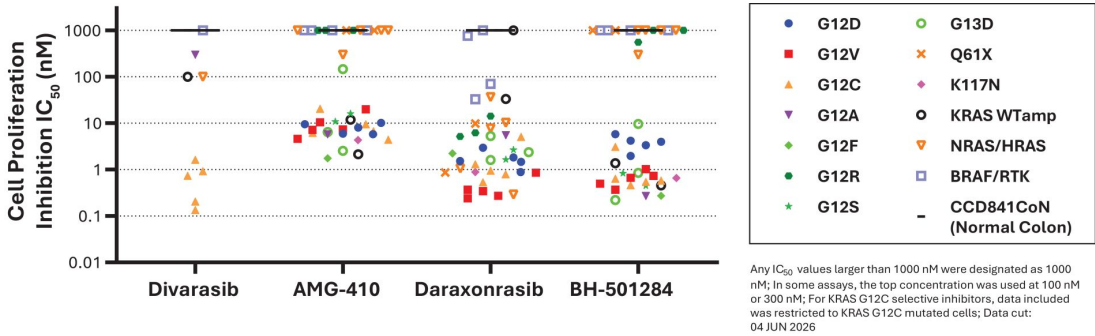


Figure 49. Cellular potency of BH-501284 vs. selected KRAS and pan-RAS inhibitors. Cell proliferation IC₅₀ (nM) across KRAS-mutant, KRAS-wild-type and normal colon (CCD841CoN) cell lines. Any IC₅₀ value greater than 300 nM or 1,000 nM was plotted as 300 nM or 1,000 nM, respectively.

Pseudo-irreversible kinetic profile

In a surface plasmon resonance (SPR) study performed at Reaction Biology, BH-501284 exhibited picomolar binding affinity to KRAS G12D in the GDP-bound state (K_D <0.015 nM) and a target residence time exceeding

54 hours in the GDP (Off) state and approximately 37.5 hours in the GTP (On) state, compared to approximately 1.4 hours and 1.2 hours, respectively, for the clinical non-covalent Switch-II inhibitor AMG410 in the same assays (Figure 50) – supporting the pseudo-irreversible binding profile of BH-501284.

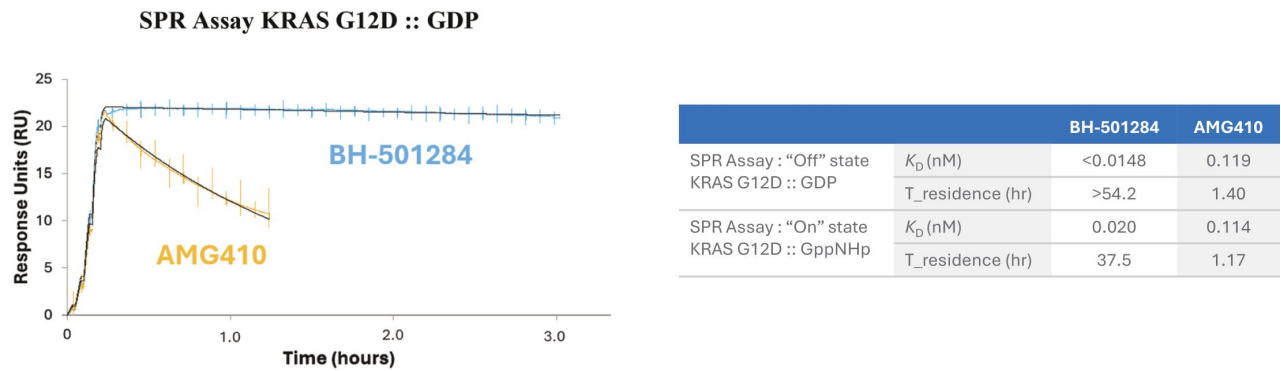


Figure 50. In an SPR study, BH-501284 showed pseudo-irreversible binding characteristics with long residence time.

In a separate study evaluating the kinetics of RAS pathway modulation in the KRAS G12D-mutant GP2D cell line, BH-501284 and daraxonrasib both reduced RAS-GTP levels rapidly. BH-501284 achieved a greater maximal reduction in RAS-GTP than daraxonrasib, consistent with more complete elimination of GTP-bound RAS, which we believe may result in deeper inhibition of KRAS signaling and a more durable response (Figure 51).

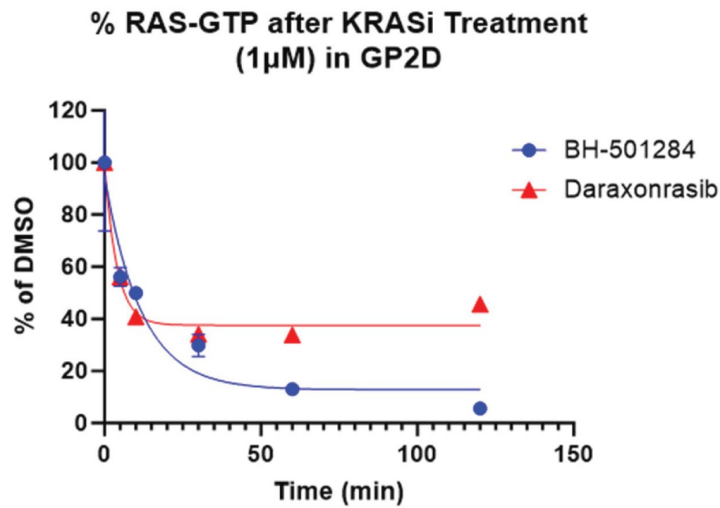


Figure 51. Kinetics of RAS-GTP reduction following KRAS inhibitor treatment in the GP2D (KRAS G12D) cell line. RAS-GTP levels (% of DMSO control) over time for BH-501284 and daraxonrasib at 1 µm.

Pseudo-irreversible pharmacological effect

To evaluate the impact of the pseudo-irreversible properties on the pharmacological effect, BH-501284 was studied in a cellular washout experiment in H358 cells with KRAS G12C mutation with the covalent, irreversible KRAS G12C inhibitor, divarasib, and non-covalent, reversible pan-KRAS inhibitor AMG410 as controls (Figure 52).

BH-501284 sustained the inhibition of phosphorylation of ERK kinase comparably to the covalent, irreversible KRAS G12C inhibitor, divarasib over 24 hours after washing out the compounds in cells, while AMG410 lost inhibition quickly.

The sustained pharmacological activity of pseudo-irreversible binding enabled BH-501284 to achieve 149% tumor growth inhibition (49% tumor regression) at 5 mg/kg twice a day (BID) dosing schedule, which was comparable with the covalent inhibitor divarasib, while the reversible AMG410 only showed 59% tumor growth inhibition at 100 mg/kg BID in the same study (Figure 52).

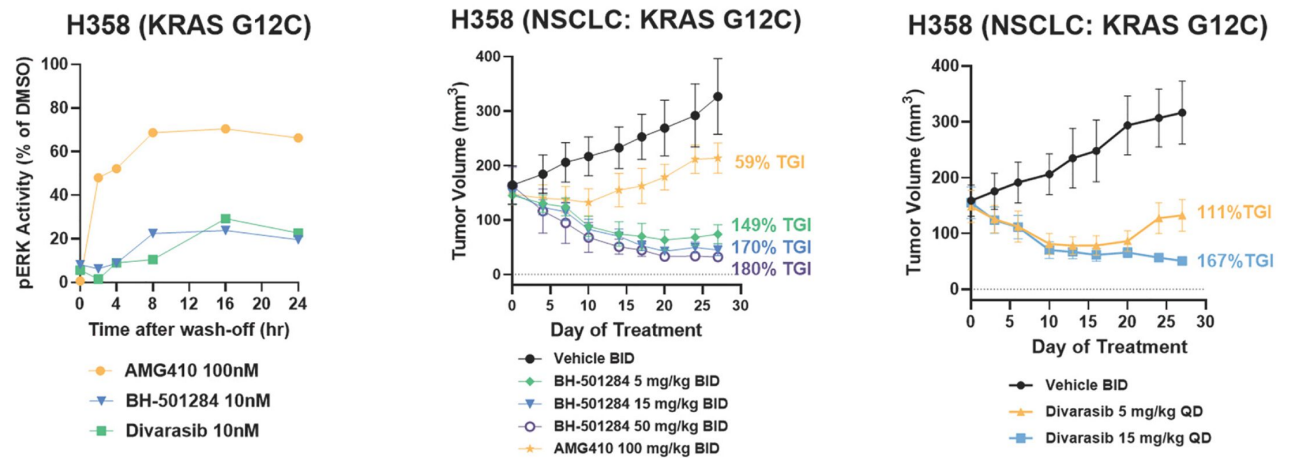


Figure 52. BH-501284 vs. selected covalent and non-covalent inhibitors: Cellular washout and tumor growth inhibition in H358 cells and in tumor mouse model.

Antitumor activity in KRAS-mutant mouse tumor models

In multiple KRAS-mutant cell-derived and one patient-derived (LU2529) xenograft mouse tumor models spanning NSCLC, leiomyosarcoma and pancreatic cancer histologies—and across G12V, G12C and G12D alleles—oral administration of BH-501284 achieved dose-dependent increase of exposure at steady state, tumor growth inhibition and tumor regression at low and clinically relevant dose levels (Figure 53).

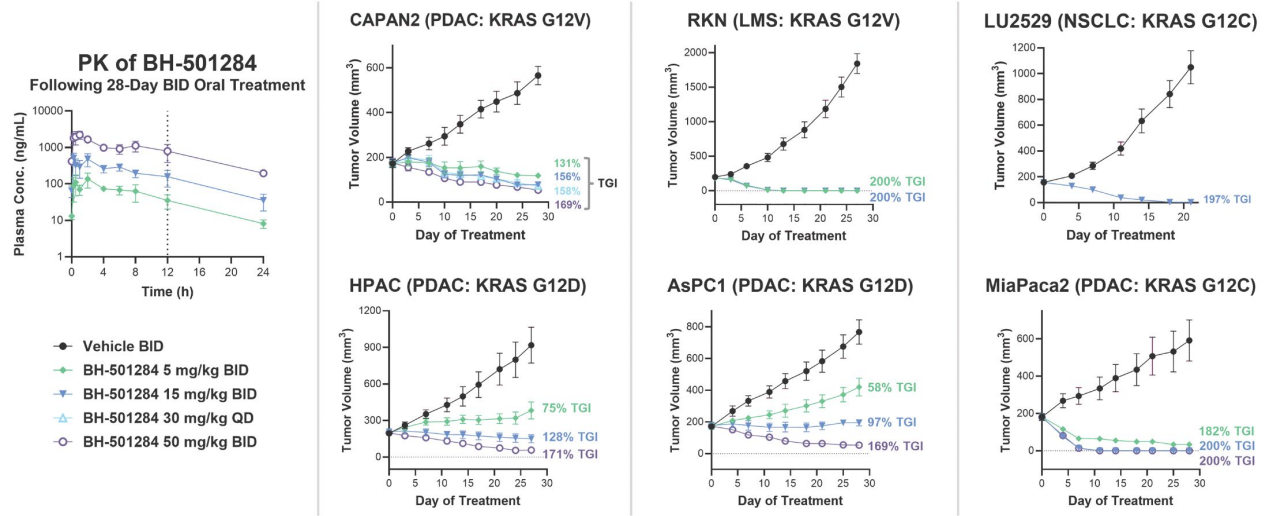


Figure 53. Steady state mouse oral PK exposures at 5, 15, and 50 mg/kg after 28-day BID dosing and in vivo activity of BH-501284 in five KRAS-mutant CDX and one PDX (LU2529) tumor models spanning NSCLC (G12C), leiomyosarcoma (G12V), and pancreatic cancer (G12V, G12D, G12C) at 5, 15, and 50 mg/kg BID or 30 mg/kg QD oral dosing. TGI = tumor growth inhibition.

In a CDX tumor model derived from the KRAS G12D-mutant PANC04.03 cell line (Figure 54), oral administration of BH-501284 at 30 mg/kg once daily induced deeper and more durable tumor regression than daraxonrasib (25 mg/kg once daily) or zoldonrasib (30 mg/kg once daily). After stopping treatment, the tumors gradually grew back for daraxonrasib and zoldonrasib groups while tumors remained minimal in the BH-501284 group. Body

weight remained stable across all treatment arms over the course of dosing, consistent with the tolerability observed for BH-501284 in other preclinical models.

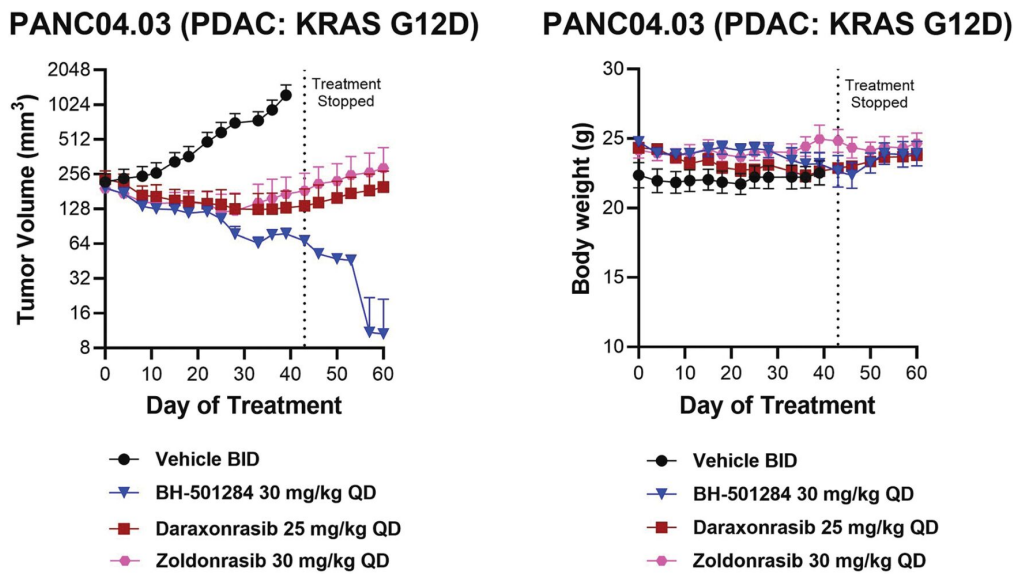


Figure 54. In vivo activity of BH-501284 in the PANC04.03 (KRAS G12D) PDAC CDX tumor model. Left: tumor volume over time for vehicle, BH-501284 (30 mg/kg QD), daraxonrasib (25 mg/kg QD) and zoldonrasib (30 mg/kg QD). Right: body weight over time.

Across in vivo efficacy studies, BH-501284 was well-tolerated, with stable body weight maintained in tumor-bearing animals, and demonstrated good oral bioavailability across species, including approximately 30% in mouse, 27% in rat, 13% in dog and 12% in Bama miniature pig.

Development plan

Based on the data from our preclinical studies, we selected BH-501284 to conduct IND-enabling studies. Subsequently, we are planning for clinical evaluation in advanced KRAS-mutant solid tumors, with an initial focus on NSCLC, pancreatic cancer and CRC.

Our discovery programs

We are also advancing multiple discovery-stage efforts focused on validated and emerging new oncology targets. In addition, we believe our drug discovery approach may also have applicability beyond oncology.

Competition

The development and commercialization of oncology therapeutics is highly competitive. Many of the companies developing therapies in our targeted indications have substantial resources, extensive oncology development experience, and greater commercial infrastructure than we do. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize therapies that are safer, more effective, better tolerated, more convenient to administer or less expensive than ours, or if they obtain regulatory approval more rapidly than we are able to.

BH-30643: OMNI-EGFR

The EGFR-mutant NSCLC landscape is particularly competitive, with multiple approved therapies and numerous investigational agents in active clinical development across modalities. Given our focus on small molecule development, we describe below the competitive targeted therapies and programs we are aware of that are relevant to the patient populations we are targeting.

C797S-resistant population.

There are currently no approved targeted therapies for patients with C797S-mediated resistance to osimertinib or other third-generation EGFR TKIs. The most recently approved post-osimertinib regimen—amivantamab (RYBREVANT) in combination with platinum-based chemotherapy—was approved in September 2024. Platinum-based chemotherapy remains the predominant systemic option for C797S-resistant patients.

We are aware of numerous companies targeting C797S-mediated resistance to EGFR TKIs or broader EGFR resistance mutations in early clinical development, such as Abbisko Therapeutics, Betta Pharma, Black Diamond Therapeutics, Bridge Therapeutics, Chia Tai Tianqing, Dizal Pharmaceuticals Co., Hansoh Pharma, J INTS BIO, Qilu, Voronoi and Wayshine Biopharm. Additionally, Blueprint Medicines advanced two programs targeting C797S into clinical development; both programs have been discontinued.

Classical mutation setting.

Osimertinib (TAGRISSO), marketed by AstraZeneca, is the current standard of care in the first-line setting for classical EGFR mutations. Amivantamab (RYBREVANT) in combination with lazertinib (LAZCLUZE), marketed by Johnson & Johnson, is also approved in the first-line classical mutation setting and would represent additional competition in any first-line program we may pursue. We are aware of numerous companies developing EGFR TKIs in the classical mutation setting, such as ArriVent BioPharma, Black Diamond Therapeutics, TYK Medicines and Voronoi.

Uncommon EGFR mutation setting (including atypical and exon 20 insertion).

Afatinib (GILOTRIF), marketed by Boehringer Ingelheim, is the only FDA-approved TKI specifically indicated for a subset of atypical mutations (G719X, L861Q and S768I). Amivantamab (RYBREVANT) in combination with platinum-pemetrexed chemotherapy is approved as a first-line regimen for EGFR exon 20 insertion-positive NSCLC. Mobocertinib (EXKIVITY), the first oral agent approved in this setting, was voluntarily withdrawn from the U.S. market in 2024 following its failure to demonstrate a benefit over chemotherapy. We are aware of numerous companies developing inhibitors against uncommon EGFR mutations (including atypical mutations including exon 20 insertions), such as ArriVent BioPharma, Avistone Pharma, Black Diamond Therapeutics, Cullinan Therapeutics, Dizal Pharmaceuticals Co., ORIC Pharmaceuticals, Taiho Oncology and Voronoi.

BH-30236: CLK inhibitor

The AML and HR-MDS landscapes are competitive, with multiple approved therapies and numerous investigational agents in active clinical development. We describe below the principal competitive agents and programs relevant to the patient populations we are targeting.

CLK inhibitor class.

There are currently no approved CLK inhibitors. We are aware of several companies developing CLK inhibitors, including Biosplice Therapeutics and Chordia Therapeutics.

R/R AML and HR-MDS; venetoclax-resistant setting.

Although multiple therapies are approved for AML and HR-MDS in earlier lines of treatment or in molecularly defined subsets, there are currently no approved targeted therapies specifically indicated for patients whose disease is resistant to or has relapsed following venetoclax-based therapy. In this setting, treatment typically consists of salvage chemotherapy, hypomethylating agents (e.g., azacitidine (VIDAZA), marketed by Bristol Myers Squibb), FLT3 inhibitors for patients with FLT3-mutant disease, IDH inhibitors for patients with IDH1- or IDH2-mutant disease, or supportive care. Allo-HCT may be potentially curative for a subset of patients, but is available only to a minority given the age, fitness, comorbidities, donor availability and disease-control requirements of the affected population.

We are aware of several approved agents that may compete for patients in R/R AML including gilteritinib (XOSPATA), marketed by Astellas Pharma, for FLT3-mutant AML; ivosidenib (TIBSOVO), marketed by Servier, for IDH1-mutant AML; enasidenib (IDHIFA), marketed by Bristol Myers Squibb, for IDH2-mutant AML; and menin inhibitors in molecularly defined subsets, including ziftomenib (KOMZIFTI), marketed by Kura Oncology, for NPM1-mutant AML, and revumenib (REVUFORJ), marketed by Syndax Pharmaceuticals, for NPM1-mutant AML and acute leukemia with a KMT2A translocation. In HR-MDS, approved therapies include hypomethylating agents and other agents used in selected settings, but there remains no approved targeted therapy specifically indicated for the broader population following hypomethylating agent failure or venetoclax-based treatment failure.

Combination setting and broader competition.

A key component of our development strategy for BH-30236 is combination therapy with venetoclax. As a result, we expect competition not only from monotherapy approaches in R/R AML and HR-MDS, but also from investigational combination regimens intended to improve upon or restore sensitivity to venetoclax-based treatment, including BCL-2 pathway-directed regimens, FLT3-directed therapies, menin inhibitors, TP53-associated approaches and other targeted therapies intended to address leukemic survival and resistance mechanisms. Although these programs may not directly inhibit CLK, they may compete for the same patients, clinical trial sites, investigators and future treatment settings.

BH-501284: pan-KRAS

The KRAS inhibition landscape is competitive, with multiple approved therapies and numerous investigational agents in active clinical development. We describe below the principal competitive agents and programs relevant to the patient populations we are targeting, including agents targeting a subset of mutations.

KRAS G12C / G12D inhibitors.

There are two approved KRAS G12C inhibitors – sotorasib (LUMAKRAS), marketed by Amgen, and adagrasib (KRAZATI), marketed by Bristol-Myers Squibb. We are aware of numerous companies developing inhibitors targeting a single mutant allele, such as KRAS G12C and KRAS G12D, such as Astellas, D3 Bio, Eli Lilly, Frontier Medicines, Genfleet, Hansoh Pharma Quanta, Revolution Medicines and Roche.

Pan-RAS tricomplex inhibitors.

There are currently no approved pan-RAS inhibitors. We are aware of numerous companies developing pan-RAS tricomplex inhibitors, such as Adlai Nortye, Betta Pharmaceuticals, Erasca, Revolution Medicines and Roche. To our knowledge, Revolution Medicines is the most advanced in development and recently reported positive pivotal Phase 3 results for daraxonrasib in previously treated metastatic pancreatic cancer, which could become the first pan-RAS inhibitor approved in that indication.

Pan-KRAS (non-covalent Switch-II pocket inhibitors and degraders).

We are aware of numerous companies developing pan-KRAS non-covalent Switch-II pocket inhibitors and/or degraders, such as Amgen, Astellas, AstraZeneca, BeOne, Boehringer Ingelheim, BridgeBio Oncology Therapeutics, Erasca, Eli Lilly, PAQ Therapeutics, Pfizer and Roche.

Intellectual property

Our commercial success depends in part on our ability (i) to obtain and maintain patent and other proprietary and intellectual property protection for our technology, inventions and improvements; (ii) to protect and preserve the confidentiality of our trade secrets and know-how; (iii) to defend and enforce our intellectual property rights, including patents we own, patents we may own in the future, and patents for which we may acquire a license in the future; and (iv) to operate without infringing the valid and enforceable patents and other proprietary rights of third parties. We own provisional applications and non-provisional patent applications (including PCT applications) directed to our discovery programs and product candidates, including methods for use. Currently, our intellectual property portfolio is wholly owned by us—we do not hold any in-licenses, we do not have government-funded intellectual property, and we are not party to any joint ownership arrangements. As of June 1, 2026, our wholly owned patent estate contains 29 patent families, including 10 pending U.S. non-provisional patent applications, 13 pending U.S. provisional patent applications, 11 pending PCT applications, 265 pending patent applications in various jurisdictions outside of the United States, one (1) issued composition of matter patent in Taiwan encompassing BH-30236 and having an expected natural expiry date of December 16, 2041, and three (3) total issued patents in China, Japan, and Taiwan that do not encompass a product candidate and having an expected natural expiry date in July 2041, as further described below. The pending patent applications for our lead product candidates, BH-30643, BH-30236 and BH-501284, if granted, are currently expected to expire between 2041 and 2047 for composition of matter claims, absent any patent term adjustment, extension or terminal disclaimers, and assuming payment of all appropriate maintenance, renewal, annuity and other governmental fees, but we cannot guarantee that any such patents will issue as expected or that such expiry estimates will remain accurate.

We strive to protect our proprietary position in our technology, inventions, improvements and product candidates that are important to the development and implementation of our business by, among other methods, filing patent applications in the United States and in jurisdictions outside of the United States. We also rely, in part, on trade secrets and know-how relating to our proprietary technology and product candidates and continuing innovation to develop, strengthen and maintain our proprietary position in the field of precision oncology. Our future plans also include reliance on data exclusivity, market exclusivity, patent term adjustments in the United States, and patent term extensions when and where available.

The patent rights of biotechnology and pharmaceutical companies like ours are generally uncertain and can involve complex legal, scientific and factual issues. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any of our product candidates will be protectable or remain protected by enforceable patents that we own or in-license now or in the future. Our pending and future patent applications may not result in the issuance of any patent in any particular jurisdiction, and the claims of any current or future issued patents may not provide sufficient protection from competitors. Moreover, any patent we may own may be challenged, circumvented or invalidated by third parties. Notwithstanding the scope of the patent protection available to us, a competitor could develop competitive technologies and products that are not covered by our patents, and we may be unable to stop such competitor from commercializing such technologies and products. For a more comprehensive description of risks related to our intellectual property, see *“Risk factors—Risks related to our intellectual property.”*

We have filed patent applications directed generally to compositions of matter, solid forms, pharmaceutical formulations and therapeutic methods of use related to our EGFR, CLK and KRAS programs, as summarized below.

BH-30643

With regard to BH-30643, as of June 1, 2026, we own six (6) pending U.S. patent applications (including three (3) provisional patent applications) and 100 pending foreign non-provisional patent applications in Europe, Asia, South America, North America, Africa, and Australia relating to BH-30643 as a composition of matter, to solid forms of BH-30643, to related EGFR inhibitory compounds, and methods of use of such compounds and solid forms. Any U.S. and foreign patents with claims encompassing BH-30643, its solid forms, or its use that may issue based on these applications and are not found to be invalid or unenforceable during their patent term or are not abandoned for any other reason, are expected to expire as early as December 2041 and as late as January 2047, exclusive of possible patent term adjustments, extensions or terminal disclaimers, and assuming payment of all appropriate maintenance, renewal, annuity and other governmental fees. We intend to timely file the related non-provisional applications claiming priority to any pending provisional patent applications related to BH-30643; however, we cannot predict whether any such application will result in the issuance of patents that provide us with any competitive advantage. We also intend to file new provisional applications related to BH-30643 to capture any future new inventions; however, we cannot predict whether any such application will result in the issuance of patents that provide us with any competitive advantage.

BH-30236

With regard to BH-30236, as of June 1, 2026, we own one (1) granted composition of matter patent in Taiwan, seven (7) pending U.S. patent applications (including four (4) provisional patent applications) and 104 pending foreign non-provisional patent applications in Europe, Asia, South America, North America, Africa, and Australia relating to BH-30236 as a composition of matter, to solid forms of BH-30236, to related CLK inhibitory compounds and methods of use of such compounds and solid forms. Any U.S. and foreign patents with claims encompassing BH-30236, its solid forms, or its use that may issue based on these applications and are not found to be invalid or unenforceable during their patent term or are not abandoned for any other reason, are expected to expire as early as December 2041 and as late as January 2047, exclusive of possible patent term adjustments, extensions or terminal disclaimers, and assuming payment of all appropriate maintenance, renewal, annuity and other governmental fees. We intend to timely file the related non-provisional applications claiming priority to any pending provisional patent applications related to BH-30236; however, we cannot predict whether any such application will result in the issuance of patents that provide us with any competitive advantage. We also intend to file new provisional applications related to BH-30236 to capture any future new inventions; however, we cannot predict whether any such application will result in the issuance of patents that provide us with any competitive advantage.

BH-501284

With regard to BH-501284, as of June 1, 2026, we own six (6) pending U.S. provisional patent applications and nine (9) pending foreign non-provisional patent applications in Asia, South America, and North America relating to BH-501284 as a composition of matter, to solid forms thereof, and to related methods of use of such compounds and solid forms. Any U.S. and foreign patents with claims encompassing our lead and backup KRAS compounds that may issue based on these applications are not found to be invalid or unenforceable during their patent term or are not abandoned for any other reason are expected to expire as early as July 2045 or as late as January 2047, exclusive of possible patent term adjustments, extensions or terminal disclaimers, and assuming payment of all appropriate maintenance, renewal, annuity and other governmental fees. Any provisional patent applications

describing KRAS inhibitory compounds are not eligible to become an issued patent unless and until we file a non-provisional patent application within 12 months of the provisional filing date. We intend to timely file the related non-provisional applications; however, we cannot predict whether any such application will result in the issuance of patents that provide us with any competitive advantage. We also intend to file new provisional applications related to BH-501284 to capture any future new inventions; however, we cannot predict whether any such application will result in the issuance of patents that provide us with any competitive advantage.

Other programs

We also own pending patent applications directed to our other preclinical programs. We intend to continue to file patent applications related to these programs as they advance.

Individual patents have terms of 20 years from the earliest effective filing date of a non-provisional patent application or PCT application to which priority is claimed, subject to the payment of applicable maintenance, renewal, annuity and other governmental fees. In addition, patent term adjustments may be available to compensate for USPTO examination delays, and patent term extensions of up to five years may be available under the Hatch-Waxman Act as compensation for time spent in FDA regulatory review process, subject to applicable statutory and regulatory requirements and a cap of 14 years of patent protection remaining from the date of product approval by the FDA. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of patents that cover an approved drug. When available, we intend to apply for patent term extensions for any approved product candidates, including BH-30643 and BH-30236, if and when approved, and to seek similar extensions in applicable foreign jurisdictions, although there is no guarantee such extensions will be granted or, if granted, will be of the requested length.

In addition to patent protection, we rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary position, including aspects of our synthetic chemistry processes. We seek to protect our proprietary information by entering into non-disclosure, confidentiality, non-competition and invention assignment agreements with our employees, consultants, scientific advisors and contractors, although these agreements may be breached and may not provide adequate protection.

We also pursue trademark protection for our company name, brand and product designations, including our OMNI-EGFR™ platform. As of June 1, 2026, we own two registered trademarks and one allowed trademark application in the United States, including the registered trademarks for our company name and logo, and the allowed trademark application for OMNI-EGFR™ in the United States.

For more information regarding the risks related to our intellectual property, see *“Risk factors—Risks related to our intellectual property.”*

Commercialization

None of our product candidates have been approved for sale. If and when our product candidates receive marketing approval, we intend to commercialize them on our own, or jointly with a partner, in the United States and potentially in other geographies. We plan to continually evaluate the economics of commercializing our product candidates versus other strategic commercialization arrangements.

Manufacturing

We do not own or operate manufacturing facilities for the production of our product candidates and currently have no immediate plans to build our own clinical or commercial scale manufacturing capabilities. We currently engage with third-party manufacturers in other geographies for the manufacture of our product candidates. We rely on and expect to continue to engage third-party manufacturers for the production of both drug substance

and finished drug product. We currently obtain our supplies from these manufacturers on a purchase order basis and do not have long-term supply arrangements in place. Should any of these manufacturers become unavailable to us for any reason, we believe that there are a number of potential replacements. We believe our current manufacturers have the scale, systems, and experience to supply our currently planned clinical trials.

Government regulation

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of human drug products. We, along with any third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory authorities of the countries in which we wish to conduct studies or seek approval of our product candidates. The process of obtaining regulatory approvals and ensuring compliance with applicable federal, state, local and foreign statutes, regulations and requirements both during development and post-approval requires the expenditure of substantial time and financial resources.

U.S. drug development process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations. A new drug must be approved by the FDA through the New Drug Application (NDA) process before it may be legally marketed in the United States. Failure to comply with the applicable U.S. requirements at any time during the product development or approval process, or after approval, may subject an applicant to administrative or judicial sanctions brought by the FDA and the U.S. Department of Justice (DOJ), or other governmental entities. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, including animal studies and formulation studies, certain of which must be completed in accordance with FDA's good laboratory practice (GLP) regulations, and other applicable requirements;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an Institutional Review Board (IRB) or ethics committee before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices (GCPs) requirements to evaluate the safety and efficacy of the proposed drug for its intended use;
- preparation of and submission to the FDA of an NDA;
- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of FDA inspections of the manufacturing facility or facilities at which the drug is produced to assess readiness for commercial manufacturing and conformance to the manufacturing-related elements of the application, to conduct a data integrity audit, and to assess compliance with current Good Manufacturing Practice (cGMP) regulations to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- satisfactory completion of potential inspections of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the NDA.

Preclinical studies and IND application

Once a product candidate is identified for development, it enters the preclinical development stage. The preclinical development stage generally involves laboratory evaluations of chemistry, formulation, and stability, as well as studies to evaluate the product candidate's toxicity, in an effort to support subsequent clinical testing.

Prior to beginning the first clinical trial with a product candidate in the United States, the product's developer, also referred to as the IND sponsor, must submit the results of preclinical testing, together with manufacturing information and analytical data, to the FDA as part of an IND. An IND is a request for allowance from the FDA to administer an investigational drug product to humans, and must become effective before human clinical trials may begin. In addition to including the results of these nonclinical studies, the IND will also include a general investigational plan and a study protocol, detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the trial protocol includes an efficacy evaluation. The IND may also include any available human data or literature to support the use of the product candidate. Additional nonclinical testing may continue even after the IND is submitted.

The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the IND on a full or partial clinical hold. In such case, the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin or begin as proposed. Submission of an IND therefore may or may not result in FDA allowance to begin a clinical trial. Clinical holds also may be imposed by the FDA at any time after initiation of clinical trials due to safety concerns about ongoing or proposed clinical trials or non-compliance with specific FDA requirements, and in such case, the applicable trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted. A clinical hold may affect one or more specific studies or all studies conducted under an active IND.

Human clinical trials in support of an NDA

All clinical trials must be conducted under the supervision of one or more qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include, among other things, the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials must be conducted under protocols detailing, among other things, the objectives of the trial, dosing procedures, research subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and a separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent material amendments to a protocol. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA. Sponsors also must submit written IND safety reports to the FDA and investigators in a timely manner for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Furthermore, an IRB must review and approve the protocol before a clinical trial commences and must also approve the information regarding the trial and the consent form that must be signed by each research subject or the research subject's legal representative, monitor the study until completed, and otherwise comply with IRB regulations. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. In addition, some clinical trials also include oversight by an

independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The product candidate is initially introduced into healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, excretion, distribution and elimination, and, if possible, to gain an early indication of its effectiveness.
- Phase 2: The product candidate is administered to a limited patient population with a specified disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for specific targeted diseases, and to determine dosage tolerance and optimal dosage.
- Phase 3: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide substantial evidence of efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.

In some cases, the FDA may require, or sponsors may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product within the intended indication. These post-marketing clinical trials, sometimes referred to as “Phase 4” studies, may be used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice and for the sponsor and the FDA to reach alignment on the next phase of development.

Concurrent with clinical trials, sponsors usually complete additional nonclinical studies and must also develop additional information about the chemical and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the finished drug product. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf life.

Disclosure of clinical trial information

Sponsors of clinical trials of certain FDA-regulated products, including prescription drugs, are required to register and disclose certain clinical trial information on a public registry maintained by the U.S. National Institutes of Health (NIH). In particular, information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs. Although sponsors are also obligated to disclose the results of their clinical trials after completion, disclosure of the results can be delayed, in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government.

U.S. review and approval process

Assuming successful completion of the required clinical testing, the results of nonclinical studies and clinical trials, along with detailed descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of a substantial user fee, unless a waiver or exemption applies. An annual program fee is also assessed on sponsors of approved prescription drug products. FDA adjusts these user fees on an annual basis.

The FDA conducts a preliminary review of a submitted NDA within the first 60 days after submission, before accepting the application for filing, to determine whether it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once filed, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether it is being manufactured in accordance with cGMP requirements to assure and preserve the product's identity, strength, quality and purity. Under the Prescription Drug User Fee Act (PDUFA), guidelines that are currently in effect, the FDA has a goal of ten months from the filing date to complete its review of a standard application for a drug that is a new molecular entity, and six months from the filing date for an NDA that has been granted priority review. The FDA does not always meet its PDUFA goal dates and the review process may be extended for a three-month period by FDA to respond to new information deemed a "major amendment" to the application.

The FDA also may require the development of a risk evaluation and mitigation strategy (REMS) if it determines that a REMS is necessary to ensure that the benefits of the drug outweigh its risks and to assure the safe use of the product. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS can include medication guides, physician communication plans and/or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making product approval and risk mitigation decisions.

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to ensure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to ensure that the clinical trials were conducted in compliance with GCP regulations and to assure the integrity of the clinical data submitted to the FDA.

After the FDA completes its evaluation of the NDA and any required inspections or advisory committee consultations, the FDA will issue either an approval letter or a Complete Response Letter (CRL), to the NDA applicant. An approval letter authorizes commercial marketing of the drug for specific indications for use. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL usually describes the specific deficiencies in the NDA identified by the FDA. Such deficiencies may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials or other significant and time-consuming requirements related to nonclinical studies or manufacturing. If a CRL is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies

that the FDA has identified in the letter, or withdraw the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter to the applicant. The FDA has committed to reviewing such resubmissions in response to an issued CRL in either two or six months from the date of receipt depending on the type of information included. Even if such additional data and information are submitted, however, the FDA may ultimately decide that the resubmitted NDA does not satisfy the regulatory criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct Phase 4 or other post-market trials to further assess a drug's safety and effectiveness after NDA approval, and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized. The FDA may also place other conditions on approval, including the requirement for a REMS, to assure the safe use of the drug. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products.

In addition, the Pediatric Research Equity Act (PREA), requires a sponsor to conduct pediatric clinical trials for most drugs; specifically, in relation to applications for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements thereto must contain a pediatric assessment unless the sponsor has received a deferral or waiver. Sponsors must also submit Pediatric Study Plans (PSPs), to the agency for review within sixty days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 clinical trial. The initial PSP must include an outline of the pediatric trial or trials that the sponsor plans to conduct, including trial objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric trials along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials or other clinical development programs.

The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless a waiver or deferral has been granted. The FDA may defer, on its own initiative or upon the sponsor's request, submission of the pediatric assessments for some or all pediatric subpopulations until a specified date after approval. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a PREA non-compliance letter to any sponsor that fails to submit the required assessment, fails to keep a deferral current or fails to submit a request for approval of a pediatric formulation. The agency publicly posts such PREA non-compliance letters and sponsor's response.

Orphan drug designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat patients with a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA. After the FDA grants Orphan Drug

Designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The Orphan Drug Designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has Orphan Drug Designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same approved use or indication within such rare disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity within the relevant indication or use, or if the holder of the orphan drug exclusivity cannot assure the availability of sufficient quantities of the orphan drug to meet the needs relating to the approved indication or use of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for any indication or use, or the same drug or biologic for a different indication or use. Among the other benefits of Orphan Drug Designation are tax credits for certain research and a waiver of the NDA application user fee.

Fast track, breakthrough therapy, and priority review designations

The FDA offers a number of programs intended to expedite the development or review of a marketing application for an investigational drug. For example, the Fast Track designation program is intended to expedite or facilitate the process for developing and reviewing product candidates that are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during development and, once an NDA is submitted, the application may be eligible for priority review. An NDA for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for Breakthrough Therapy designation to expedite its development and review. A product candidate can receive Breakthrough Therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

In addition, an NDA may be eligible for priority review if the product candidate is designated to treat a serious condition, and if approved, would provide a significant improvement in safety or efficacy compared to available therapies for such disease or condition. The FDA will attempt to direct additional resources to the evaluation of an NDA designated for priority review in an effort to facilitate the review. For new-molecular-entity NDAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date, as compared to ten months for standard review of new-molecular-entity NDAs under its current PDUFA review goals.

Fast Track designation, Breakthrough Therapy designation, and priority review do not change the standards for approval, but they may expedite the development or approval process. Even if a product candidate qualifies for

one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Accelerated approval pathway

Additionally, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval. Such products may be approved on the basis of adequate and well-controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on an intermediate clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM), that is reasonably likely to predict an effect on IMM or other clinical benefits, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA will generally require the sponsor of a drug receiving accelerated approval to perform adequate and well-controlled confirmatory clinical trials to verify and describe the drug's clinical benefit, and may require that such confirmatory trials be underway prior to granting accelerated approval. Sponsors are also required to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets and other milestones.

NDA sponsors must conduct such post-approval confirmatory studies in a diligent manner, and as a result a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements.

Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory studies in a timely manner or if such studies fail to verify the predicted clinical benefit. In addition, all promotional materials for product candidates being considered and approved under the accelerated approval pathway are subject to prior review by the FDA, which could adversely impact the timing of the commercial launch of the product. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

Post-approval requirements

Following approval of a new drug, the manufacturer and the approved product are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to monitoring and record-keeping, reporting of adverse experiences with the product, periodic reporting, product sampling and distribution and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Certain modifications may require the NDA sponsor to develop additional data or conduct additional nonclinical studies and clinical trials.

There also are continuing, annual program fees for any marketed products. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies to assess compliance with cGMP requirements and other laws. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting requirements on the NDA applicant and any third-party manufacturers involved in producing the approved drug.

product. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of quality control and quality assurance. The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of requirements for post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- mandated modification of promotional materials or labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product;
- fines, warning letters or untitled letters;
- clinical holds on ongoing or planned clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of prescription drug products following approval. A company can make only those claims relating to safety and efficacy that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, e.g., unapproved uses or unapproved patient populations. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Although physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested and approved by the FDA, manufacturers may not market or promote such uses. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. Manufacturers may also share truthful and not misleading information about their products that is otherwise consistent with a product's FDA-approved labeling, which helps to support well-informed clinical decision-making by physicians and other health care professionals.

Marketing and data exclusivity

Orange book listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims covering the applicant's product or method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with

Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an Abbreviated New Drug Application (ANDA). An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, nonclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as generic equivalents to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a Section VIII statement certifying that its proposed ANDA labeling does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been received by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

An applicant may also submit an NDA under Section 505(b)(2) of the FDCA, also referred to as a 505(b)(2) NDA, which permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. A 505(b)(2) NDA sponsor is required to certify to the FDA regarding any patents listed in the Orange Book for the approved product it references to the same extent that an ANDA applicant would.

Exclusivity

Regulatory exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications that seek to reference an FDA-approved product. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA, or file a 505(b)(2) NDA, for another version of such drug where the applicant does not own or have a legal right of reference to such data required for approval. However, an application may be submitted after four years if it contains a Paragraph IV certification.

The FDCA alternatively provides three years of non-patent exclusivity for an original NDA, 505(b)(2) NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, such as studies conducted for new indications, dosages or strengths of an existing drug. This three-year exclusivity period covers only the modification or change for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for

different conditions of approval. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA that does not reference the approved application. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. If granted, pediatric exclusivity provides for the attachment of an additional six months of marketing exclusivity to the term of any existing regulatory exclusivity or listed patent terms. Pediatric exclusivity is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. A product may be eligible for this six-month period of exclusivity if the NDA sponsor voluntarily conducts clinical trials in pediatric studies and submits information requested in writing by the FDA, referred to as a Written Request, relating to the use of the product's active moiety in pediatric patients. The issuance of a Written Request does not require the sponsor to undertake the described clinical trials. In addition, the clinical trial data do not need to show the product to be effective in the pediatric population studied; rather, the additional protection is granted if the pediatric clinical trial is deemed to have fairly responded to the FDA's Written Request. Although the FDA may issue a Written Request for studies on either approved or unapproved indications, it may only do so where it determines that information relating to that use of a product candidate in a pediatric population, or part of the pediatric population, may produce health benefits in that population.

Other U.S. healthcare laws and compliance requirements

In the United States, our current and future operations are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services (CMS), other divisions of the U.S. Department of Health and Human Services (HHS) (e.g., the Office of Inspector General, the Office for Civil Rights), the DOJ and individual U.S. Attorney offices within the DOJ, the U.S. Federal Trade Commission, and state and local governments. For example, our business practices, including our clinical research program and any future sales, marketing and scientific/educational grant programs may be required to comply with the anti-fraud and abuse laws, the false claims laws, transparency requirements, health information privacy and security laws, and similar state laws, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Rather, if "one purpose" of the remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances.

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to, among others, a federal healthcare

program that the person knows or should know is for a medical or other item or service that was not provided as claimed or is false or fraudulent.

The federal false claims laws, including the False Claims Act (FCA), impose significant penalties and can be enforced by private citizens through civil qui tam actions, prohibit, any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, including federal healthcare programs such as Medicare and Medicaid, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. For instance, historically, pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies’ marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses. In addition, a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA.

The Health Insurance Portability and Accountability Act (HIPAA), created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Additionally, the federal Physician Payments Sunshine Act (Sunshine Act), and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) report information annually to CMS related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (such as physician assistants and nurse practitioners), and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to report accurately could result in penalties. In addition, many states also govern the reporting of payments or other transfers of value, many which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

Also, many states have similar, and typically more prohibitive, fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. In order to distribute pharmaceutical products commercially in the future, should FDA approval be granted to any of our candidates, we must comply with state laws that require the licensure or registration of manufacturers and wholesale distributors of drug products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices.

Ensuring business arrangements with third parties comply with applicable healthcare laws and regulations is a costly endeavor. Violation of any of the federal and state healthcare laws described above or any other current or future governmental regulations that apply to drug manufacturers can result in significant penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private “qui tam” actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of operations.

Coverage, pricing, and reimbursement

Our ability to commercialize any products successfully will also depend in part on the extent to which coverage and adequate reimbursement for our drug candidates, if approved, will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which products they will cover and establish reimbursement levels. Assuming coverage is obtained for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Therefore, coverage and adequate reimbursement for new products is critical to the acceptance of such products. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

Government authorities and other third-party payors are developing increasingly sophisticated methods of cost containment, such as including price controls, restrictions on coverage and reimbursement and requirements for substitution of less expensive products and procedures. For example, HHS, imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to 20 products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. Government and other third-party payors are increasingly challenging the prices charged for health care products, examining the cost effectiveness of new drugs, in addition to their safety and efficacy, and limiting or attempting to limit both coverage and the level of reimbursement.

Further, no uniform policy requirement for coverage and reimbursement exists among third-party payors in the United States, which causes significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Therefore, coverage and reimbursement can differ significantly from payor to payor and health care provider to health care provider. As a result, the coverage determination process is often a time-consuming and costly process that requires the provision of scientific and clinical support for the use of new products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

There may also be significant delays in obtaining coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate

which the health care providers who purchase those products will find cost effective. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. Additionally, there may be pricing pressures in connection with the sale of any of our drug candidates, once approved, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes.

Coverage and reimbursement may impact the demand for, the price of, or our ability to successfully commercialize, any drug candidate for which we obtain marketing approval.

Healthcare reform in the United States and potential changes to healthcare laws

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. By way of example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA), was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act (the OBBBA) was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

Other legislative changes have been proposed and adopted in the United States since the ACA. These changes include aggregate reductions to Medicare payments to providers, which began in 2013 and will remain in effect until 2032 unless additional Congressional action is taken.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform (TrumpRx), U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again (MAHA) Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager (PBM) payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's

Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

At the state level, individual states in the United States have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards with the goal of imposing price limits on certain drugs in these states, while some states are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Some measures are designed to encourage importation from other countries. Some third-party payors also require prior authorization before they will cover new or innovative devices or therapies and reimburse healthcare providers that use such therapies.

Foreign government regulation

To market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products.

The approval process varies from country to country, can involve additional testing beyond that required by FDA, and may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing, promotion, and reimbursement vary greatly from country to country. Failure to comply with applicable foreign regulatory requirements, may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act prohibits any U.S. individual or business, as well as their employees, representatives, and agents, from providing, paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for foreign political office for the purpose of influencing any act or decision in order to obtain or retain business or otherwise obtain an improper advantage. Under the FCPA, health care professionals and other employees of foreign hospitals, clinics, research facilities and medical schools in countries with public health care or public education systems are considered “foreign officials” under the FCPA. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls.

Additional regulation

In addition to the foregoing, state, federal, and foreign laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material

compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Data privacy and security

Numerous state, federal, and foreign laws, regulations, and standards govern the collection, use, access to, confidentiality, security, and other processing of personal data and health-related data, including clinical trial data, and could apply now or in the future to our operations or the operations of our partners. For example, in the United States numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, comprehensive data privacy laws, and consumer protection laws and regulations, govern the collection, use, disclosure, protection, and other processing of personal data, including health-related data. Further, to the extent we collect personal data from individuals outside of the United States, through clinical trials or otherwise, we could be subject to foreign laws, such as China's Personal Information Protection Act or Australia's Privacy Act 1988 (Cth) and Australian Privacy Principles, which govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on personal data processing.

Facilities

Our principal office is located in San Diego, California, where we lease approximately 46,300 square feet of office and laboratory space. This lease is expected to expire in June 2035. We believe that our facilities are adequate for our current needs and that suitable additional or substitute space would be available if needed.

Employees and human capital resources

As of March 31, 2026, we had 63 full-time employees and no part-time employees. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Our human capital resources objectives include identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. We have not experienced any work stoppages as a result of labor disputes or strikes. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Legal proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. There are currently no claims or actions pending against us, the ultimate disposition of which we believe could have a material adverse effect on our results of operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Management

The following table sets forth certain information for our executive officers and directors as of July 1, 2026:

Name	Age	Position(s)
Executive officers		
J. Jean Cui, Ph.D.	63	President, Chief Executive Officer, Director
Y. Peter Li, Ph.D., MBA	61	Executive Chairman
Jason Keyes, MBA	55	Chief Financial Officer, Executive Vice President
Vincent Liptak, J.D., Ph.D., MBA	55	General Counsel, Executive Vice President
Geoff Oxnard, M.D.	49	Chief Medical Officer, Executive Vice President
Non-employee directors		
Sundeep Agrawal, M.D.(2)(3)	41	Director
Bihua Chen, MBA(1)(2)	58	Director
Carl L. Gordon, Ph.D., CFA(1)(3)	61	Director
Sheila Gujrathi, M.D.(2)(3)	55	Director
John Schmid, MBA(1)	63	Director
Timothy Stubbs, M.D.(4)	38	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee.

(4) Dr. Stubbs resigned from our board of directors effective as of immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

Executive officers

J. Jean Cui, Ph.D. Dr. Cui is our Scientific Founder, President, Chief Executive Officer and a member of our board of directors and has served in these roles since founding our company in June 2020. Prior to BlossomHill, Dr. Cui was the scientific founder of Turning Point Therapeutics, Inc. Dr. Cui served as Turning Point's Chief Scientific Officer and a member of its board of directors from October 2013 to June 2020. Prior to Turning Point, Dr. Cui was a Senior Principal Scientist and Associate Research Fellow at Pfizer. Prior to Pfizer, Dr. Cui served as Project Leader and Group Leader at Sugan, Inc., a Pharmacia Corporation. Dr. Cui received her B.S. and M.S. in chemistry from the University of Science and Technology of China, her Ph.D. in organic chemistry from The Ohio State University and her postdoctoral training in chemistry at Lawrence Berkeley National Laboratory and the University of California, Berkeley.

We believe that Dr. Cui is qualified to serve on our board of directors based on her distinguished scientific background, track record with drug design and FDA approvals and experience in leadership roles in the biopharmaceutical industry.

Y. Peter Li, Ph.D., MBA Dr. Li is our cofounder and Executive Chairman and has served in these roles since the founding of our company in June 2020. Before BlossomHill, Dr. Li co-founded Turning Point Therapeutics, Inc. in October 2013. Dr. Li served as Turning Point's Chief Executive Officer and Chairman of its board of directors

from October 2013 through October 2018, and as a member of its board of directors through April 2019. Prior to Turning Point, Dr. Li served in roles of increasing responsibility at Epitomics, Inc., an antibody technology company that was acquired by Abcam plc in March 2012, including as Executive Vice President. Dr. Li received his B.S. from the University of Science and Technology of China, his MBA from the Haas School of Business at the University of California, Berkeley, his Ph.D. in biochemistry from The Ohio State University and his postdoctoral training in molecular biology at the University of California, Berkeley.

We believe that Dr. Li is qualified to serve on our board of directors based on his business and leadership experience as an executive in the biopharmaceutical industry, including his experience co-founding and scaling biopharmaceutical companies.

Jason Keyes, MBA Mr. Keyes has served as our Executive Vice President and Chief Financial Officer since May 2025. Prior to joining BlossomHill, Mr. Keyes served as the Chief Financial Officer of Equillum, Inc. from March 2018 through April 2025. From January 2013 through February 2018, Mr. Keyes served in various roles of increasing responsibility at Orexigen Therapeutics, Inc. (Orexigen), a publicly held pharmaceutical company, serving most recently as Executive Vice President and Chief Financial Officer. From August 2007 through January 2013, Mr. Keyes served in various financial leadership roles, including as Senior Director of Finance, at Amylin Pharmaceuticals, Inc., which was acquired by Bristol-Myers Squibb in 2012. Earlier in his career, Mr. Keyes also held leadership positions in finance and corporate strategy at Amgen Inc. and at Baxter Healthcare Corporation. Since August 2024, Mr. Keyes has served on the board of directors and as chair of the audit committee of Actuate Therapeutics, Inc. From February 2020 to March 2023, Mr. Keyes also served on the board of directors and as chair of the audit committee and member of the compensation committee of Sesen Bio, Inc. Mr. Keyes received his B.S. and M.S. in civil engineering from Stanford University and his MBA from the Anderson School at the University of California, Los Angeles.

Vincent Liptak, J.D., Ph.D., MBA Dr. Liptak has served as our Executive Vice President and General Counsel since April 2023. Prior to joining BlossomHill, Dr. Liptak was a partner at Barnes & Thornburg, LLP from June 2014 to October 2023 and also served as co-chair of the firm's Life Sciences Practice Group. Prior to Barnes & Thornburg, Dr. Liptak served as corporate counsel in the intellectual property division at Pfizer from 2009 to 2012, and as a Director of Licensing and Intellectual Property at HUYA Bioscience International LLC from 2013 to 2014. Prior to entering the legal profession, Dr. Liptak was a postdoctoral researcher in chemistry and neuroscience at the California Institute of Technology. Dr. Liptak received his B.S. in chemistry and mathematics from Loyola University Chicago, his M.S. from the University of Chicago, his MBA and J.D. from the University of San Diego and his Ph.D. from the University of Chicago.

Geoff Oxnard, M.D. Dr. Oxnard has served as our Executive Vice President and Chief Medical Officer since January 2025. Dr. Oxnard also has had a medical practice since April 2021, serving as a part-time thoracic oncologist at Boston Medical Center, a safety-net hospital in Boston. Prior to joining BlossomHill, Dr. Oxnard served as Vice President, Global Head of Thoracic Cancers at Eli Lilly & Co. from September 2023 through January 2025. From April 2021 through September 2023, Dr. Oxnard served as Senior Vice President, Head of Clinical Development at Foundation Medicine, a F. Hoffmann-La Roche AG company. Prior to joining Foundation Medicine, Dr. Oxnard spent nearly 10 years on faculty at the Dana-Farber Cancer Institute and Harvard Medical School from 2011 through 2020 where his research focused on molecular drivers of sensitivity and resistance to precision cancer therapies and the application of molecular diagnostics to advance cancer care and drug development. Dr. Oxnard received his B.A. in chemistry from Harvard University and his M.D. from the University of Chicago-Pritzker School of Medicine. He completed his residency in internal medicine at Massachusetts General Hospital and completed a fellowship in medical oncology at Memorial Sloan-Kettering Cancer Center in New York City.

Non-employee directors

Sundee Agrawal, M.D. Dr. Agrawal has served as a member of our board of directors since December 2023. Dr. Agrawal is the Founder and Managing Partner of Brahma Capital, a biotechnology-focused investment firm he founded in February 2019. Previously, he was a General Partner at Colt Ventures, a U.S. based investment firm, from February 2019 to November 2024. Earlier in his career, Dr. Agrawal served as a Vice President at Longitude Capital, a healthcare investment firm, from July 2017 to December 2019, and as an Executive Director in Healthcare Investment Banking at Oppenheimer & Co., from September 2010 to May 2017. He has served on the board of directors of PAVmed Inc., a publicly held medical technology company, since September 2024, and previously served on the board of directors of FoxWayne Enterprises Acquisition Corp from January 2021 to January 2023. Dr. Agrawal received his B.A. in biology from George Washington University and his M.D. from the George Washington School of Medicine. He completed his clinical training at Lenox Hill Hospital in New York.

We believe that Dr. Agrawal is qualified to serve on our board of directors based on his significant experience in investment banking and private equity, his medical and scientific background, and his extensive relationships in the biopharmaceuticals industry and broader life sciences community.

Bihua Chen, MBA Ms. Chen has served as a member of our board of directors since February 2021. Ms. Chen is the founder of Cormorant Asset Management, LP, an investment firm focused on innovative biotechnology, medical technology and life science companies, and has managed Cormorant's hedge fund as well as its private equity funds since its founding in February 2013. Prior to founding Cormorant, from 2005 to 2010, Ms. Chen served as a sub-adviser to Millennium Management LLC, a multi-strategy hedge fund. Previously, from 2001 to 2002, Ms. Chen was a healthcare analyst and sector portfolio manager for investment advisor American Express Asset Management. Ms. Chen also served as a portfolio manager for the Asterion Life Science Fund from 2001 to 2002, an equity analyst and portfolio manager for Bellevue Research from 2000 to 2001 and an equity analyst for Putnam Investments from 1998 to 2001. Ms. Chen has served on the board of directors of Helix Acquisition Corp III, a publicly traded biotechnology special purpose acquisition company, since January 2026, and BridgeBio Oncology Therapeutics, Inc. since August 2025. Ms. Chen served on the board of directors of Biomea Fusion, Inc. from December 2020 to July 2025, Erasca, Inc. from March 2021 through August 2023, Helix Acquisition Corp II, a publicly traded biotechnology special purpose acquisition company that entered into a business combination with BridgeBio Oncology Therapeutics in August 2025, from January 2024 to August 2025, and Atea Pharmaceuticals, Inc. from June 2018 through October 2020. From August 2020 to April 2022, Ms. Chen served as the Chief Executive Officer and Chairman of the board of directors of Helix Acquisition Corp., a publicly traded biotechnology special purpose acquisition company that entered into a business combination with MoonLake Immunotherapeutics AG in April 2022. Ms. Chen received her B.S. in genetics and genetic engineering from Fudan University, Shanghai, China, her M.S. in molecular biology from the Weill Cornell Graduate School of Medical Sciences and her MBA from the Wharton School of the University of Pennsylvania.

We believe that Ms. Chen is qualified to serve on our board of directors based on her extensive experience in the biopharmaceutical industry, including as a board member of various biotechnology and pharmaceutical companies, and her experience with life sciences investments.

Carl L. Gordon, Ph.D., CFA Dr. Gordon has served as a member of our board of directors since February 2021. Dr. Gordon is a Managing Partner at OrbiMed Advisors LLC, an investment firm, where he has served since January 1998. Dr. Gordon has served on the board of directors of Compass Therapeutics Inc., a publicly held biopharmaceutical company, since September 2015, and on the board of directors of Lomond Therapeutics Holdings, Inc., a privately held biotechnology company, since August 2024, as well as several other privately held companies. He previously served on the boards of directors of Adicet Bio, Inc. from August 2015 to April 2025, ArriVent BioPharma, Inc. from December 2022 to June 2025, Gemini Therapeutics Inc., from April 2016 until December 2022 (acquired by Disc Medicine, Inc.), Keros Therapeutics, Inc. from March 2020 to March

2026, Kinnate Biopharma Inc. from December 2019 to April 2024, MBX Biosciences, Inc. from July 2020 to June 2025, ORIC Pharmaceuticals, Inc. from November 2015 until November 2021, Terns Pharmaceuticals, Inc. from October 2018 to February 2025, and Theseus Pharmaceuticals, Inc. from June 2018 until February 2024 (acquired by Concentra Biosciences, LLC). Dr. Gordon earned a B.A. in chemistry from Harvard College, a Ph.D. in molecular biology from the Massachusetts Institute of Technology and was a Postdoctoral Fellow at the Rockefeller University.

We believe that Dr. Gordon is qualified to serve on our board of directors based on his scientific expertise, extensive business experience, and experience in venture capital and the life science industry, including as a board member of various biotechnology and pharmaceutical companies.

Sheila Gujrathi, M.D. Dr. Gujrathi has served as a member of our board of directors since May 2026. Dr. Sheila Gujrathi is a seasoned biotech entrepreneur, physician executive, translational scientist, and drug developer. She has served as founder and Chief Executive Officer of Prana Therapies since March 2023, as founder and Executive Chair of the board of directors of Lila Biologics, Inc., a privately held biopharmaceutical company, since March 2023, as founder and Executive Chair of the board of directors of Vidya Therapeutics, Inc., a privately held biotechnology company, since March 2023, as a member of the board of directors of Janux Therapeutics, Inc., a publicly held biopharmaceutical company, since March 2021, as Executive Chair of the board of directors of Ventyx Biosciences, Inc., a publicly held biopharmaceutical company, since May 2021, and as Executive Chair of the board of directors of Generian Pharmaceuticals, Inc., a privately held biotechnology company, since May 2023. Dr. Gujrathi previously served as Chair of the board of directors of ADARx Pharmaceuticals, Inc., a privately held biopharmaceutical company, from June 2020 to January 2025, as Chair of the board of directors of ImmPACT Bio USA Inc., a privately held biotechnology company, from December 2021 until its acquisition by Lyell Immunopharma, Inc. in October 2024, as a member of the board of directors of Turning Point Therapeutics, Inc. (acquired by Bristol-Myers Squibb Company in August 2022) (Turning Point), a then-publicly held biopharmaceutical company, from November 2017 to March 2021, and as Chair of the board of directors of Turning Point from April 2019 to March 2021. Dr. Gujrathi previously served as a member of the board of directors of Five Prime Therapeutics, Inc. (acquired by Amgen, Inc. in April 2021) from December 2015 to June 2019 and as a member of the board of directors of Ambrx, Inc., a then-publicly held biopharmaceutical company, from February 2014 until its acquisition by Johnson & Johnson in June 2015. Dr. Gujrathi is a Co-Founder of Gossamer Bio, Inc., a publicly held biopharmaceutical company, and served as its President and Chief Executive Officer from July 2018 to November 2020 and as its President and Chief Operating Officer from October 2015 to June 2018 and as a member of its board of directors from October 2015 to November 2020. Previously, Dr. Gujrathi was the Chief Medical Officer of Receptos, Inc., a then-publicly held biopharmaceutical company, a position she held from June 2011 until its acquisition by Celgene Corporation in August 2015. Previously, Dr. Gujrathi worked at Bristol-Myers Squibb Company, where she served as Vice President of the Global Clinical Research Group in Immunology from August 2008 to June 2011. Prior, Dr. Gujrathi worked at Genentech, Inc., where she held roles of increasing responsibility in the Immunology, Tissue Growth and Repair clinical development group from Oct 2002 to July 2008. From 1999 until 2002, Dr. Gujrathi was a management consultant at McKinsey & Company in the healthcare practice, where she provided strategic advice on a variety of projects in the healthcare and pharmaceutical industry. Dr. Gujrathi received her B.S. in biomedical engineering and M.D. from Northwestern University. Dr. Gujrathi completed her internal medicine internship and residency at Brigham and Women's Hospital, Harvard Medical School and is board certified in internal medicine. Dr. Gujrathi received additional training at the University of California, San Francisco and Stanford University in their Allergy and Immunology Fellowship Program.

We believe that Dr. Gujrathi is qualified to serve on our board of directors based on her extensive experience as a leader in the biopharmaceutical industry, including as a board member of multiple biotechnology and biopharmaceutical companies.

John Schmid, MBA Mr. Schmid has served as a member of our board of directors since May 2026. Mr. Schmid has served as a member of the boards of directors of AnaptysBio, Inc., a publicly held biotechnology company (AnaptysBio), since June 2015, Design Therapeutics, Inc., a publicly held biopharmaceutical company, since November 2020, Bright Peak Therapeutics, Inc., a privately held biopharmaceutical company, since March 2025, Helix Acquisition Corp III, a special purpose acquisition company (Helix Acquisition Corp III), since January 2026, and First Tracks Biotherapeutics, Inc., a publicly held biopharmaceutical company, since April 2026 and following its spin out from AnaptysBio. Mr. Schmid serves as chairman of the board of directors of Speak, Inc., a speakers bureau, which he helped found in 1989. Mr. Schmid previously served as a member of the board of directors of Xeris Pharmaceuticals, Inc. from September 2017 to June 2025, Poseida Therapeutics, Inc. from July 2018 until its acquisition by Roche in January 2025, Blacksmith Medicines (formerly known as Forge Therapeutics, Inc.) from May 2017 to April 2024, Neos Therapeutics LP from June 2015 until its acquisition by Aytu BioSciences, Inc. in March 2021, Helix Acquisition Corporation, a special purpose acquisition company, from October 2020 to April 2022 and Helix Acquisition Corporation II from February 2024 to August 2025. From September 2013 to June 2015, Mr. Schmid served as Chief Financial Officer of Auspex Pharmaceuticals, Inc. until its sale to Teva Pharmaceutical Industries Ltd in May 2015. From June 2004 to September 2013, Mr. Schmid co-founded Trius Therapeutics, Inc. where he served as Chief Financial Officer until its merger with Cubist Pharmaceuticals, Inc. in September 2013. Mr. Schmid served as Chief Financial Officer of GeneFormatics, Inc. from 1998 until its acquisition by Cergent Therapeutics in May 2003. From 1995 to 1998, Mr. Schmid served as Chief Financial Officer of Endonetics Inc. Mr. Schmid received his B.A. in economics from Wesleyan University and his MBA from the University of San Diego.

We believe that Mr. Schmid is qualified to serve on our board of directors based on his extensive financial experience, including his leadership positions at multiple biopharmaceutical companies, and his experience as a board member of various biotechnology and pharmaceutical companies.

Timothy Stubbs, M.D. Dr. Stubbs served as a member of our board of directors from March 2024 to August 2026. Dr. Stubbs has served as an Executive Director at Vivo Capital LLC, a public and crossover biotech investment firm, since March 2022. Prior to Vivo, Dr. Stubbs was a Vice President at Morgan Stanley from March 2015 through March 2022. Prior to Morgan Stanley, Dr. Stubbs worked as a National Health Service physician in London, where he spent time in medical and surgical specialties, as well as the emergency room. Dr. Stubbs received his B.S. in anatomical science and MBChB from the University of Bristol, United Kingdom.

Dr. Stubbs' medical background and his experience with the global pharmaceutical industry, including in healthcare investment banking and private and public biotech investing contributed to our board of directors' conclusion that he should serve as a director of our company. Dr. Stubbs resigned from our board of directors immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

Involvement in certain legal proceedings

None of our directors or executive officers has been involved in any legal proceeding listed in Item 401(f) of Regulation S-K in the past 10 years except as follows:

Mr. Keyes served in various roles of increasing responsibility at Orexigen from January 2013 to February 2018, serving most recently as Executive Vice President and Chief Financial Officer. In March 2018, Orexigen filed a voluntary petition for Chapter 11 bankruptcy in the U.S. Bankruptcy Court for the District of Delaware (Bankruptcy Court). In June 2018, the Bankruptcy Court entered an order (i) approving the sale of substantially all of the assets of Orexigen free and clear of all liens, encumbrances, claims, and interests, (ii) approving the assumption and assignment of designated executory contracts and unexpired leases, and (iii) granting related relief (the Sale Order). Pursuant to the Sale Order, the sale of substantially all of Orexigen's assets closed in July 2018.

Family relationships and other arrangements

J. Jean Cui, Ph.D., our President, Chief Executive Officer and member of our board of directors, is the spouse of Y. Peter Li, Ph.D., MBA, our Executive Chairman and Chair of our board of directors. There are no other family relationships among the directors and executive officers. Pursuant to our amended and restated voting agreement, which will terminate upon the closing of this offering, the following directors were designated as members of our board of directors:

- Dr. Cui, designated pursuant to her service as our Chief Executive Officer;
- Dr. Li, designated by majority agreement of the then-holders of our Series Angel convertible preferred stock;
- Dr. Gordon, designated by OrbiMed Private Investments VIII, LP;
- Dr. Gujrathi, designated by majority agreement of the then-holders of our Series A convertible preferred stock;
- Ms. Chen, designated by Cormorant Private Healthcare Fund III, LP and Cormorant Global Healthcare Master Fund, LP;
- Dr. Agrawal, designated by Brahma BlossomHill Partners, LLC; and
- Mr. Schmid, designated by majority agreement of the then-holders of our common stock and preferred stock.

Composition of our board of directors

Our business and affairs are organized under the direction of our board of directors, which currently consists of eight members. Dr. Stubbs resigned from our board of directors effective as of immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. As a result, our board of directors consists of seven members. Such resignation from our board of directors is an ordinary course transition in connection with our public company preparedness. There were no disagreements between us and the resigning director on any matter relating to our operations, policies or practices. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and on an ad hoc basis as required. In accordance with the terms of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to and upon the closing of this offering, respectively, we will divide our board of directors into three classes, as follows:

- Class I, which will consist of Dr. Li, Dr. Gordon and Mr. Schmid, whose terms will expire at our first annual meeting of stockholders to be held following this offering;
- Class II, which will consist of Dr. Cui and Dr. Agrawal, whose terms will expire at our second annual meeting of stockholders to be held following this offering; and
- Class III, which will consist of Ms. Chen and Dr. Gujrathi, whose terms will expire at our third annual meeting of stockholders to be held following this offering.

At each annual meeting of stockholders to be held after the initial classification, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized size of our board of directors is currently eight members. The authorized number of directors may be changed only by resolution of our board of directors. Any

additional directorships resulting from an increase in the number of directors will be distributed among three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of our board of directors may have the effect of delaying or preventing changes in our control or management. Our directors may be removed for cause by the affirmative vote of the holders of at least 66-2/3% of our voting stock.

Board leadership structure

Our board of directors is currently chaired by Dr. Li, who has authority, among other things, to call and preside over board of directors meetings, to set meeting agendas and to determine materials to be distributed to the board of directors. Accordingly, the Chair has substantial ability to shape the work of the board of directors. Our board of directors has also appointed Dr. Gujrathi to serve as our lead independent director. The lead independent director's responsibilities include: facilitating communication between management, the independent directors, and the Chair; actively participating in setting agendas for meetings of our board of directors; presiding at executive sessions of the board of directors; and performing such other duties as specified by the board of directors.

In addition, we have a separate chair for each committee of our board of directors. The chair of each committee is expected to report annually to our board of directors on the activities of their committee in fulfilling their responsibilities as detailed in their respective charters or specify any shortcomings should that be the case. We believe that the separation of responsibilities as among our President and Chief Executive Officer, Executive Chairman, our lead independent director and our committee chairs provides a balanced approach to managing the board of directors and overseeing our company. Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Role of the board in risk oversight

The audit committee of our board of directors is primarily responsible for overseeing our risk management processes on behalf of our board of directors. Going forward, we expect that the audit committee will receive reports from management periodically regarding our assessment of risks. In addition, the audit committee reports regularly to our board of directors, which also considers our risk profile. The audit committee and our board of directors focus on the most significant risks we face and our general risk management strategies. While our board of directors oversees our risk management, management is responsible for day-to-day risk management processes. Our board of directors expects management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the audit committee and our board of directors. We believe this division of responsibilities is the most effective approach for addressing the risks we face and that our board of directors' leadership structure, which also emphasizes the independence of our board of directors in its oversight of its business and affairs, supports this approach.

Committees of our board of directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. Our board of directors may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Our board of directors may establish other committees as it deems necessary or appropriate from time to time. Each committee has adopted a written charter that satisfies the applicable rules and regulations of the Sarbanes-Oxley Act, the SEC and the listing standards of the Nasdaq Stock Market LLC (Nasdaq), which we will post on our website, www.bhtherapeutics.com, upon the closing of this offering. We have included our website in this prospectus solely as a textual reference. The information contained in, or accessible through, our website is not

incorporated by reference into this prospectus, and you should not consider any information contained in, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common stock.

Audit committee

Upon the closing of this offering, our audit committee will consist of Ms. Chen, Dr. Gordon and Mr. Schmid. Mr. Schmid will serve as the chair of our audit committee. Our board of directors has determined that each of the members of our audit committee satisfies Nasdaq and SEC independence requirements. The primary functions of this committee include, among other things:

- evaluating the performance, qualifications and independence of our independent auditor and determining whether to retain our existing independent auditor or engage new independent auditor;
- determining and approving the engagement of our independent auditor to perform audit services and any permissible non-audit services;
- monitoring the rotation of partners of our independent auditor on our engagement team as required by law;
- prior to engagement of any independent auditor, and at least annually thereafter, reviewing relationships that may reasonably be thought to bear on their independence, and assessing and otherwise taking the appropriate action to oversee the independence of our independent auditor;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption “Management’s discussion and analysis of financial condition and results of operations,” and discussing the statements and reports with our independent auditor and management;
- reviewing, with our independent auditor and management, major issues that arise regarding accounting principles and financial statement presentation, including any significant changes in selection or application of accounting principles, significant regulatory or accounting initiatives or developments, as well as off-balance sheet structures, that may have a material impact on our financial statements;
- reviewing, with our management, the scope, adequacy and effectiveness of our internal control over financial reporting;
- reviewing with management and our independent auditor any earnings announcements and other public announcements regarding material developments;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or auditing matters, as well as other matters;
- preparing the audit committee report required by the rules of the SEC to be included in our annual proxy statement;
- reviewing, approving or ratifying and providing oversight of any related-person transactions in accordance with our related-person transaction policy;
- reviewing and monitoring compliance with programs and policies designed to ensure adherence to applicable laws and our code of business conduct and ethics;
- reviewing and assessing our risk management, risk assessment and major risk exposures with respect to financial, accounting, operational, tax, privacy and cybersecurity and information technology risks;
- reviewing on a periodic basis our investment policy and related-person transactions policy; and

- reviewing and evaluating, at least on an annual basis, the performance of the audit committee and the adequacy of the audit committee charter.

Our board of directors has determined that Mr. Schmid qualifies as an “audit committee financial expert” within the meaning of SEC regulations and meets the financial sophistication requirements of the Nasdaq Listing Standards. In making this determination, our board has considered prior experience, business acumen and independence. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

We believe that the composition and functioning of our audit committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Compensation committee

Upon the closing of this offering, our compensation committee will consist of Dr. Agrawal, Ms. Chen, and Dr. Gujrathi. Ms. Chen will serve as the chair of our compensation committee. Our board of directors has determined that each of the members of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act and satisfies the independence requirements. The primary functions of this committee include, among other things:

- overseeing our overall compensation practices and objectives, and assessing whether our compensation practices establish appropriate incentives in light of our specific business objectives;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the compensation and other terms of employment of our executive officers;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) corporate goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the establishment or modification of our equity-based compensation plans and any other of our incentive compensation plans;
- evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;
- reviewing and discussing with management our policies and practices related to our management of human capital resources and corporate culture;
- modifying and overseeing the compensation clawback or similar policies;
- reviewing and making recommendations to the full board of directors regarding the form and amount of director compensation;
- providing recommendations to the full board of directors on compensation-related proposals to be considered at our annual meeting of stockholders, including any applicable advisory votes on executive compensation and the frequency of such votes, incentive and other compensation plans and amendments to such plans;

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- reviewing and assessing the independence of compensation consultants, legal counsel and other advisors as required by Section 10C of the Exchange Act;
- administering our incentive and equity-based compensation plans;
- establishing policies with respect to equity compensation arrangements;
- reviewing and approving the list of companies, if any, to be included in any compensation peer group used to determine pay levels based on criteria the compensation committee deems appropriate;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) any employment or post-employment agreement or arrangement (including severance and change in control benefits) applicable to any of our executive officers;
- reviewing with management and approving our disclosures under the caption “Compensation Discussion and Analysis” to be included in our annual proxy statement or annual report on Form 10-K, in accordance with the rules of the SEC;
- preparing the compensation committee report on executive officer compensation as required by the SEC to be included in our annual proxy statement or annual report on Form 10-K filed with the SEC;
- reviewing with management and making recommendations to the full board of directors regarding the plans for succession of our Chief Executive Officer and other key executives; and
- reviewing and assessing on an annual basis the performance of the compensation committee and the compensation committee charter.

We believe that the composition and functioning of our compensation committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Nominating and corporate governance committee

Upon the closing of this offering, our nominating and corporate governance committee will consist of Dr. Agrawal, Dr. Gordon, and Dr. Gujrathi. Dr. Gujrathi will serve as the chair of our nominating and corporate governance committee. Our board of directors has determined that each of the members of this committee satisfies the independence requirements. The primary functions of this committee include, among other things:

- identifying, reviewing, screening and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors;
- determining the minimum qualifications for service on our board of directors;
- overseeing evaluations of director performance on the board and applicable committees of the board and determining whether continued service on our board is appropriate;
- reviewing and making recommendations to the board of directors concerning the size, structure, composition and functioning of the board and its committees;
- reviewing any stockholder proposals submitted for inclusion in our proxy statement and recommending to the full board of directors any statements by us in response, and considering stockholder nominees for election to our board of directors at our annual meeting of stockholders;
- considering and assessing the independence of members of our board of directors and executive officers;

- periodically reviewing the corporate governance guidelines and recommending to our board of directors any changes to such guidelines;
- overseeing our environmental, social and governance strategies, targets, policies, performance and reporting; and
- reviewing and assessing on an annual basis the performance of the nominating and corporate governance committee and the nominating and corporate governance committee charter.

We believe that the composition and functioning of our nominating and corporate governance committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Compensation committee interlocks and insider participation

None of our current or former executive officers serve as a member of the compensation committee. None of our officers serve, or have served during the last completed fiscal year, on the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or our compensation committee.

Code of business conduct and ethics

In connection with this offering, we have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or person performing similar functions. Following this offering, a current copy of the code will be available on the Corporate Governance section of our website, www.bhtherapeutics.com. We have included our website in this prospectus solely as a textual reference. The information contained in, or accessible through, our website is not incorporated by reference into this prospectus, and you should not consider any information contained in, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common stock.

Director independence

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning his or her background, employment and affiliations, our board of directors has determined that, with the exception of Dr. Cui and Dr. Li, none of our directors have relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is “independent” as that term is defined under the applicable listing standards. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our shares held by each non-employee director and the transactions described in the section titled “Certain relationships and related party transactions.”

Executive and director compensation

Our named executive officers for the year ended December 31, 2025, consisting of our principal executive officer and the next two most highly compensated executive officers, were:

- J. Jean Cui, Ph.D., our President and Chief Executive Officer;
- Jason Keyes, MBA, our Executive Vice President and Chief Financial Officer; and
- Geoff Oxnard, M.D., our Executive Vice President and Chief Medical Officer.

Summary compensation table for the year ended December 31, 2025

The following table presents all of the compensation awarded to, earned by or paid to our named executive officers during the year ended December 31, 2025.

Name and principal position	Year	Salary (\$)	Bonus (\$)	Option awards (\$) ⁽¹⁾	Non-equity incentive plan compensation (\$) ⁽²⁾	All other compensation (\$) ⁽³⁾	Total (\$)
J. Jean Cui, Ph.D. President and Chief Executive Officer	2025	500,000	—	—	250,000	13,947	763,947
Jason Keyes, MBA ⁽⁴⁾ Executive Vice President and Chief Financial Officer	2025	295,890	40,000 ⁽⁵⁾	808,211	118,356	10,500	1,272,957
Geoff Oxnard, M.D. ⁽⁶⁾ Executive Vice President and Chief Medical Officer	2025	450,000	153,000 ⁽⁵⁾	850,435	180,000	14,000	1,647,435

(1) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the stock options granted during the year ended December 31, 2025. These amounts have been computed in accordance with Financial Accounting Standards Board (FASB), Accounting Standards Codification (ASC) Topic 718. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. Assumptions used in the calculation of these amounts are described in Note 2 to our financial statements included elsewhere in this prospectus. These amounts do not reflect the actual economic value that may be realized by our named executive officers upon vesting or exercise of the stock options or the sale of the common stock underlying such awards.

(2) The amounts disclosed represent performance-based bonuses earned with respect to the year ended December 31, 2025, as described in the subsection below titled “—Annual bonus.”

(3) The amounts disclosed represent 401(k) matching contributions. For additional information, please see the subsection titled “—401(k) plan.”

(4) Mr. Keyes commenced employment as our Executive Vice President and Chief Financial Officer in May 2025.

(5) The amounts disclosed represent signing bonuses received by Mr. Keyes and Dr. Oxnard upon their respective commencement of employment in 2025, as described in the subsection below titled “—Employment arrangements with our named executive officers.”

(6) Dr. Oxnard commenced employment as our Executive Vice President and Chief Medical Officer in January 2025.

Narrative to summary compensation table

Annual base salary

Our named executive officers receive base salaries to compensate them for services rendered to us. The base salary payable to each named executive officer is intended to provide a fixed component of compensation, taking into account such named executive officer’s qualifications, experience, the scope of such named executive officer’s responsibilities and competitive market compensation paid by other companies for similar

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positions within the industry and geography. Base salaries are reviewed periodically and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. The 2025 annual base salary rates for our named executive officers are set forth in the table below, and the base salaries ultimately earned by our named executive officers for 2025 are reported above in the “Salary” column of the Summary Compensation Table. Mr. Keyes’ base salary was prorated to reflect the portion of the year that he was employed by us during 2025.

Name	2025 Base salary
J. Jean Cui, Ph.D.	\$500,000
Jason Keyes, MBA	\$450,000
Geoff Oxnard, M.D.	\$450,000

Annual bonus

In addition to base salaries, our named executive officers are eligible to receive annual bonuses based on the achievement of certain performance criteria approved by our board of directors, including those related to research and development and clinical milestones and other corporate goals, as well as individual performance. The amount of any annual bonus is based on a quantitative assessment of the extent to which the corporate goals were achieved, with the ultimate amount paid, if any, determined by the board of directors. For the year ended December 31, 2025, annual cash bonus targets, as a percentage of base salary, were 50% for Dr. Cui, 40% for Mr. Keyes and 40% for Dr. Oxnard. Following its assessment of 2025 corporate and individual performance, the board of directors determined that each named executive officer had earned a 2025 annual bonus at 100% of target (for Mr. Keyes, prorated based on the part of the year that he served as our Executive Vice President and Chief Financial Officer). The annual bonuses ultimately earned by our named executive officers for 2025 are reported above in the “Non-equity incentive plan compensation” column of the Summary Compensation Table.

Equity-based incentive awards

Our equity-based incentive awards are designed to align the interests of our stockholders with those of our employees, including our named executive officers. The board of directors or an authorized committee thereof is responsible for approving equity grants.

Prior to this offering, we have granted stock options pursuant to our 2020 Equity Incentive Plan (2020 Plan), to certain of our executives. Following this offering, we will grant equity awards under the terms of our 2026 Equity Incentive Plan (2026 Plan). The terms of our equity plans are described below under the subsection titled “—Equity benefit plans.” Our named executive officers received the following stock option awards in the year ended December 31, 2025:

- On January 3, 2025, our board of directors granted an option award to Dr. Oxnard, covering 170,159 shares of our common stock. This award has an exercise price of \$5.63 per share and vests over a period of four years, with 25% of the option vesting on the first anniversary of the vesting commencement date and the remaining 75% of the option vesting ratably on a monthly basis thereafter, subject to Dr. Oxnard’s continued service with us through each vesting date.
- On May 15, 2025, our board of directors granted an option award to Mr. Keyes, covering 175,417 shares of our common stock. This award has an exercise price of \$6.28 per share and vests over a period of four years, with 25% of the option vesting on the first anniversary of the vesting commencement date and the remaining 75% of the option vesting ratably on a monthly basis thereafter, subject to Mr. Keyes’ continued service with us through each vesting date.

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- On August 24, 2025, in recognition of his contributions toward achieving certain clinical milestones, our board of directors granted an option award to Dr. Oxnard, covering 34,031 shares of our common stock. This award has an exercise price of \$6.28 per share and vests over a period of four years, with 25% of the option vesting on the first anniversary of the vesting commencement date and the remaining 75% of the option vesting ratably on a monthly basis thereafter, subject to Dr. Oxnard's continued service with us through each vesting date.

IPO option awards

- In July 2026, our board of directors approved the grant of the following options to purchase shares of our common stock under our 2026 Plan, effective upon the effectiveness of the registration statement of which this prospectus forms a part: (i) an option to purchase 676,205 shares to Dr. Cui; (ii) an option to purchase 61,783 shares to Dr. Oxnard; (iii) an option to purchase 56,746 shares to Mr. Keyes; and (iv) options to purchase an aggregate of approximately 0.7 million shares to employees of the Company other than the named executive officers (including an option to purchase 112,701 shares to Dr. Li, our Executive Chairman and a member of our board of directors). These options have an exercise price equal to the initial public offering price of a share of our common stock. Each such option vests over a period of four years, with 25% of the option vesting on the first anniversary of the vesting commencement date and the remaining 75% of the option vesting ratably on a monthly basis thereafter, subject to the applicable recipient's continuous service with us through each vesting date.

Outstanding equity awards as of December 31, 2025

The following table presents the outstanding equity awards held by each named executive officer as of December 31, 2025.

Name	Grant date	Vesting commencement date	Option awards ⁽¹⁾			
			Number of securities underlying unexercised options exercisable (#)	Number of securities underlying unexercised options unexercisable (#)	Option exercise price (\$)	Option expiration date
Jason Keyes, MBA	5/15/2025	5/5/2025 ⁽²⁾	—	175,417	\$ 6.28	5/5/2035
Geoff Oxnard, M.D.	1/3/2025	1/1/2025 ⁽²⁾	—	170,159	\$ 5.63	1/2/2035
	8/24/2025	8/21/2025 ⁽²⁾	—	34,031	\$ 6.28	8/21/2035

(1) All of the option awards were granted under the 2020 Plan, the terms of which plan is described below under “—Equity benefit plans—2020 Equity incentive plan.”

(2) 25% of the total shares vest on the first anniversary of the vesting commencement date and the remaining 75% of the total shares vest ratably in monthly installments over the three-year period thereafter, subject to continuous service with us through each vesting date. In addition, the shares subject to this option are subject to acceleration as set forth in our Severance Plan (as described below). For more information, please see the subsection titled “—Potential payments upon termination or change of control” below.

Employment arrangements with our named executive officers

We have entered into an employment agreement or employment offer letter, as applicable, with each of our named executive officers. The material terms of each such agreement are described below. The employment of each of our named executive officers is “at will” and may be terminated at any time.

J. Jean Cui, Ph.D.

Effective March 2021, we entered into an executive employment agreement with Dr. Cui in connection with her service as our President and Chief Executive Officer (Cui Agreement). Under the Cui Agreement, Dr. Cui's initial annual base salary was set at \$350,000 (which was increased to \$500,000 effective January 1, 2025), subject to review and adjustment from time to time. The Cui Agreement also provides that Dr. Cui is eligible to receive an annual discretionary bonus at a target amount of 45% of her then-current base salary (increased to 50% of her then-current base salary effective beginning with her 2025 bonus opportunity), based upon our and Dr. Cui's achievement of objectives and milestones to be determined on an annual basis by our board of directors.

On July 31, 2026, we entered into an amended and restated executive employment agreement with Dr. Cui in connection with her service as our President and Chief Executive Officer (A&R Cui Agreement), which became effective upon the effectiveness of the registration statement of which this prospectus forms a part. Under the A&R Cui Agreement, Dr. Cui's annual base salary is set at \$660,000, subject to review and adjustment from time to time. The A&R Cui Agreement also provides that Dr. Cui is eligible to receive an annual discretionary bonus at a target amount of 55% of her then-current base salary, based upon our and Dr. Cui's achievement of objectives and milestones to be approved by our board of directors.

In the event of certain qualifying terminations of her employment, Dr. Cui will be entitled to receive severance benefits pursuant to our Severance Plan, as described below under "—Potential payments upon termination or change of control."

Jason Keyes, MBA

Effective May 2025, we entered into an employment offer letter with Mr. Keyes in connection with his service as our Executive Vice President and Chief Financial Officer (Keyes Agreement). Under the Keyes Agreement, Mr. Keyes' initial annual base salary was set at \$450,000, subject to review and adjustment from time to time. The Keyes Agreement also provides that Mr. Keyes is eligible to receive an annual discretionary bonus at a target amount of 40% of his then-current base salary, based on the achievement of individual and corporate performance targets and metrics to be approved by our board of directors. Under the Keyes Agreement and following approval by our board of directors, in May 2025, Mr. Keyes was granted an option under our 2020 Plan to purchase 175,417 shares of our common stock, 25% of which will vest on the first anniversary of the date that Mr. Keyes commenced employment with us, with the remaining 75% vesting ratably on a monthly basis over the three-year period thereafter, subject to Mr. Keyes' continuous service with us through each such vesting date. Under the Keyes Agreement, Mr. Keyes also received a signing bonus of \$40,000, subject to repayment in the event of a termination of employment for any reason (other than an involuntary termination without cause (as defined in our Severance Plan)) prior to the first anniversary of Mr. Keyes' start date.

On July 31, 2026, we entered into an amended and restated executive employment agreement with Mr. Keyes in connection with his service as our Executive Vice President and Chief Financial Officer (A&R Keyes Agreement), which became effective upon the effectiveness of the registration statement of which this prospectus forms a part. Under the A&R Keyes Agreement, Mr. Keyes' annual base salary is set at \$509,000, subject to review and adjustment from time to time. The A&R Keyes Agreement also provides that Mr. Keyes is eligible to receive an annual discretionary bonus at a target amount of 40% of his then-current base salary, based on the achievement of individual and corporate performance targets and metrics to be approved by our board of directors.

In the event of certain qualifying terminations of his employment, Mr. Keyes will be entitled to receive severance benefits pursuant to our Severance Plan, as described below under "—Potential payments upon termination or change of control."

Geoff Oxnard, M.D.

Effective January 2025, we entered into an employment offer letter with Dr. Oxnard in connection with his service as our Executive Vice President and Chief Medical Officer (Oxnard Agreement). Under the Oxnard Agreement, Dr. Oxnard's initial annual base salary was set at \$450,000, subject to review and adjustment from time to time. The Oxnard Agreement also provides that Dr. Oxnard is eligible to receive an annual discretionary bonus at a target amount of 40% of his then-current base salary, based on the achievement of individual and corporate performance targets and metrics to be approved by our board of directors. Under the Oxnard Agreement and following approval by our board of directors, in January 2025 and August 2025, Dr. Oxnard was granted, under our 2020 Plan, (i) an option to purchase 170,159 shares of our common stock, 25% of which vested on the first anniversary of the date that Dr. Oxnard commenced employment with us, with the remaining 75% vesting ratably on a monthly basis over the three-year period thereafter, subject to his continuous service with us through each such vesting date, and (ii) in recognition of his contributions toward the achievement of certain clinical milestones, an option to purchase 34,031 shares of our common stock, 25% of which will vest on the first anniversary of the vesting commencement date, with the remaining 75% vesting ratably on a monthly basis over the three-year period thereafter, subject to Dr. Oxnard's continuous service with us through each such vesting date. Under the Oxnard Agreement, Dr. Oxnard also received a signing bonus of \$153,000, which was subject to repayment in the event of a termination of employment for any reason (other than an involuntary termination without cause (as defined in our Severance Plan)) prior to the first anniversary of Dr. Oxnard's start date.

On July 31, 2026, we entered into an amended and restated executive employment agreement with Dr. Oxnard in connection with his service as our Executive Vice President and Chief Medical Officer (A&R Oxnard Agreement), which became effective upon the effectiveness of the registration statement of which this prospectus forms a part. Under the A&R Oxnard Agreement, Dr. Oxnard's annual base salary is set at \$535,000, subject to review and adjustment from time to time. The A&R Oxnard Agreement also provides that Dr. Oxnard is eligible to receive an annual discretionary bonus at a target amount of 40% of his then-current base salary, based on the achievement of individual and corporate performance targets and metrics to be approved by our board of directors.

In the event of certain qualifying terminations of his employment, Dr. Oxnard will be entitled to receive severance benefits pursuant to our Severance Plan, as described below under "—Potential payments upon termination or change of control."

Potential payments upon termination or change of control

Upon and following this offering, each of our named executive officers will be eligible to receive severance benefits upon certain terminations of employment under the terms of our Severance Plan, which was adopted in June 2026 (Severance Plan). The Severance Plan supersedes and replaces in its entirety our prior Severance Benefit Plan, which was adopted in October 2024.

Upon a termination without Cause or resignation for Good Reason (each as defined in our Severance Plan) outside of the period beginning 3 months prior to and ending 12 months following a change in control (CIC Period), each of our named executive officers will be entitled to receive the following severance benefits: (i) a lump sum cash payment equal to a specified portion of the named executive officer's base salary (15 months for Dr. Cui and 9 months for each of Mr. Keyes and Dr. Oxnard) and (ii) payment of COBRA premiums for the duration of the applicable severance period (15 months for Dr. Cui and 9 months for each of Mr. Keyes and Dr. Oxnard).

Upon a termination without Cause or resignation for Good Reason during the CIC Period, each of our named executive officers will be entitled to receive the following severance benefits in lieu of those described above:

(i) a lump sum cash payment equal to a specified portion of the named executive officer's base salary (18 months for Dr. Cui and 12 months for each of Mr. Keyes and Dr. Oxnard), (ii) a lump sum cash payment equal to a specified percentage of the named executive officer's annual target bonus for the year in which the change in control termination occurs (150% for Dr. Cui and 100% for each of Mr. Keyes and Dr. Oxnard), (iii) payment of COBRA premiums for the duration of the applicable severance period (18 months for Dr. Cui and 12 months for each of Mr. Keyes and Dr. Oxnard), and (iv) accelerated vesting of all then-outstanding and unvested time-based equity awards held by the named executive officer.

All severance benefits under our Severance Plan are subject to the named executive officer's execution (and non-revocation) of an effective release of claims against us.

Our named executive officers' equity awards are further subject to the terms of our 2020 Plan and 2026 Plan, as applicable, and the applicable award agreements thereunder. A description of the termination and change in control provisions in our 2020 Plan and 2026 Plan and awards granted thereunder is provided below under "—Equity Benefit Plans," and a description of the vesting provisions of each equity award held by our named executive officers which is outstanding and unvested as of December 31, 2025 is provided above under "—Outstanding equity awards as of December 31, 2025."

Other compensation and benefits

All of our current named executive officers are eligible to participate in our employee benefit plans, which includes medical, dental and life insurance coverage, in each case on the same basis as all of our other employees. We pay a portion of the premiums for the medical and dental insurance, including our named executive officers. We generally do not provide perquisites or personal benefits to our named executive officers. In addition, we provide the opportunity to participate in a 401(k) plan to our employees, including each of our named executive officers, as discussed in the subsection titled "—401(k) plan" below.

401(k) plan

Our named executive officers are eligible to participate in a defined contribution retirement plan that provides eligible employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees may defer eligible compensation on a pre-tax or after-tax (Roth) basis, up to the statutorily prescribed annual limits on contributions under the Internal Revenue Code of 1986, as amended (Code). Contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. The 401(k) plan is intended to be qualified under Section 401(a) of the Code with the 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan (except for Roth contributions) and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan. Our board of directors may elect to adopt qualified or nonqualified benefit plans in the future, if it determines that doing so is in our best interests.

Clawback policy

In connection with this offering, we have adopted a compensation recovery policy that is compliant with the Nasdaq Listing Rules, as required by the Dodd-Frank Act, to be effective upon the consummation of this offering.

Equity benefit plans

We believe that our ability to grant equity-based awards is a valuable and necessary compensation tool that aligns the long-term financial interests of our employees, consultants and directors with the financial interests

of our stockholders. In addition, we believe that our ability to grant stock options and other equity-based awards helps us to attract, retain and motivate employees, consultants and directors, and encourages them to devote their best efforts to our business and financial success. The principal features of our equity incentive plans are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which are filed as exhibits to the registration statement of which this prospectus forms a part.

2026 Equity incentive plan

Our board of directors adopted our 2026 Plan in June 2026 and our stockholders approved our 2026 Plan in July 2026. Our 2026 Plan is a successor to our 2020 Plan and became effective on the execution of the underwriting agreement related to this offering. No further grants will be made under our 2020 Plan.

Types of awards. Our 2026 Plan provides for the grant of incentive stock options (ISOs) to employees, including employees of any parent or subsidiary, and for the grant of nonstatutory stock options (NSOs), stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of stock awards to employees, directors, and consultants, including employees and consultants of our affiliates.

Authorized shares. Initially, the maximum number of shares of our common stock that may be issued under our 2026 Plan will be 5,280,528 shares, which is the sum of: (i) 3,781,612 new shares, plus (ii) 168,984 shares available for issuance under the 2020 Plan as of the effective date of the 2026 Plan, plus (iii) up to 1,329,932 shares subject to outstanding awards under the 2020 Plan that, following the effective date of the 2026 Plan, are not issued because such awards expire, are settled in cash, or are forfeited, or such shares are withheld to satisfy the exercise price thereof or to satisfy tax withholding obligations. In addition, the number of shares of our common stock reserved for issuance under our 2026 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2027 through January 1, 2036, in an amount equal to 5.0% of the total number of shares of our capital stock (including shares issuable upon exercise, conversion, or exchange of all then-outstanding pre-funded warrants, or other rights exercisable for or convertible into, directly or indirectly, shares of common stock (whether vested or unvested), but excluding shares issuable upon the exercise of then-outstanding options and the shares reserved and available for issuance under our then-existing equity incentive plan(s) and employee stock purchase plan(s), if any) outstanding as of the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by our board of directors. The maximum number of shares of our common stock that may be issued on the exercise of ISOs under our 2026 Plan is 15,841,584 shares.

Shares subject to stock awards granted under our 2026 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, do not reduce the number of shares available for issuance under our 2026 Plan. Additionally, shares become available for future grant under our 2026 Plan if they were issued under stock awards under our 2026 Plan and we repurchase them or they are forfeited. This includes shares used to pay the exercise price of a stock award or to satisfy the tax withholding obligations related to a stock award.

Plan administration. Our board of directors, or a duly authorized committee of our board of directors (referred to herein as the plan administrator), will administer our 2026 Plan. Our board of directors may also delegate to one or more persons or bodies the authority to do one or more of the following (i) designate recipients (other than officers) of specified stock awards provided that no person or body may be delegated authority to grant a stock award to themselves; (ii) determine the number of shares subject to such stock award; and (iii) determine the terms of such stock awards. Under our 2026 Plan, our board of directors has the authority to determine and amend the terms of awards and underlying agreements, including recipients, the exercise, purchase or strike price of stock awards, if any, the number of shares subject to each stock award, the vesting schedule applicable

to the awards, together with any vesting acceleration and the form of consideration, if any, payable on exercise or settlement of the award.

In addition, subject to the terms of the 2026 Plan, the administrator also has the power to modify outstanding awards under our 2026 Plan, including the authority to reprice any outstanding option or stock appreciation right, cancel and re-grant any outstanding option or stock appreciation right in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any materially adversely affected participant.

Stock options. ISOs and NSOs are granted under stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for stock options, within the terms and conditions of the 2026 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2026 Plan vest at the rate specified in the stock option agreement as determined by the plan administrator.

Tax limitations on ISOs. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an option holder during any calendar year under all of our stock plans may not exceed \$100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant; and (ii) the option is not exercisable after the expiration of five years from the date of grant.

Restricted stock unit awards. Restricted stock units are granted under restricted stock unit award agreements adopted by the plan administrator. Restricted stock units may be granted in consideration for any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. A restricted stock unit may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit. Except as otherwise provided in the applicable award agreement, restricted stock units that have not vested will be forfeited once the participant's continuous service ends for any reason.

Restricted stock awards. Restricted stock awards are granted under restricted stock award agreements adopted by the plan administrator. A restricted stock award may be awarded in consideration for cash, check, bank draft or money order, past services to us, or any other form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. The plan administrator determines the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with us ends for any reason, we may receive any or all of the shares of our common stock held by the participant that have not vested as of the date the participant terminates service with us through a forfeiture condition or a repurchase right.

Stock appreciation rights. Stock appreciation rights are granted under stock appreciation grant agreements adopted by the plan administrator. The plan administrator determines the purchase price or strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. A stock appreciation right granted under the 2026 Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator.

Performance awards. The 2026 Plan permits the grant of performance-based stock and cash awards. The plan administrator may structure awards so that the shares of our stock, cash, or other property will be issued or paid only following the achievement of certain pre-established performance goals during a designated

performance period. The performance criteria that will be used to establish such performance goals may be based on any one of, or combination of, the following as determined by the plan administrator: earnings (including earnings per share and net earnings); earnings before interest, taxes and depreciation; earnings before interest, taxes, depreciation and amortization; total stockholder return; return on equity or average stockholder's equity; return on assets, investment, or capital employed; share price; margin (including gross margin); income (before or after taxes); operating income; operating income after taxes; pre-tax profit; operating cash flow; sales or revenue targets; increases in revenue or product revenue; expenses and cost reduction goals; improvement in or attainment of working capital levels; economic value added (or an equivalent metric); market share; cash flow; cash flow per share; share price performance; debt reduction; customer satisfaction; stockholder's equity; capital expenditures; debt levels; operating profit or net operating profit; growth of net income or operating income; billings; financing; regulatory milestones; stockholder liquidity; corporate governance and compliance; intellectual property; personnel matters; progress of internal research; progress of partnered programs; partner satisfaction; budget management; partner or collaborator achievements; internal controls, including those related to the Sarbanes-Oxley Act of 2002; investor relations, analysts and communication; implementation or completion of projects or processes; employee retention; number of users, including unique users; strategic partnerships or transactions (including in-licensing and out-licensing of intellectual property); establishing relationships with respect to the marketing, distribution and sale of our products; supply chain achievements; co-development, co-marketing, profit sharing, joint venture or other similar arrangements; individual performance goals; corporate development and planning goals; and other measures of performance selected by the plan administrator.

The performance goals may be based on a company-wide basis, with respect to one or more business units, divisions, affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise (i) in the award agreement at the time the award is granted or (ii) in such other document setting forth the performance goals at the time the goals are established, we will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock based compensation and the award of bonuses under our bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; and (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles. In addition, we retain the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of the goals. The performance goals may differ from participant to participant and from award to award.

Other stock awards. The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the stock award and all other terms and conditions of such awards.

Non-employee director compensation limit. The aggregate value of all compensation granted or paid to any non-employee director with respect to any fiscal year following the year in which the underwriting agreement for this offering is executed, including stock awards granted and cash fees paid by us to such non-employee director, will not exceed \$750,000 in total value, or in the event such non-employee director is first appointed or elected to the board of directors during such fiscal year, \$1,000,000 in total value (in each case, calculating the value of any such stock awards based on the grant date fair value of such stock awards for financial reporting purposes).

Changes to capital structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split, or recapitalization, appropriate adjustments will be made to (i) the class and maximum number of shares reserved for issuance under the 2026 Plan; (ii) the class and maximum number of shares by which the share reserve may increase automatically each year; (iii) the class and maximum number of shares that may be issued on the exercise of ISOs; and (iv) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

Corporate transactions. The following applies to stock awards under the 2026 Plan in the event of a corporate transaction, unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the plan administrator at the time of grant.

In the event of a corporate transaction (as defined in the 2026 Plan), any stock awards outstanding under the 2026 Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the stock award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full to a date prior to the effective time of the transaction (contingent upon the effectiveness of the transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the transaction, and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse (contingent upon the effectiveness of the transaction). With respect to performance awards with multiple vesting levels depending on performance level, unless otherwise provided by an award agreement or by the plan administrator, the award will accelerate at 100% of target. If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then with respect to any such stock awards that are held by persons other than current participants, such awards will terminate if not exercised (if applicable) prior to the effective time of the transaction, except that any reacquisition or repurchase rights held by us with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the transaction. The plan administrator is not obligated to treat all stock awards or portions of stock awards in the same manner and is not obligated to take the same actions with respect to all participants.

In the event a stock award will terminate if not exercised prior to the effective time of a transaction, the plan administrator may provide, in its sole discretion, that the holder of such stock award may not exercise such stock award but instead will receive a payment equal in value to the excess (if any) of (i) the value of the property the participant would have received upon the exercise of the stock award over (ii) any exercise price payable by such holder in connection with such exercise.

Under our 2026 Plan, a corporate transaction is defined to include: (i) a sale of all or substantially all of our assets; (ii) the sale or disposition of more than 50% of our outstanding securities; (iii) the consummation of a merger or consolidation where we do not survive the transaction; and (iv) the consummation of a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding before such

transaction are converted or exchanged into other property by virtue of the transaction, unless otherwise provided in an award agreement or other written agreement between us and the award holder.

Change in control. In the event of a change in control, as defined under our 2026 Plan, awards granted under our 2026 Plan will not receive automatic acceleration of vesting and exercisability, although this treatment may be provided for in an award agreement.

Under the 2026 Plan, a change in control is defined to include (i) the acquisition by any person or company of more than 50% of the combined voting power of our then outstanding stock; (ii) a merger, consolidation or similar transaction in which our stockholders immediately before the transaction do not own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity); (iii) a sale, lease, exclusive license or other disposition of all or substantially all of our assets other than to an entity more than 50% of the combined voting power of which is owned by our stockholders; and (iv) an unapproved change in the majority of the board of directors.

Clawback. All awards granted under the 2026 Plan will be subject to recoupment in accordance with any clawback policy that we are required to adopt pursuant to the listing standards of any national securities exchange or association on which our securities are listed or as is otherwise required by the U.S. Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, our board of directors may impose such other clawback, recovery or recoupment provisions in a stock award agreement as our board of directors determines necessary or appropriate.

Transferability. A participant may not transfer stock awards under our 2026 Plan other than by will, the laws of descent and distribution, or as otherwise provided under our 2026 Plan.

Plan amendment or termination. Our board of directors has the authority to amend, suspend, or terminate our 2026 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted our 2026 Plan. No stock awards may be granted under our 2026 Plan while it is suspended or after it is terminated.

2026 Employee stock purchase plan

Our board of directors adopted our ESPP in June 2026 and our stockholders approved our ESPP in July 2026. The ESPP became effective upon the execution of the underwriting agreement for this offering. The purpose of the ESPP is to secure and retain the services of new employees, to retain the services of existing employees, and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. Our ESPP will include two components. One component will be designed to allow eligible U.S. employees to purchase our common stock in a manner that may qualify for favorable tax treatment under Section 423 of the Code. The other component will permit the grant of purchase rights that do not qualify for such favorable tax treatment in order to allow deviations necessary to permit participation by eligible employees who are foreign nationals or employed outside of the United States while complying with applicable foreign laws.

Share reserve. The ESPP authorizes the issuance of 302,529 shares of our common stock under purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, beginning on January 1, 2027 through January 1, 2036, by the lesser of (i) 1.0% of the total number of shares of our capital stock (including shares issuable upon exercise, conversion, or exchange of all then-outstanding pre-funded

warrants, or other rights exercisable for or convertible into, directly or indirectly, shares of common stock (whether vested or unvested), but excluding shares issuable upon the exercise of then-outstanding options and the shares reserved and available for issuance under our then-existing equity incentive plan(s) and employee stock purchase plan(s), if any) outstanding as of the last day of the calendar month before the date of the automatic increase; and (ii) 907,587 shares; provided that before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). As of the date hereof, no shares of our common stock have been purchased under the ESPP.

Administration. Our board of directors, or a duly authorized committee thereof, will administer our ESPP. Our board of directors may delegate concurrent authority to administer the ESPP to our compensation committee under the terms of the compensation committee's charter. The ESPP is implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our common stock on specified dates during such offerings. Under the ESPP, we may specify offerings with durations of not more than 27 months and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering under the ESPP may be terminated under certain circumstances.

Payroll deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings (as defined in the ESPP) for the purchase of our common stock under the ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for the accounts of employees participating in the ESPP at a price per share that is at least the lesser of (i) 85% of the fair market value of a share of our common stock on the first date of an offering; or (ii) 85% of the fair market value of a share of our common stock on the date of purchase.

Limitations. Employees may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by our board of directors, including: (i) customary employment with us or one of our affiliates for more than 20 hours per week and more than five months per calendar year; or (ii) continuous employment with us or one of our affiliates for a minimum period of time (not to exceed two years). No employee may purchase shares under the ESPP at a rate in excess of \$25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value under Section 424(d) of the Code.

Changes to capital structure. In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or similar transaction, the board of directors will make appropriate adjustments to: (i) the number of shares reserved under the ESPP; (ii) the maximum number of shares by which the share reserve may increase automatically each year; (iii) the number of shares and purchase price of all outstanding purchase rights; and (iv) the number of shares that are subject to purchase limits under ongoing offerings.

Corporate transactions. In the event of certain significant corporate transactions (as defined in the ESPP), including: (i) a sale of all or substantially all of our assets; (ii) the sale or disposition of more than 50% of our outstanding securities; (iii) the consummation of a merger or consolidation where we do not survive the transaction; and (iv) the consummation of a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the

ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue, or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within ten business days before such corporate transaction, and such purchase rights will terminate immediately.

ESPP amendment or termination. Our board of directors has the authority to amend or terminate our ESPP, provided that except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

2020 Equity incentive plan

Our board of directors adopted, and our stockholders approved, our 2020 Plan in June 2020. Our 2020 Plan was most recently amended in March 2025. The 2020 Plan terminated on the date the 2026 Plan became effective, and thereafter no further stock awards will be granted under the 2020 Plan. However, any outstanding stock awards granted under the 2020 Plan will remain outstanding, subject to the terms of our 2020 Plan and award agreements, until such outstanding stock awards are exercised or until such outstanding stock awards terminate or expire by their terms.

Types of awards. Our 2020 Plan provides for the grant of ISOs to employees, including employees of our affiliates, and for the grant of NSOs, stock bonuses and rights to acquire restricted stock to employees, directors, and consultants, including employees and consultants of our affiliates.

Share reserve. Subject to certain capitalization adjustments, the common stock that may be issued pursuant to stock awards under the 2020 Plan will not exceed in the aggregate 1,921,534 shares of our common stock. The shares of our common stock subject to the 2020 Plan may be unissued shares or reacquired shares, bought on the market or otherwise. As of December 31, 2025, only options have been granted under the 2020 Plan.

Administration. Our board of directors or one or more duly authorized committees of our board of directors (referred to herein as the plan administrator) administers our 2020 Plan and the stock awards granted under it. Under our 2020 Plan, the board has the power, subject to, and within the limitations of, the express provisions of the 2020 Plan (i) to determine from time to time which of the persons eligible under the 2020 Plan will be granted stock awards; when and how each stock award will be granted; what type or combination of types of stock award will be granted; the provisions of each stock award granted; and the number of shares of our common stock with respect to which a stock award will be granted to each such person; (ii) to construe and interpret the 2020 Plan and stock awards granted under it, and to establish, amend and revoke rules and regulations for its administration; (iii) to amend the 2020 Plan or a stock award; (iv) to terminate or suspend the 2020 Plan; and (v) generally, to exercise such powers and to perform such acts as our board of directors deems necessary or expedient to promote our best interests and that are not in conflict with the provisions of the 2020 Plan.

Options. Each option under the 2020 Plan will be in such form and will contain such terms and conditions as determined by the plan administrator. The exercise price of an ISO under the 2020 Plan generally will not be less than 100% of the fair market value of our common stock on the date of grant (or 110% of the fair market value for certain major stockholders). The exercise price of an NSO under the 2020 Plan generally will not be less than 85% of the fair market value of our common stock on the date of grant.

The purchase price of shares of our common stock acquired pursuant to an option under the 2020 Plan will be paid, to the extent permitted by applicable statutes and regulations, either (i) in cash at the time the option is

exercised or (ii) at the discretion of the plan administrator at the time the option is granted (or subsequently in the case of an NSO) (1) by delivery to us of other shares of our common stock, (2) according to a deferred payment or other similar arrangement with the optionholder or (3) in any other form of legal consideration that may be acceptable to the plan administrator.

ISOs are not transferable except by will or by the laws of descent and distribution and are exercisable during the lifetime of the optionholder only by the optionholder. NSOs generally are transferable to the extent provided in the option agreement. If an NSO does not provide for transferability, then the NSO is not transferable except by will or by the laws of descent and distribution and is exercisable during the lifetime of the optionholder only by the optionholder.

In the event that an optionholder's continuous service terminates (other than upon the optionholder's death or disability), the optionholder may exercise his or her option (to the extent that the optionholder was entitled to exercise such option as of the date of termination) but only within such period of time ending on the earlier of (i) the date three months following the termination of the optionholder's continuous service (or such longer or shorter period specified in the option agreement), or (ii) the expiration of the term of the option as set forth in the option agreement. If, after termination, the optionholder does not exercise his or her option within the time specified in the option agreement, the option will terminate.

Corporate transactions. In the event of a corporate transaction (as defined in the 2020 Plan), including: (i) a sale of all or substantially all of our assets; (ii) the sale or disposition of at least 90% of our outstanding securities; (iii) the consummation of a merger or consolidation where we do not survive the transaction; and (iv) the consummation of a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction, then any surviving corporation or acquiring corporation may assume any or all stock awards outstanding under the 2020 Plan or may substitute similar stock awards for stock awards outstanding under the 2020 Plan. In the event that any surviving corporation or acquiring corporation does not assume any or all such outstanding stock awards or substitute similar stock awards for such outstanding stock awards, then with respect to stock awards that have been neither assumed nor substituted and that are held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction, the vesting of such stock awards will (contingent upon the effectiveness of the corporate transaction) be accelerated in full to a date prior to the effective time of such corporate transaction as determined by our board of directors, and the stock awards will terminate if not exercised (if applicable) at or prior to such effective time. With respect to any other stock awards outstanding under the 2020 Plan that have been neither assumed nor substituted, the vesting of such stock awards will not be accelerated unless otherwise provided in a written agreement between us or any affiliate and the holder of such stock award, and such stock awards will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction.

Capitalization adjustments. In the event of certain changes in our capitalization, the 2020 Plan will be appropriately adjusted in the class(es) and maximum number of securities subject to the 2020 Plan and the maximum number of securities subject to award to any person, and the outstanding stock awards under the 2020 Plan will be appropriately adjusted in the class(es) and number of securities and price per share of our common stock subject to such outstanding stock awards.

Plan amendment or termination. Our board of directors may amend, suspend, or terminate the 2020 Plan at any time. Unless terminated sooner, the 2020 Plan will automatically terminate on June 29, 2030. No stock awards may be granted under the 2020 Plan while it is suspended or after it is terminated.

Director compensation

Historically, we have not had a formal compensation policy with respect to service on our board of directors, and in 2025, we did not provide compensation to any of our non-employee directors (all of whom are investor designee directors) related to their board service.

Each of Dr. Cui, our President and Chief Executive Officer, and Y. Peter Li, Ph.D., MBA, the Executive Chairman of our board of directors, is a member of our board of directors and an employee of the Company, but does not receive any additional compensation for service as a director. The compensation earned by or paid to Dr. Cui as a named executive officer for the fiscal year ended December 31, 2025 is set forth above under “—Summary compensation table for the year ended December 31, 2025.” Dr. Li received compensation in 2025 pursuant to his employment with us as Executive Chairman, as shown in the table and described below. Dr. Agrawal received compensation in 2025 pursuant to his consulting agreement with us, as shown in the table and described below.

The following table sets forth information regarding the compensation earned by or paid to our non-employee directors and Dr. Li during the fiscal year ended December 31, 2025.

Name	Non-equity incentive plan compensation (\$)	Option awards (\$) ⁽¹⁾	All other compensation (\$)	Total (\$)
Sundeep Agrawal, M.D.	—	—	46,439 ⁽²⁾	46,439
Bihua Chen, MBA	—	—	—	—
Carl L. Gordon, Ph.D., CFA	—	—	—	—
George Lee, Ph.D.	—	—	—	—
Y. Peter Li, Ph.D., MBA	160,000 ⁽³⁾	—	414,000 ⁽⁴⁾	574,000
Timothy Stubbs, M.D. ⁽⁵⁾	—	—	—	—

(1) As of December 31, 2025, Dr. Agrawal held an outstanding option to purchase 10,671 shares of our common stock. As of December 31, 2025, neither our other non-employee directors nor Dr. Li held options to purchase shares of our common stock. As of December 31, 2025, none of our non-employee directors or Dr. Li held any unvested stock awards.

(2) Amount reflects the aggregate grant date fair value of a stock option granted to Dr. Agrawal pursuant to the Agrawal Consulting Agreement (as described below) during the year ended December 31, 2025, computed in accordance with FASB ASC Topic 718. See Note 2 to our financial statements included elsewhere in this prospectus for a discussion of the assumptions used in the calculation.

(3) The amount disclosed represents a performance-based bonus earned by Dr. Li with respect to the year ended December 31, 2025, in connection with his employment with us as Executive Chairman, as described in the subsection below titled “—Li employment agreement.”

(4) The amount disclosed represents (i) \$400,000 in base salary earned by Dr. Li in 2025 in connection with his employment with us as Executive Chairman, as described in the subsection below titled “—Li employment agreement,” and (ii) \$14,000 in 401(k) matching contributions, as described in the subsection above titled “—401(k) plan.”

(5) Dr. Stubbs resigned from our board of directors effective as of immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

Agrawal consulting agreement

In August 2025, we entered into a consulting agreement with Dr. Agrawal (Agrawal Consulting Agreement), pursuant to which Dr. Agrawal agreed to render general advisory services in the field of business development and investor relations to us. As compensation for services provided to us pursuant to the Agrawal Consulting Agreement, in August 2025, Dr. Agrawal received a nonqualified option to purchase 10,671 shares of our common stock under our 2020 Plan, which vests in equal monthly installments over the 12-month period starting on the one-month anniversary of the vesting commencement date.

Li employment agreement

Effective March 2021, we entered into an executive employment agreement with Dr. Li in connection with his service as our Executive Chairman (Li Agreement). Under the Li Agreement, Dr. Li's initial annual base salary was set at \$300,000 (which was increased to \$400,000 effective January 1, 2025), subject to review and adjustment from time to time. The Li Agreement also provides that Dr. Li is eligible to receive an annual discretionary bonus at a target amount of 40% of his then-current base salary, based upon our and Dr. Li's achievement of objectives and milestones to be determined on an annual basis by our board of directors. On July 31, 2026, we entered into an amended and restated executive employment agreement with Dr. Li in connection with his service as our Executive Chairman (A&R Li Agreement), which became effective upon the effectiveness of the registration statement of which this prospectus forms a part. Under the A&R Li Agreement, Dr. Li's annual base salary is set at \$490,000, subject to review and adjustment from time to time. The A&R Li Agreement also provides that Dr. Li is eligible to receive an annual discretionary bonus at a target amount of 40% of his then-current base salary, based upon our and Dr. Li's achievement of objectives and milestones to be approved by our board of directors.

In the event of certain qualifying terminations of his employment, Dr. Li will be entitled to receive severance benefits pursuant to our Severance Plan, consistent with those described above for Dr. Cui under "—Potential payments upon termination or change of control."

Li IPO option award

In July 2026, as described above under "Narrative to summary compensation table—IPO option grants," our board of directors approved the grant to Dr. Li of an option under our 2026 Plan to purchase 112,701 shares of our common stock, effective as of the effectiveness of the registration statement of which this prospectus forms a part and with an exercise price equal to the initial public offering price. The option will vest over a period of four years, with 25% of the option vesting on the first anniversary of the vesting commencement date and the remaining 75% of the option vesting ratably on a monthly basis thereafter, subject to Dr. Li's continuous service with us through each vesting date.

Non-employee director compensation policy

In June 2026, our board of directors adopted a non-employee director compensation policy (Director Compensation Policy), pursuant to which our non-employee directors will be eligible to receive compensation for service on our board of directors and committees of our board of directors, which became effective upon the execution and delivery of the underwriting agreement related to this offering. The Director Compensation Policy provides that each non-employee director will receive the following compensation for service on our board of directors:

- an annual cash retainer of \$40,000;
- an additional cash retainer of \$30,000 for service as lead independent director;
- an additional annual cash retainer of \$10,000, \$7,500, and \$5,000 for service as a non-chair member of the audit committee, compensation committee, and the nominating and corporate governance committee, respectively;
- an additional annual cash retainer of \$20,000, \$15,000, and \$10,000 for service as chairman of the audit committee, chairman of the compensation committee, and chairman of the nominating and corporate governance committee, respectively (in lieu of the committee member retainer above);

- an initial option grant to purchase 23,904 shares of our common stock, vesting in equal monthly installments over 3 years from the date of grant; and
- an annual option grant to purchase 11,952 shares of our common stock, vesting on the earlier of (i) the date that is 12 months following the date of grant or (ii) the date of the next annual meeting.

Each of the option grants described above will be granted under our 2026 Plan, the terms of which are described in more detail above under “Equity benefit plans—2026 Equity incentive plan.” Each such option grant will vest and become exercisable subject to the director’s continuous service with us, provided that each option will vest in full upon a change in control (as defined in the 2026 Plan) of the company. The term of each option will be 10 years, subject to earlier termination as provided in the 2026 Plan.

Non-employee director IPO option awards

In July 2026, our board of directors also approved the grant of an initial option under our 2026 Plan to purchase 23,904 shares of our common stock, effective as of the effectiveness of the registration statement of which this prospectus forms a part and with an exercise price equal to the initial public offering price, to each of the following non-employee directors (who had not previously received equity grants in respect of their service as non-employee directors): Dr. Agrawal, Ms. Chen and Dr. Gordon. The terms of such option grants are as set forth above with respect to initial option grants under our Director Compensation Policy.

Limitations of liability and indemnification matters

Our amended and restated certificate of incorporation that will become effective immediately prior to the closing of this offering limits the liability of our current and former directors and officers for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors and officers of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors or officers, except liability for:

- any breach of the director’s or officer’s duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- as a director, unlawful payments of dividends or unlawful stock repurchases or redemptions;
- as an officer, derivative claims brought on behalf of the corporation by a stockholder; or
- any transaction from which the director or officer derived an improper personal benefit.

This limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation will authorize us to indemnify our directors, officers, employees, and other agents to the fullest extent permitted by Delaware law. Our amended and restated bylaws will provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our amended and restated bylaws will also provide that, on satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee, or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers, and other employees as determined by the board of directors. With certain exceptions, these agreements provide for indemnification for related expenses including attorneys’ fees, judgments, fines, and settlement amounts incurred by any of these individuals in any action or proceeding.

We believe that the amended and restated certificate of incorporation, amended and restated bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended (Securities Act), may be permitted for directors, executive officers, or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

At present, there is no pending litigation or proceeding involving any of our directors, executive officers or employees for which indemnification is sought, and we are not aware of any threatened litigation that may result in claims for indemnification.

Rule 10b5-1 sales plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or executive officer when entering into the plan, without further direction from them. The director or executive officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a Rule 10b5-1 plan at any time. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information subject to compliance with the terms of our insider trading policy and any applicable Rule 10b5-1 guidelines.

Certain relationships and related party transactions

The following includes a summary of transactions since January 1, 2023, to which we have been a party, in which the amount involved in the transaction exceeded the lesser of \$120,000 or 1% of the average of our total assets as of December 31, 2024 and 2025, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock at the time of such transaction, or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described in the sections titled “Executive and director compensation” and “Executive and director compensation—Non-employee director compensation.”

Series B preferred stock financing

In December 2023 and January 2024, we issued and sold to investors, in our Series B preferred stock financing, an aggregate of 5,671,768 shares of our Series B preferred stock (Series B Preferred) at a purchase price of \$17.63 per share for aggregate cash proceeds of approximately \$100 million.

The following table summarizes the shares of Series B Preferred issued in our Series B preferred stock financing to holders of more than 5% of our capital stock and entities affiliated with our directors and executive officers.

Participants	Series B preferred	Aggregate purchase price (\$)
Entities affiliated with Cormorant Asset Management ⁽¹⁾	1,134,360	19,999,994
OrbiMed Private Investments VIII, LP ⁽²⁾	623,898	10,999,999
Colt Blossom Hill, LLC ⁽³⁾	582,777	10,274,994
Vivo Innovation Fund II Holdings, L.P. ⁽⁴⁾	340,308	5,999,997
RongShan, LLC ⁽⁵⁾	56,717	999,998
Jingwei Cui ⁽⁶⁾	35,448	624,999
Walter T. Liptak Revocable Trust ⁽⁷⁾	11,343	199,998

(1) Entities affiliated with Cormorant Asset Management LP hold more than 5% of our outstanding capital stock. The shares consist of (i) 1,052,460 shares purchased by Cormorant Private Healthcare Fund V, LP and (ii) 81,900 shares purchased by Cormorant Global Healthcare Master Fund, LP. Cormorant Asset Management LP is the investment manager to Cormorant Private Healthcare Fund V, LP and Cormorant Global Healthcare Master Fund, LP, and, in such capacity, exercises shared voting and dispositive power over the securities held by the entities affiliated with Cormorant Asset Management LP and may be deemed to beneficially own such securities. Bihua Chen, a member of our board of directors, serves as the managing member of Cormorant Asset Management LP and, as such, shares voting and dispositive power over the securities held by the entities affiliated with Cormorant Asset Management LP.

(2) OrbiMed Private Investments VIII, LP (OPI VIII) holds more than 5% of our outstanding capital stock. OrbiMed Capital GP VIII LLC (GP VIII) is the general partner of OPI VIII, and OrbiMed Advisors LLC (Advisors) is the managing member of GP VIII. By virtue of such relationships, GP VIII and Advisors may be deemed to have voting power and investment power over the securities held by OPI VIII and as a result, may be deemed to have beneficial ownership of such securities. Advisors exercises voting and investment power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and W. Carter Neild, each of whom disclaims beneficial ownership of the shares held by OPI VIII. Dr. Gordon, a member of our board of directors, is a Founding Member and Managing Partner at OrbiMed Advisors.

(3) Sundeep Agrawal, M.D., a member of our board of directors, was a General Partner at Colt Blossom Hill, LLC during a portion of the period encompassing the closings of the Series B preferred stock financing that occurred in December 2023 and January 2024, and, as such, may have been deemed to have voting and dispositive power over the securities held by Colt Blossom Hill, LLC.

(4) Vivo Innovation Fund II Holdings, L.P. holds more than 5% of our outstanding capital stock. Timothy Stubbs, M.D., a former member of our board of directors, has served as an Executive Director at Vivo Capital LLC since March 2022. Dr. Stubbs resigned from our board of directors effective as of immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

(5) Y. Peter Li, Ph.D., MBA, our Executive Chairman and a member of our board of directors, is manager of RongShan, LLC.

(6) Jingwei Cui is a sibling of J. Jean Cui, our President and Chief Executive Officer.

(7) Walter T. Liptak is a beneficiary and trustee of the Walter T. Liptak Revocable Trust. Vincent Liptak, J.D., Ph.D., MBA, our Executive Vice President and General Counsel, is a co-beneficiary and co-trustee of the Walter T. Liptak Revocable Trust.

Series B bridge preferred stock financing

In November and December 2025, we issued and sold to investors, in our Series B preferred stock bridge financing, an aggregate of 4,772,985 shares of our Series B Preferred at a purchase price of \$17.63 per share for aggregate cash proceeds of approximately \$84.2 million.

The following table summarizes the shares of Series B Preferred issued in our Series B bridge financing to holders of more than 5% of our capital stock and entities affiliated with our directors and executive officers.

Participants	Series B preferred	Aggregate purchase price (\$)
Janus Henderson Biotech Innovation Master Fund Limited ⁽¹⁾	1,134,361	19,999,997.89
Brahma BlossomHill Partners, LLC ⁽²⁾	578,524	10,199,999
Entities affiliated with Cormorant Asset Management ⁽³⁾	567,181	9,999,997
OrbiMed Private Investments VIII, LP ⁽⁴⁾	425,385	7,499,998
Vivo Innovation Fund II Holdings, L.P. ⁽⁵⁾	113,436	1,999,996
The Li and Cui Family Trust ⁽⁶⁾	113,435	1,999,996
RongShan, LLC ⁽⁷⁾	68,062	1,199,996
Jingwei Cui ⁽⁸⁾	28,359	499,999
Walter T. Liptak Revocable Trust ⁽⁹⁾	19,851	349,999

(1) Janus Henderson Biotech Innovation Master Fund Limited holds more than 5% of our outstanding capital stock.

(2) Sundee Agrawal, M.D., a member of our board of directors, is the Founder and Managing Partner of Brahma Capital, LLC, which manages Brahma BlossomHill Partners, LLC, and, as such, may be deemed to have voting and dispositive power over the securities held by Brahma BlossomHill Partners, LLC.

(3) Entities affiliated with Cormorant Asset Management LP hold more than 5% of our outstanding capital stock. See footnote (1) to the Series B Preferred Stock Financing table above. The shares consist of (i) 374,169 shares purchased by Cormorant Private Healthcare Fund VI, LP and (ii) 193,012 shares purchased by Cormorant Global Healthcare Master Fund, LP. Cormorant Asset Management LP is the investment manager to Cormorant Private Healthcare Fund VI, LP and Cormorant Global Healthcare Master Fund, LP, and, in such capacity, exercises shared voting and dispositive power over the securities held by the entities affiliated with Cormorant Asset Management LP and may be deemed to beneficially own such securities. Bihua Chen, a member of our board of directors, serves as the managing member of Cormorant Asset Management LP and, as such, shares voting and dispositive power over the securities held by the entities affiliated with Cormorant Asset Management LP.

(4) See footnote (2) to the Series B Preferred Stock Financing table above.

(5) See footnote (4) to the Series B Preferred Stock Financing table above.

(6) Y. Peter Li, Ph.D., MBA, our Executive Chairman and a member of our board of directors, is trustee of The Li and Cui Family Trust.

(7) See footnote (5) to the Series B Preferred Stock Financing table above.

(8) See footnote (6) to the Series B Preferred Stock Financing table above.

(9) See footnote (7) to the Series B Preferred Stock Financing table above.

Investor agreements

In connection with our convertible preferred stock financings, we entered into investor rights, right of first refusal and co-sale and voting agreements, which contain, among other things, registration rights, information rights, voting rights and rights of first refusal, with certain holders of our capital stock, including entities affiliated with Cormorant Asset Management LP, OrbiMed Private Investments VIII, LP, entities affiliated with Vivo Capital LLC, Janus Henderson Biotech Innovation Master Fund Limited, Y. Peter Li, Ph.D., MBA, Brahma BlossomHill Partners, LLC, the Walter T. Liptak Revocable Trust and certain of our other stockholders. These agreements will terminate upon the closing of this offering, except for the registration rights granted under our investor rights agreement (defined below), as more fully described in the section titled “Description of capital stock—Registration rights.” See also the section titled “Principal stockholders” for additional information regarding beneficial ownership of our capital stock.

Employment arrangements, severance benefit plan and indemnification agreements

We have entered into employment agreements with certain of our executive officers. For more information regarding these agreements with our named executive officers, see the section titled “Executive and director compensation—Employment arrangements with our named executive officers.”

We have also entered into agreements with our executive officers pursuant to which each such executive officer is a participant under our Severance Plan. For more information regarding the rights of our named executive officers under our Severance Plan, see the section titled “Executive and director compensation—Potential payments upon termination or change of control.”

Our amended and restated certificate of incorporation upon the closing of this offering will contain provisions limiting the liability of directors, and our amended and restated bylaws that will be in effect upon the closing of this offering will provide that we will indemnify each of our directors and officers to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws upon the closing of this offering will also provide our board of directors with discretion to indemnify our employees and other agents when determined appropriate by the board.

In addition, we have entered, and intend to enter, into an indemnification agreement with each of our directors and executive officers, which requires us to indemnify them. For more information regarding these agreements, see the section titled “Executive and director compensation—limitations of liability and indemnification matters.”

Stock option grants to directors and executive officers

We have granted stock options to our directors and executive officers, as more fully described in the section titled “Executive and director compensation.”

Directed share program

At our request, the underwriters have reserved for sale, at the initial public offering price, up to approximately 93,750 shares of our common stock being offered hereby (approximately 1%) to our directors, officers, employees, business associates, investors and friends and family of our directors, officers, employees, business associates and investors, as part of a directed share program. The directed share program will not limit the ability of our directors, officers and their family members, or holders of more than 5% of our capital stock, to purchase more than \$120,000 in value of our common stock. We do not currently know the extent to which these related persons will participate in our directed share program, if at all, or the extent to which they will purchase more than \$120,000 in value of our common stock.

Policies and procedures for related party transactions

Prior to the closing of this offering, we will adopt a written related person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and continuing oversight of “related person transactions.” For purposes of our policy only, a “related person transaction” is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any “related person” are participants involving an amount that exceeds the lesser of \$120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years. Transactions involving compensation for services provided to us as an employee, consultant or director are not considered related person transactions under this policy. A related person is any executive officer, director, nominee to become a director or a holder of more than 5% of any class of our voting securities, including any of their immediate

family members and affiliates, and entities owned or controlled by such persons or entities in which such person has a 5% or greater beneficial ownership interest.

Under the policy, where a transaction has been identified as a related person transaction, management must present information regarding the proposed related person transaction to our audit committee (or, where review by our audit committee would be inappropriate for reasons of conflict of interest or otherwise, to another independent body of our board of directors) for review. The presentation must include a description of, among other things, all of the parties thereto, the direct and indirect interests of the related persons, the purpose of the transaction, the material facts, the benefits of the transaction to us and whether any alternative transactions are available, an assessment of whether the terms are comparable to the terms available from unrelated third parties or to employees generally and management's recommendation. To identify related person transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related person transactions, our audit committee or another independent body of our board of directors takes into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties.

In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval.

Principal stockholders

The following table sets forth information with respect to the beneficial ownership of our capital stock as of June 30, 2026, as adjusted to reflect the sale of our common stock offered by us in this offering assuming no exercise of the underwriters' option to purchase additional shares, for:

- each of our named executive officers;
- each of our directors;
- all of our executive officers and directors as a group; and
- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock.

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership before the offering is based on 21,249,872 shares of our common stock outstanding as of June 30, 2026, assuming the automatic conversion of all outstanding shares of our convertible preferred stock into 18,258,960 shares of our common stock upon the closing of this offering. Applicable percentage ownership after the offering is based on the sale of 9,375,000 shares of our common stock in this offering, assuming no exercise by the underwriters of their option to purchase additional shares. In computing the number of shares beneficially owned by a person and the percentage ownership of such person, we deemed to be outstanding all shares subject to options held by the person that are currently exercisable, or exercisable within 60 days of June 30, 2026. However, except as described above, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed below is c/o BlossomHill Therapeutics, Inc., 10255 Science Center Drive, Suite 200, San Diego, California 92121. We believe, based on information provided to us, that each of the stockholders listed below has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

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The following table does not reflect any potential purchases by our executive officers, directors, their affiliated entities, certain other parties related to us pursuant to the directed share program, holders of more than 5% of our common stock in this offering or any equity awards granted to our executive officers or directors contingent on this offering. If any shares are purchased by and to the extent any such equity awards have been granted to these persons or entities, the number and percentage of shares of our common stock beneficially owned by them after this offering will differ from the amounts set forth in the following table.

Name of beneficial owner	Shares beneficially owned prior to offering		Shares beneficially owned after offering	
	Number	Percentage	Number	Percentage
5% or Greater Stockholders:				
J. Jean Cui, Ph.D. and Y. Peter Li, Ph.D., MBA and related affiliates ⁽¹⁾	3,973,138	18.7%	3,973,138	13.0%
Entities affiliated with Cormorant Asset Management LP ⁽²⁾	3,301,534	15.5%	3,301,534	10.8%
OrbiMed Private Investments VIII, LP ⁽³⁾	2,089,279	9.8%	2,089,279	6.8%
Vivo Innovation Fund II Holdings, L.P. ⁽⁴⁾	1,493,740	7.0%	1,493,740	4.9%
Janus Henderson Biotech Innovation Master Fund Limited ⁽⁵⁾	1,134,361	5.3%	1,134,361	3.7%
Named Executive Officers and Directors:				
J. Jean Cui, Ph.D. ⁽¹⁾	3,973,138	18.7%	3,973,138	13.0%
Y. Peter Li, Ph.D., MBA ⁽¹⁾	3,973,138	18.7%	3,973,138	13.0%
Geoff Oxnard, M.D. ⁽⁶⁾	75,861	*	75,861	*
Jason Keyes, MBA ⁽⁷⁾	54,818	*	54,818	*
Sundeep Agrawal, M.D. ⁽⁸⁾	589,195	2.8%	589,195	1.9%
Bihua Chen, MBA ⁽⁹⁾	3,301,534	15.5%	3,301,534	10.8%
Carl L. Gordon, Ph.D., CFA ⁽¹⁰⁾	2,089,279	9.8%	2,089,279	6.8%
Sheila Gujrathi, M.D. ⁽¹¹⁾	90,160	*	90,160	*
John Schmid, MBA ⁽¹²⁾	67,620	*	67,620	*
Timothy Stubbs, M.D. ⁽¹³⁾	—	—	—	—
All directors and executive officers as a group (11 persons) ⁽¹⁴⁾	10,371,004	48.4%	10,371,004	33.7%

* Represents beneficial ownership of less than 1%.

- (1) Consists of (i)(a) 1,600,682 shares of common stock issuable upon conversion of our Series Angel Preferred Stock and (b) 113,435 shares of common stock issuable upon conversion of our Series B Preferred, in each case held by The Li and Cui Family Trust, (ii) 124,779 shares of common stock issuable upon conversion of our Series B Preferred held by RongShan, LLC (RongShan), (iii) 1,067,121 shares of common stock held directly by Dr. Cui, and (iv) 1,067,121 shares of common stock held directly by Dr. Li. Both Dr. Cui and Dr. Li have voting and dispositive power over the securities held by The Li and Cui Family Trust, and both are beneficiaries and serve as trustees of such trust. Dr. Li is the manager of RongShan and may be deemed to have voting and dispositive power over the securities held by RongShan. Dr. Li disclaims beneficial ownership of the securities held by RongShan. Dr. Cui and Dr. Li are married, and each may be deemed to have indirect beneficial ownership of the securities held by each other.
- (2) Consists of (i) 1,052,460 shares of common stock issuable upon conversion of our Series B Preferred held by Cormorant Private Healthcare Fund V, LP, (ii) 1,228,315 shares of common stock issuable upon conversion of our Series A Preferred Stock held by Cormorant Private Healthcare Fund III, LP, (iii)(a) 371,678 shares of common stock issuable upon conversion of our Series A Preferred Stock and (b) 274,912 shares of common stock issuable upon conversion of our Series B Preferred, in each case held by Cormorant Global Healthcare Master Fund, LP, and (iv) 374,169 shares of common stock issuable upon conversion of our Series B Preferred held by Cormorant Private Healthcare Fund VI, LP. Cormorant Asset Management LP is the investment manager to Cormorant Private Healthcare Fund III, LP, Cormorant Private Healthcare Fund V, LP, Cormorant Private Healthcare Fund VI, LP and Cormorant Global Healthcare Master Fund, LP, and, in such capacity, exercises shared voting and dispositive power over the securities held by the entities affiliated with Cormorant Asset Management LP and may be deemed to beneficially own such securities. Bihua Chen, a member of our board of directors, serves as the managing member of Cormorant Asset Management LP and, as such, shares voting and dispositive power over the securities held by the entities affiliated with Cormorant Asset Management LP. The principal address for the Cormorant Asset Management LP entities is 200 Clarendon Street, 52nd Floor, Boston, Massachusetts 02116.

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- (3) Consists of (i) 1,039,996 shares of common stock issuable upon conversion of our Series A Preferred Stock and (ii) 1,049,283 shares of common stock issuable upon conversion of our Series B Preferred, in each case held by OrbiMed Private Investments VIII, LP. (OPI VIII). OrbiMed Capital GP VIII LLC (GP VIII) is the general partner of OPI VIII, and OrbiMed Advisors LLC (Advisors) is the managing member of GP VIII. By virtue of such relationships, GP VIII and Advisors may be deemed to have voting power and investment power over the securities held by OPI VIII and, as a result, may be deemed to have beneficial ownership of such securities. Advisors exercise voting and investment power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and W. Carter Neild, each of whom disclaims beneficial ownership of the shares held by OPI VIII. The principal business address of each of the foregoing entities is 601 Lexington Avenue, 54th Floor, New York, NY 10022.
- (4) Consists of (i) 1,039,996 shares of common stock issuable upon conversion of our Series A Preferred Stock and (ii) 453,744 shares of common stock issuable upon conversion of our Series B Preferred, in each case held by Vivo Innovation Fund II Holdings, L.P. Vivo Innovation II, LLC is the general partner of Vivo Innovation Fund II Holdings, L.P. Frank Kung, Edgar Engleman, Gaurav Aggarwal, Michael Chang and David Liu are voting members of Vivo Innovation II, LLC and have power to vote and dispose of the securities held by Vivo Innovation Fund II Holdings. None of such voting members have individual voting or investment power with respect to these securities, and each of such voting members disclaims beneficial ownership of such securities. Timothy Stubbs, M.D., a former member of our board of directors, has served as an Executive Director at Vivo Capital LLC since March 2022. The principal business address of each of the foregoing entities is c/o Vivo Capital LLC, 192 Lytton Avenue, Palo Alto, CA 94301.
- (5) Consists of 1,134,361 shares of common stock issuable upon conversion of our Series B Preferred held by Janus Henderson Biotech Innovation Master Fund Limited (JHBIF). Such securities may be deemed to be beneficially owned by Janus Henderson Investors US LLC (Janus), an investment adviser registered under the Investment Advisers Act of 1940, who acts as investment adviser for JHBIF and has the ability to make decisions with respect to the voting and disposition of the shares subject to the oversight of the board of directors of JHBIF. Under the terms of its management contract with JHBIF, Janus has overall responsibility for directing the investments of JHBIF in accordance with JHBIF's investment objective, policies and limitations. JHBIF has one or more portfolio managers appointed by and serving at the pleasure of Janus who makes decisions with respect to the disposition of these securities. The portfolio managers for JHBIF are: Andrew Acker, Daniel S. Lyons and Agustin Mohedas. The principal business address of JHBIF is c/o Janus Henderson Investors US LLC, 151 Detroit Street, Denver, Colorado 80206.
- (6) Consists of (i) 17,785 shares of common stock held directly and (ii) 58,076 shares of common stock subject to options that are exercisable within 60 days of June 30, 2026.
- (7) Consists of shares of common stock subject to options that are exercisable within 60 days of June 30, 2026.
- (8) Consists of (i) 10,671 shares of common stock subject to options held by Dr. Agrawal that are exercisable within 60 days of June 30, 2026, and (ii) 578,524 shares of common stock issuable upon conversion of our Series B Preferred held by Brahma BlossomHill Partners, LLC. Dr. Agrawal is the Founder and Managing Partner of Brahma Capital, LLC, which manages Brahma BlossomHill Partners, LLC. The principal business address of Brahma BlossomHill Partners, LLC is 713 Creek Bluff Drive, Keller, Texas 76248.
- (9) Consists of the securities described in footnote (2) above.
- (10) Consists of the securities described in footnote (3) above.
- (11) Consists of shares of common stock held directly, of which 88,282 remain subject to a right of repurchase as of June 30, 2026.
- (12) Consists of shares of common stock subject to options that are exercisable within 60 days of June 30, 2026.
- (13) Dr. Stubbs resigned from our board of directors effective as of immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.
- (14) Consists of (i) the shares described in footnotes (1) and (6)-(12) above, (ii) 106,712 shares of common stock held directly by Dr. Liptak, of which 22,231 remain subject to a right of repurchase as of June 30, 2026, and (iii) 22,687 shares of common stock issuable upon conversion of our Series B Preferred held by the Walter T. Liptak Revocable Trust (Liptak Trust). Dr. Liptak is a co-beneficiary and co-trustee of the Liptak Trust.

Description of capital stock

Upon the filing of our amended and restated certificate of incorporation and the closing of this offering, our authorized capital stock will consist of 700,000,000 shares of our common stock, par value \$0.0001 per share, and 10,000,000 shares of preferred stock, par value \$0.0001 per share. All of our authorized preferred stock upon the closing of this offering will be undesignated. The following is a summary of the rights of our common and preferred stockholders and some of the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to and upon the closing of this offering, respectively, and of the Delaware General Corporation Law (DGCL). This summary is not complete. For more detailed information, please see our amended and restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant provisions of the DGCL.

Common stock

Outstanding shares

As of March 31, 2026, we had 2,644,326 shares of our common stock outstanding held of record by 37 stockholders. This amount excludes our outstanding shares of convertible preferred stock, which will convert into 18,258,960 shares of our common stock in connection with the closing of this offering. Based on the number of shares of our common stock outstanding as of March 31, 2026, and assuming (i) the automatic conversion of all of our outstanding shares of convertible preferred stock, (ii) the Exercised Option Share Issuance, (iii) the issuance by us of 9,375,000 shares of our common stock in this offering and (iv) no exercise by the underwriters of their option to purchase additional shares, there will be 30,643,660 shares of our common stock outstanding upon the closing of this offering.

Voting

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of stockholders, except as otherwise expressly provided in our amended and restated certificate of incorporation or required by applicable law. There are no cumulative voting rights.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, the holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding-up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Rights, preferences and privileges

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Fully paid and nonassessable

All of our outstanding shares of our common stock are, and the shares of our common stock to be issued in this offering will be, fully paid and nonassessable.

Convertible preferred stock

As of March 31, 2026, there were 18,258,960 shares of convertible preferred stock outstanding, held of record by 77 stockholders.

In connection with the closing of this offering, all outstanding shares of convertible preferred stock will automatically convert into 18,258,960 shares of our common stock.

Under the amended and restated certificate of incorporation that will become effective immediately prior to the closing of this offering, our board of directors will have the authority, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control that may otherwise benefit holders of our common stock and may adversely affect the market price of the common stock and the voting and other rights of the holders of our common stock. We have no current plans to issue any shares of preferred stock.

Stock options

As of March 31, 2026, 1,128,299 shares of our common stock were issuable upon the exercise of outstanding stock options, issued under our 2020 Plan, at a weighted-average exercise price of \$5.54 per share. Subsequent to March 31, 2026, an additional 339,502 stock options were granted under our 2020 Plan at a weighted-average exercise price of \$12.78 per share, and subsequent to March 31, 2026, we issued 365,374 shares of our common stock upon the exercise of outstanding options, at a weighted-average exercise price of \$7.25 per share, of which 227,514 shares remain subject to a right of repurchase as of the date of this prospectus. For information regarding the terms of our equity incentive plans, see the section titled “Executive and director compensation—Equity benefit plans.”

Registration rights

Upon the closing of this offering, certain holders of shares of our common stock, including those issuable upon the automatic conversion of preferred stock, will be entitled to rights with respect to the registration of these securities under the Securities Act. These rights are provided under the terms of an amended and restated investor rights agreement (investor rights agreement) between us and holders of our preferred stock. These shares are collectively herein referred to as registrable securities. The investor rights agreement includes demand registration rights, Form S-3 registration rights and piggyback registration rights. All fees, costs and expenses of underwritten registrations under this agreement will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

Form S-1 demand registration rights

Beginning 180 days after the effective date of the registration statement of which this prospectus is a part, certain holders of registrable securities are entitled to demand registration rights. Under the terms of the investor rights agreement, we will be required, upon the request of the holders of at least 70% of our outstanding registrable securities, as defined in the investor rights agreement, to file a registration statement with respect to outstanding registrable securities having an anticipated aggregate gross offering price to the public, of at least \$15 million, and use best efforts to effect, as expeditiously as reasonably possible, the registration of all or a portion of their registrable securities for public resale. We are not obligated to take any action in response to such request (i) during the period starting from the date of filing of, and ending 180 days after the effective date of, our initial public offering, (ii) if we have already effected two registrations pursuant to such requests for registration on Form S-1, (iii) if within 30 days of receipt of a written request from initiating holders, the company gives notice to such holders of its intention to file a registration statement within 90 days, or (iv) if the initiating holders propose to dispose of shares of registrable securities that may be immediately registered on Form S-3. Additionally, if we furnish to the holders requesting such registration a certificate signed by our Chair stating that, in the good faith judgment of our board of directors, it would be seriously detrimental to us and our stockholders for such registration statement to either become effective at such time, then we shall have the right to defer taking action with respect to such filing, and any time periods with respect to filing or effectiveness thereof shall be tolled correspondingly, for a period of not more than 180 days after the request of the initiating holders is given; provided, however, that we may not invoke this right more than twice in any 12-month period, as described in the investor rights agreement.

Form S-3 demand registration rights

Pursuant to the investor rights agreement, if we are eligible to file a registration statement on Form S-3, we will be required, upon request of the holders of at least 30% of our outstanding registrable securities, as defined in the investor rights agreement, to register their registrable securities under the Securities Act so long as the total amount of registrable shares requested to be registered has an anticipated aggregate offering price to the public, net of selling expenses, of at least \$1 million. We are not obligated to take any action in response to such request if, within 30 days of receipt of a written request from initiating holders, we give notice to such holders of our intention to make a public offering within 90 days. We are required to effect only two registrations in any twelve-month period (and three registrations in the aggregate) pursuant to this provision of the investor rights agreement. Additionally, if we furnish to the holders requesting such registration a certificate signed by our Chair stating that, in the good faith judgment of our board of directors, it would be materially detrimental to us and our stockholders for such registration statement to either become effective at such time, then we shall have the right to defer taking action with respect to such filing, and any time periods with respect to filing or effectiveness thereof shall be tolled correspondingly, for a period of not more than 120 days after the request of the initiating holders is given; provided, however, that we may not invoke this right more than twice in any 12-month period, as described in the investor rights agreement.

Piggyback registration rights

If we propose to register any of our securities under the Securities Act in another offering, either for our own account or for the account of other security holders, the holders of registrable securities will be entitled to notice of the registration and will be entitled to include their shares of our common stock in the registration, subject to certain conditions and limitations, including the right of the underwriters to limit the number of shares included in such registration under specified circumstances.

Anti-takeover effects of provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and Delaware law

Delaware anti-takeover law

We are subject to Section 203 of the DGCL (Section 203). Section 203 generally prohibits a public Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a period of three years following the time that such stockholder became an interested stockholder, unless:

- prior to such time the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to such time, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a “business combination” to include (subject to exceptions):

- any merger or consolidation involving the corporation or any direct or indirect majority-owned subsidiary of the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder (in one transaction or a series of transactions);
- any transaction that results in the issuance or transfer by the corporation or by any direct or indirect majority-owned subsidiary of the corporation of any stock of the corporation or of such subsidiary to the interested stockholder;
- any transaction involving the corporation or any direct or indirect majority-owned subsidiary of the corporation that has the effect, directly or indirectly, of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit, directly or indirectly, of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an “interested stockholder” as any entity or person who, together with the person’s affiliates and associates, beneficially owns, or within the three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

A Delaware corporation may “opt out” of these provisions with an express provision in its original certificate of incorporation or an express provision in its amended and restated certificate of incorporation or amended and restated bylaws resulting from a stockholders’ amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Amended and restated certificate of incorporation and amended and restated bylaws

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to and upon the closing of this offering, respectively, may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66-2/3% of the voting power of all of our then outstanding common stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes with each class serving three-year staggered terms;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of our common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the Chair of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors;
- provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware and any appellate court therefrom shall be the sole and exclusive forum for: (i) any derivative claim or cause of action brought on our behalf, (ii) any claim or cause of action that is based upon a violation of a duty owed by any of our current or former director, officer, employees or stockholder, to us or our stockholders; (iii) any claim or cause of action against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our bylaws; (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our bylaws; (v) any claim or cause of action as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any claim or cause of action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees governed by the internal-affairs doctrine or otherwise related to our internal affairs, in all cases to the fullest extent permitted by applicable law and

subject to the court's having personal jurisdiction over the indispensable parties named as defendants; provided, however, that if the designation of such court as the sole and exclusive forum for a claim or action referred to in foregoing clauses (i) through (vi) would violate applicable law, then the U.S. District Court for the District of Delaware shall be the sole and exclusive forum for such claim or cause of action; and

- provide that unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters for any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66-2/3% of our then-outstanding common stock.

Exchange listing

Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol "BLSM."

Transfer agent and registrar

Upon the closing of this offering, the transfer agent and registrar for our common stock will be Computershare Trust Company, N.A. The transfer agent and registrar's address is 150 Royall Street, Canton, Massachusetts 02021, and its telephone number is (781) 575-4019.

Shares eligible for future sale

Prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of our common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock. Furthermore, because only a limited number of shares of our common stock will be available for sale shortly after this offering due to certain contractual and legal restrictions on resale described below, sales of substantial amounts of our common stock in the public market after such restrictions lapse, or the anticipation of such sales, could adversely affect the prevailing market price of our common stock and our ability to raise equity capital in the future.

Following the closing of this offering, based on 2,644,326 shares of our common stock outstanding as of March 31, 2026 and assuming (i) the issuance of shares of our common stock in this offering, (ii) the automatic conversion of all outstanding shares of our convertible preferred stock into 18,258,960 shares of our common stock, which will automatically occur upon the closing of the offering, (iii) the Exercised Option Share Issuance, and (iv) no exercise of the underwriters' option to purchase additional shares, we will have an aggregate of approximately 30,643,660 shares of our common stock outstanding.

Of these shares, all shares of our common stock sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares of our common stock purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act or any shares, including any shares purchased by any of our affiliates pursuant to our directed share program, subject to lock-up agreements. Shares purchased by our affiliates would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining shares of our common stock outstanding after this offering will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act, each of which is summarized below and, if subject to lock-up agreements, may only be sold after the expiration of the 180-day lock-up period. We expect that substantially all of these shares will be subject to a 180-day lock-up period under the lock-up and market stand-off agreements described below.

We may issue shares of our common stock from time to time as consideration for future acquisitions, investments or other corporate purposes. In the event any such acquisition, investment or other transaction is significant, the number of shares of our common stock that we may issue may also be significant. We may also grant registration rights covering those shares of our common stock issued in connection with any such acquisition, investment or other transaction.

In addition, shares of our common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements described below and Rules 144 and 701 under the Securities Act.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, an eligible stockholder is entitled to sell such shares without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. To be an eligible stockholder under Rule 144, such stockholder must not be deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and must have beneficially

owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144, subject to the expiration of the lock-up agreements described below.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates will be entitled to sell shares on expiration of the lock-up agreements described below. Beginning 90 days after the date of this prospectus, within any three-month period, such stockholders may sell a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 306,437 shares immediately after this offering; or
- the average weekly trading volume in our common stock on the Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale, provided in each case that we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 generally allows a stockholder who was issued shares under a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days, to sell these shares in reliance on Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits our affiliates to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares under Rule 701, subject to the expiration of the lock-up agreements described below and in the section titled “Underwriting.”

Form S-8 registration statement

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of our common stock subject to outstanding stock options and common stock issued or issuable under the 2020 Plan, the 2026 Plan and the ESPP. We expect to file the registration statement covering shares offered pursuant to these stock plans shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market subject to compliance with the resale provisions of Rule 144.

Lock-up agreements

We, our directors, executive officers and the holders of substantially all of our equity securities, have agreed with the underwriters that for a period of 180 days after the date of this prospectus, subject to specified exceptions as detailed further in the section titled “Underwriting,” we or they will not, except with the prior written consent of J.P. Morgan Securities LLC, Leerink Partners LLC and Guggenheim Securities, LLC, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to sell or otherwise dispose of or transfer any shares of our common stock or

any securities convertible into or exercisable or exchangeable for shares of our common stock, request or demand that we file a registration statement related to our common stock, or enter into any swap or other agreement that transfers to another, in whole or in part, directly or indirectly, the economic consequence of ownership of the common stock. Substantially all of our optionholders are subject to a market stand-off agreement with us, which imposes similar restrictions.

Upon expiration of the lock-up period, certain of our stockholders will have the right to require us to register their shares under the Securities Act. See the sections titled “Registration rights” below and “Description of capital stock—Registration rights.”

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above.

Registration rights

Upon the closing of this offering and the expiration or release from the terms of applicable lock-up agreements, holders of an aggregate of 18,258,960 shares of our common stock, which includes all of the shares of our common stock issuable upon the automatic conversion of our convertible preferred stock immediately prior to the closing of this offering, or their transferees, will be entitled to various rights with respect to the registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares subsequently purchased by affiliates. See the section titled “Description of capital stock—Registration rights” for additional information.

Rule 10b5-1 sales plans

After the closing of this offering, certain of our employees, including our executive officers, and/or directors, may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements relating to the offering described above.

Material U.S. federal income tax consequences to non-U.S. holders of our common stock

The following is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the acquisition, ownership, and disposition of our common stock issued pursuant to this offering. This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, does not address the potential application of the Medicare contribution tax on net investment income, the alternative minimum tax provisions of the Code, or the special tax accounting rules under Section 451(b) of the Code, and does not address any estate or gift tax consequences or any tax consequences arising under any state, local, or non-U.S. tax laws, or any U.S. federal tax laws other than U.S. federal income tax laws. This discussion is based on the Code and applicable Treasury Regulations promulgated thereunder, published rulings and administrative pronouncements of the Internal Revenue Service (IRS), and judicial decisions, all as in effect as of the date hereof. These authorities are subject to differing interpretations and may change, possibly retroactively, resulting in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This discussion is limited to non-U.S. holders who purchase our common stock pursuant to this offering and who hold our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all of the U.S. federal income tax consequences that may be relevant to a particular holder in light of such holder’s particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to holders subject to special rules under U.S. federal income tax laws, including but not limited to:

- certain former citizens or long-term residents of the United States;
- “controlled foreign corporations” or “foreign controlled foreign corporations”;
- “passive foreign investment companies”;
- corporations that accumulate earnings to avoid U.S. federal income tax;
- banks, financial institutions, investment funds, insurance companies, brokers, dealers, or traders in securities or foreign currencies;
- tax-exempt organizations and governmental organizations;
- tax-qualified retirement plans;
- “qualified foreign pension funds” as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds;
- persons that own, or have owned, actually or constructively, more than 5% of our stock at any time;
- persons who have elected to mark securities to market;
- persons holding our common stock as part of a hedging or conversion transaction or straddle, a constructive sale, or other risk reduction strategy or integrated investment;
- persons who acquire our common stock through the exercise of an employee option or otherwise as compensation; and

- corporations organized outside of the United States, any state thereof and the District of Columbia that are nonetheless treated as U.S. taxpayers for U.S. federal income tax purposes.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds our common stock, the U.S. federal income tax treatment of the partnership and the partners thereof generally depends on the status of the partner and the activities of the partnership. Partnerships holding our common stock and the partners in such partnerships are urged to consult their tax advisors about the particular U.S. federal income tax consequences to them of holding and disposing of our common stock.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING, AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, OR NON-U.S. TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS.

Definition of non-U.S. holder

For purposes of this discussion, the term “non-U.S. holder” means any beneficial owner of our common stock that is neither a “U.S. person” nor a partnership (including any entity or arrangement treated as a partnership) for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust (i) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (ii) that has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

Distributions on our common stock

As described in the section titled “Dividend policy,” we have not paid cash dividends on our common stock and do not anticipate paying cash dividends on our common stock for the foreseeable future. However, if we make cash or other property distributions on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts that exceed our current and accumulated earnings and profits and, therefore, are not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder’s tax basis in our common stock, but not below zero. Any amount distributed in excess of basis will be treated as gain realized on the sale or other disposition of our common stock and will be treated as described under the subsection titled “—Gain on disposition of our common stock” below.

Subject to the discussions below regarding effectively connected income, backup withholding and Sections 1471 through 1474 of the Code (commonly referred to as Foreign Account Tax Compliance Act (FATCA)), dividends paid to a non-U.S. holder generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish us or our paying agent with a valid IRS Form W-8BEN or

IRS Form W-8BEN-E (or applicable successor form) and satisfy applicable certification and other requirements. This certification must be provided to us or our paying agent before the payment of dividends and must be updated periodically. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries.

If a non-U.S. holder holds our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our common stock are effectively connected with such holder's U.S. trade or business (and, if required by an applicable tax treaty, are attributable to such holder's permanent establishment in the United States), the non-U.S. holder generally will be exempt from U.S. federal withholding tax, provided such non-U.S. holder complies with applicable certification and disclosure requirements. To claim the exemption, the non-U.S. holder generally must furnish a valid IRS Form W-8ECI (or applicable successor form) to the applicable withholding agent. However, any such effectively connected dividends paid on our common stock generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Non-U.S. holders that do not provide the required certification on a timely basis, but that qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

Gain on disposition of our common stock

Subject to the discussions below regarding backup withholding and FATCA, a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized on the sale or other taxable disposition of our common stock, unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States, and if required by an applicable income tax treaty, is attributable to a permanent establishment maintained by the non-U.S. holder in the United States;
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- our common stock constitutes a United States real property interest (USRPI), by reason of our status as a United States real property holding corporation (USRPHC), for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our common stock, and our common stock is not regularly traded on an established securities market as defined by applicable Treasury Regulations.

The determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of worldwide real property interests and our other assets used or held for use in a trade or business. We believe that we are not currently and do not anticipate becoming a USRPHC for U.S. federal income tax purposes, although there can be no assurance we will not become a USRPHC in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition of our common stock by a non-U.S. holder will not be subject to U.S. federal income tax if our common stock is "regularly

traded” (as defined by applicable Treasury Regulations) on an established securities market. Prospective investors are encouraged to consult their own tax advisors regarding the possible consequences to them if we are, or were to become, a USRPHC.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (unless an applicable income tax treaty provides for different treatment) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. A non-U.S. holder described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty) on gain realized upon the sale or other taxable disposition of our common stock, but such gain may be offset by certain U.S.-source capital losses (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Information reporting and backup withholding

Annual reports are required to be filed with the IRS and provided to each non-U.S. holder indicating the amount of distributions on our common stock paid to such holder and the amount of any tax withheld with respect to those distributions. These information reporting requirements apply regardless of whether such distributions constitute dividends and even if no withholding was required. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Backup withholding, currently at a 24% rate, generally will not apply to payments to a non-U.S. holder of dividends on, or the gross proceeds of a disposition of, our common stock provided the non-U.S. holder furnishes the required certification for its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E, or IRS Form W-8ECI, or certain other requirements are met. Backup withholding may apply if the applicable withholding agent has actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, the non-U.S. holder should consult with a U.S. tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-U.S. holder’s U.S. federal income tax liability, if any.

FATCA

FATCA imposes a U.S. federal withholding tax of 30% on certain payments made to a “foreign financial institution” (as specially defined under these rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding certain U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or an exemption applies. FATCA also generally will impose a U.S. federal withholding tax of 30% on certain payments made to a non-financial foreign entity unless such entity provides the withholding agent a certification identifying certain direct and indirect U.S. owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. FATCA currently applies to certain U.S. source payments such as dividends paid on our common stock. Under applicable Treasury Regulations and administrative guidance, withholding under FATCA would have applied to payments of gross proceeds from the sale or other disposition of stock, but under proposed Treasury

Regulations (the preamble to which specifies that taxpayers are permitted to rely on such proposed regulations pending finalization), no withholding would apply with respect to payments of gross proceeds.

Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of the FATCA rules on their investment in our common stock.

Underwriting

We are offering the shares of our common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC, Leerink Partners LLC and Guggenheim Securities, LLC are acting as lead book-running managers of the offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of our common stock listed next to its name in the following table:

Name	Number of shares
J.P. Morgan Securities LLC	3,562,500
Leerink Partners LLC	2,625,000
Guggenheim Securities, LLC	1,687,500
LifeSci Capital LLC	843,750
H.C. Wainwright & Co., LLC	656,250
Total	9,375,000

The underwriters are committed to purchase all the shares of our common stock offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the shares of our common stock directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$0.672 per share. After the initial offering of the shares to the public, if all of the shares of our common stock are not sold at the initial public offering price, the underwriters may change the offering price and the other selling terms. Sales of any shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to 1,406,250 additional shares of our common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased with this option to purchase additional shares, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of our common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the public offering price per share of our common stock less the amount paid by the underwriters to us per share of our common stock. The underwriting fee is \$1.12 per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Without option to purchase additional shares exercise	With full option to purchase additional shares exercise
Per share	\$ 1.12	\$ 1.12
Total	\$ 10,500,000	\$ 12,075,000

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately \$4.6 million. We have also agreed to reimburse the underwriters for certain of their expenses in an amount up to \$40,000.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that we will not (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, or submit to, or file with, the Securities and Exchange Commission a registration statement under the Securities Act relating to, any shares of our common stock or securities convertible into or exercisable or exchangeable for any shares of our common stock, or (ii) enter into any swap or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any shares of our common stock or any such other securities (regardless of whether any of these transactions are to be settled by the delivery of shares of our common stock or such other securities, in cash or otherwise), in each case without the prior written consent of the representatives for a period of 180 days after the date of this prospectus, other than the shares of our common stock to be sold in this offering.

The restrictions on our actions, as described above, do not apply to certain transactions, including (i) the issuance of shares of our common stock or securities convertible into or exercisable for shares of our common stock pursuant to the conversion or exchange of convertible or exchangeable securities or the exercise of warrants or options (including net or cashless exercise) outstanding on the date of the underwriting agreement and described in this prospectus; (ii) grants of stock options, stock awards, restricted stock, RSUs, or other equity awards and the issuance of shares of our common stock or securities convertible into or exercisable or exchangeable for shares of our common stock (whether upon the exercise, vesting or settlement of such equity awards) to our employees, officers, directors, advisors, or consultants pursuant to an equity compensation plan in effect as of the closing of this offering and described in this prospectus, provided that such recipients enter into a lock-up agreement with the underwriters; (iii) the issuance of up to 5% of the outstanding shares of our common stock, or securities convertible into, exercisable for, or which are otherwise exchangeable for, our common stock, or the entrance into an agreement to issue our common stock or any securities convertible into, exercisable for, or which are otherwise exchangeable for, our common stock immediately following the closing of this offering, in connection with any bona fide licensing, commercialization, joint ventures, technology transfer, acquisitions, mergers, development collaboration or other similar strategic transactions, provided that such recipients enter into a lock-up agreement with the underwriters; or (iv) the filing of any registration statement on Form S-8 relating to securities granted or to be granted pursuant to any plan in effect on the date of the underwriting agreement and described in this prospectus or any assumed benefit plan pursuant to an acquisition, merger or similar strategic transaction.

Our directors and executive officers, and substantially all of our shareholders (such persons, the lock-up parties) have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each lock-up party, with limited exceptions, for a period of 180 days after the date of this prospectus (such period, the restricted period), may not (and may not cause any of their direct or indirect affiliates to), without the prior written consent of the representatives, (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock (including,

without limitation, shares of our common stock or such other securities which may be deemed to be beneficially owned by such lock-up parties in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant (collectively with the shares of our common stock, the lock-up securities)), (ii) enter into any hedging, swap or other agreement or transaction that transfers, in whole or in part, any of the economic consequences of ownership of the lock-up securities, whether any such transaction described in clause (i) above or this clause (ii) is to be settled by delivery of lock-up securities, in cash or otherwise, (iii) make any demand for, or exercise any right with respect to, the registration of any lock-up securities, or (iv) publicly disclose the intention to do any of the foregoing. Such persons or entities have further acknowledged that these undertakings preclude them from engaging in any hedging or other transactions or arrangements (including, without limitation, any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) designed or intended, or which could reasonably be expected to lead to or result in, a sale or disposition or transfer (by any person or entity, whether or not a signatory to such agreement) of any economic consequences of ownership, in whole or in part, directly or indirectly, of any lock-up securities, whether any such transaction or arrangement (or instrument provided for thereunder) would be settled by delivery of lock-up securities, in cash or otherwise.

The restrictions described in the immediately preceding paragraph and contained in the lock-up agreements between the underwriters and the lock-up parties do not apply, subject in certain cases to various conditions, to certain transactions, including (a) transfers or dispositions of lock-up securities: (i) as a bona fide gift or gifts or charitable contribution, or for bona fide estate planning purposes, (ii) by will or intestacy or any other testamentary document, (iii) to any member of the lock-up party's immediate family or to any trust for the direct or indirect benefit of the lock-up party or any immediate family member, or if the lock-up party is a trust, to a trustor, trustee, or beneficiary of the trust or to the estate of a trustor, trustee, or beneficiary of such trust (iv) to a corporation, partnership, limited liability company, investment fund or other entity (A) of which the lock-up party and its immediate family members are the legal and beneficial owner of all of the outstanding equity securities or similar interests or (B) controlled by, or under common control with, the lock-up party or its immediate family member, (v) to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (i) through (iv), (vi) in the case of a corporation, partnership, limited liability company, trust or other business entity, (A) to another corporation, partnership, limited liability company, trust or other business entity that is an affiliate of the lock-up party, or to any investment fund or other entity controlling, controlled by, managing or managed by or under common control or common investment management with the lock-up party or its affiliates (including, for the avoidance of doubt, where the lock-up party is a partnership, to its general partner or a successor partnership or fund, or any other funds managed by such partnership), or (B) as part of a distribution to current or former general or limited partners, members, shareholders, equityholders or affiliates of the lock-up party, or to the estates of any of the foregoing, (vii) by operation of law, such as pursuant to a qualified domestic order, divorce settlement, divorce decree or other similar court order or separation agreement, (viii) to us from an employee, independent contractor, other service provider, or director upon death, disability or termination or cessation of employment or service, in each case, of such employee, independent contractor, service provider, or director or (B) pursuant to an agreement under which we have a right of first refusal with respect to transfers of such securities, (ix) as part of a sale of lock-up securities acquired (A) from the underwriters in this offering or (B) in open market transactions after the completion of this offering, (x) to us in connection with the vesting, settlement or exercise of RSUs, options, warrants or other rights to purchase shares of our common stock (including, in each case, by way of "net" or "cashless" exercise), including for the payment of exercise price and tax and remittance payments due as a result of the vesting, settlement, or exercise of such RSUs, options, warrants or rights, or (xi) pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction, in one transaction or a series of related transactions, that is approved by our board of directors

and made to all shareholders involving a change in control, provided that if such transaction is not completed, all such lock-up securities would remain subject to the restrictions in the immediately preceding paragraph; (b) the exercise of the options, settlement of RSUs or other equity awards, or the exercise of warrants granted pursuant to plans described in this prospectus, provided that any lock-up securities received upon such exercise, vesting or settlement would be subject to the restrictions in the immediately preceding paragraph; (c) the conversion of outstanding preferred stock, warrants to acquire preferred stock, or convertible securities into shares of our common stock or warrants to acquire shares of our common stock, provided that any common stock or warrant received upon such conversion would be subject to the restrictions in the immediately preceding paragraph and (d) the establishment by lock-up parties of trading plans under Rule 10b5-1 under the Exchange Act or any amendments to such plans, provided that such plan or amendment does not provide for the transfer of lock-up securities during the restricted period.

The representatives, in their sole discretion, may release the securities subject to any of the lock-up agreements with the underwriters described above, in whole or in part at any time.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol “BLSM.”

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of our common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of our common stock, which involves the sale by the underwriters of a greater number of shares of our common stock than they are required to purchase in this offering, and purchasing shares of our common stock on the open market to cover positions created by short sales. Short sales may be “covered” shorts, which are short positions in an amount not greater than the underwriters’ option to purchase additional shares referred to above, or may be “naked” shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Exchange Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase shares of our common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on the Nasdaq Global Select Market, in the over—the—counter market or otherwise.

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters considered a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;
- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for the shares of our common stock, or that the shares will trade in the public market at or above the initial public offering price.

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

At our request, the underwriters have reserved for sale, at the initial public offering price, up to approximately 93,750 shares of our common stock being offered hereby (approximately 1.0%) to our directors and officers and certain of our employees, business associates, investors and friends and family of our directors, officers, employees, business associates and investors. The sales will be made at our direction by J.P. Morgan Securities LLC, an underwriter of this offering, and its affiliates through a directed share program. The number of shares of common stock available for sale to the general public will be reduced to the extent such persons purchase such reserved shares. Any reserved shares not so purchased will be offered by the underwriters to the general public on the same basis as the other shares offered hereby. We have agreed to indemnify J.P. Morgan Securities LLC against certain liabilities and expenses, including liabilities under the Securities Act, in connection with the sales of the directed shares.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Notice to prospective investors in Canada

The shares of our common stock may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares of our common stock must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to prospective investors in the European Economic Area

In relation to each Member State of the European Economic Area (each a Relevant State), no shares of our common stock have been offered or will be offered pursuant to this offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares of our common stock which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation (as defined below), except that offers of shares of our common stock may be made to the public in that Relevant State at any time:

- (a) to any qualified investor as defined under Article 2 of the Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of the representatives; or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that (i) no such offer of shares of our common stock shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation, supplement a prospectus pursuant to Article 23 of the Prospectus Regulation or publish an Annex IX document pursuant to Article 1(4) of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to shares of our common stock in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of our common stock to be offered so as to enable an investor to decide to purchase or subscribe for any such shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

Notice to prospective investors in the United Kingdom

No shares of our common stock have been offered or will be offered pursuant to this offering to the public in the United Kingdom, except that such shares may be offered to the public in the United Kingdom at any time:

- (a) where the offer is conditional on the admission of the shares of common stock to trading on the London Stock Exchange plc's main market (in reliance on the exception in paragraph 6(a) of Schedule 1 of the POATR);
- (b) to any qualified investor as defined under paragraph 15 of Schedule 1 of the POATR;
- (c) to fewer than 150 natural or legal persons (other than qualified investors as defined under paragraph 15 of Schedule 1 of the POATR), subject to obtaining the prior consent of the underwriters for any such offer; or
- (d) in any other circumstances falling within Schedule 1 of the POATR.

For the purposes of this provision, the expression an "offer to the public" in relation to the shares of common stock in the United Kingdom means the communication to any person which presents sufficient information on: (a) the shares of common stock to be offered; and (b) the terms on which they are to be offered, to enable an investor to decide to buy or subscribe for the shares of common stock and the expressions "POATR" means the Public Offers and Admissions to Trading Regulations 2024.

Notice to prospective investors in Switzerland

No shares of our common stock have been offered or will be offered to the public in Switzerland, except that offers of shares of our common stock may be made to the public in Switzerland at any time under the following exemptions under the Swiss Financial Services Act (FinSA):

- (a) to any person which is a professional client as defined under the FinSA;
- (b) to fewer than 500 persons (other than professional clients as defined under the FinSA), subject to obtaining the prior consent of the underwriters for any such offer; or
- (c) in any other circumstances falling within Article 36 FinSA in connection with Article 44 of the Swiss Financial Services Ordinance,

provided that no such offer of shares of our common stock shall require the company or any underwriter to publish a prospectus pursuant to Article 35 FinSA.

The shares of our common stock have not been and will not be listed or admitted to trading on a trading venue in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the shares of our common stock constitutes a prospectus as such term is understood pursuant to the FinSA and neither this prospectus nor any other offering or marketing material relating to the shares of our common stock may be publicly distributed or otherwise made publicly available in Switzerland.

Notice to prospective investors in Australia

This prospectus:

- (a) does not constitute a disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth) (the Corporations Act);

- (b) has not been, and will not be, lodged with the Australian Securities and Investments Commission (ASIC), as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document for the purposes of the Corporations Act; and
- (c) may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, available under section 708 of the Corporations Act (Exempt Investors).

The shares of our common stock may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy such shares may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any such shares may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the shares of our common stock, you represent and warrant to us that you are an Exempt Investor.

As any offer of shares of our common stock under this prospectus will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the shares of our common stock, you undertake to us that you will not, for a period of 12 months from the date of issue of such shares, offer, transfer, assign or otherwise alienate such shares to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

Notice to prospective investors in Japan

The shares of our common stock have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act of Japan. Accordingly, none of the shares of our common stock nor any interest therein may be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any “resident” of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act of Japan and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

Notice to prospective investors in Hong Kong

The shares of our common stock have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) (the SFO) of Hong Kong and any rules made thereunder; or (b) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong) (the CO) or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the shares of our common stock has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares of our common stock which are or are

intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the SFO and any rules made thereunder.

Notice to prospective investors in Singapore

Each book-running manager has acknowledged that this prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, each book-running manager has represented and agreed that it has not offered or sold any shares of our common stock or caused such shares to be made the subject of an invitation for subscription or purchase and will not offer or sell any shares of our common stock or cause such shares to be made the subject of an invitation for subscription or purchase, and has not circulated or distributed, nor will it circulate or distribute, this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares of our common stock, whether directly or indirectly, to any person in Singapore other than:

- (a) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (the SFA)) pursuant to Section 274 of the SFA;
- (b) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA; or
- (c) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares of our common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares of our common stock pursuant to an offer made under Section 275 of the SFA except:

- (i) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(c)(ii) of the SFA;
- (ii) where no consideration is or will be given for the transfer;
- (iii) where the transfer is by operation of law;
- (iv) as specified in Section 276(7) of the SFA; or
- (v) as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

Notice to prospective investors in China

This prospectus will not be circulated or distributed in the People's Republic of China (PRC) and the shares of our common stock will not be offered or sold, and will not be offered or sold to any person for re-offering or

resale directly or indirectly to any residents of the PRC (for such purposes, not including the Hong Kong and Macau Special Administrative Regions or Taiwan), except pursuant to any applicable laws and regulations of the PRC. Neither this prospectus nor any advertisement or other offering material may be distributed or published in the PRC, except under circumstances that will result in compliance with applicable laws and regulations.

Notice to prospective investors in Korea

The shares of our common stock have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea and the decrees and regulations thereunder (the FSCMA), and such shares have been and will be offered in Korea as a private placement under the FSCMA. None of the shares of our common stock may be offered, sold or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea and the decrees and regulations thereunder (the FETL). Furthermore, the purchaser of the shares of our common stock shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of such shares. By the purchase of the shares of our common stock, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased such shares pursuant to the applicable laws and regulations of Korea.

Notice to prospective investors in Taiwan

The shares of our common stock have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the shares of our common stock in Taiwan.

Notice to prospective investors in Bermuda

Shares of our common stock may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act of 2003 of Bermuda which regulates the sale of securities in Bermuda. Additionally, non-Bermudian persons (including companies) may not carry on or engage in any trade or business in Bermuda unless such persons are permitted to do so under applicable Bermuda legislation.

Notice to prospective investors in Saudi Arabia

This prospectus may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Rules on the Offer of Securities and Continuing Obligations Regulations as issued by the board of the Saudi Arabian Capital Market Authority (the CMA) pursuant to resolution number 3-123-2017 dated 27 December 2017, as amended (the CMA Regulations). The CMA does not make any representation as to the accuracy or completeness of this prospectus and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this prospectus. Prospective purchasers of the securities offered hereby should conduct their own due diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this prospectus, you should consult an authorized financial adviser.

Notice to prospective investors in the Dubai International Financial Centre (DIFC)

This prospectus relates to an Exempt Offer in accordance with and as defined in the Markets Law, DIFC Law No. 1 of 2012, as amended. This prospectus is intended for distribution only to persons of a type specified in the

Markets Law, DIFC Law No. 1 of 2012, as amended. It must not be delivered to, or relied on by, any other person. The Dubai Financial Services Authority (DFSA) has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for this prospectus. The securities to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

In relation to its use in the DIFC, this prospectus is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

Notice to prospective investors in the United Arab Emirates

The shares of our common stock have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the DIFC) other than in compliance with the laws of the United Arab Emirates (and the DIFC) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the DIFC) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority, Financial Services Regulatory Authority or the DFSA.

Notice to prospective investors in the Abu Dhabi Global Market

The Abu Dhabi Global Market (ADGM), including the Financial Services Regulatory Authority and the Registration Authority does not accept any responsibility for the content of the information included in this prospectus, including the accuracy or completeness of such information. The liability for the content of this prospectus lies with the company and other persons, such as experts, whose opinions are included in this prospectus with their consent. The ADGM has also not assessed the suitability of the securities to which this prospectus relates to any particular investor or type of investor. The securities to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this prospectus or are unsure whether the securities to which this prospectus relates are suitable for your individual investment objectives and circumstances, you should consult an authorized financial adviser.

Notice to prospective investors in the British Virgin Islands

The shares of our common stock are not being, and may not be offered to the public or to any person in the British Virgin Islands for purchase or subscription by or on behalf of the company. The shares of our common stock may be offered to companies incorporated under the BVI Business Companies Act, 2004 (British Virgin Islands), but only where the offer will be made to, and received by, the relevant BVI Company entirely outside of the British Virgin Islands.

Notice to prospective investors in Bahamas

Shares of our common stock may not be offered or sold in The Bahamas via a public offer. Shares of our common stock may not be offered or sold or otherwise disposed of in any way to any person(s) deemed "resident" for exchange control purposes by the Central Bank of The Bahamas.

Notice to prospective investors in South Africa

Due to restrictions under the securities laws of South Africa, no “offer to the public” (as such term is defined in the South African Companies Act, No. 71 of 2008 (as amended or re-enacted) (the South African Companies Act)) is being made in connection with the issue of shares of our common stock in South Africa. Accordingly, this prospectus does not, nor is it intended to, constitute a “registered prospectus” (as defined in the South African Companies Act) prepared and registered under the South African Companies Act and has not been approved by, and/or filed with, the South African Companies and Intellectual Property Commission or any other regulatory authority in South Africa. The shares of our common stock are not offered, and the offer shall not be transferred, sold, renounced or delivered, in South Africa or to a person with an address in South Africa, unless one or other of the following exemptions stipulated in section 96 (1) applies:

Section 96 (1) (a): the offer, transfer, sale, renunciation or delivery is to:

- (i) persons whose ordinary business, or part of whose ordinary business, is to deal in securities, as principal or agent;
- (ii) the South African Public Investment Corporation;
- (iii) persons or entities regulated by the Reserve Bank of South Africa;
- (iv) authorized financial service providers under South African law;
- (v) financial institutions recognized as such under South African law;
- (vi) a wholly-owned subsidiary of any person or entity contemplated in (c), (d) or (e), acting as agent in the capacity of an authorized portfolio manager for a pension fund, or as manager for a collective investment scheme (in each case duly registered as such under South African law); or
- (vii) any combination of the persons in (i) to (vi); or

Section 96 (1) (b): the total contemplated acquisition cost of the securities, for any single addressee acting as principal is equal to or greater than ZAR1,000,000 or such higher amount as may be promulgated by notice in the Government Gazette of South Africa pursuant to section 96(2)(a) of the South African Companies Act.

Information made available in this prospectus should not be considered as “advice” as defined in the South African Financial Advisory and Intermediary Services Act, 2002.

Notice to prospective investors in Israel

This prospectus does not constitute a prospectus under the Israeli Securities Law, 5728-1968 (the Israeli Securities Law), and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the shares is directed only at, (i) a limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum (the Addendum), to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and “qualified individuals,” each as defined in the Addendum (as it may be amended from time to time), or, collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

Legal matters

The validity of the shares of our common stock being offered by this prospectus will be passed upon for us by Cooley LLP, San Diego, California. Certain legal matters relating to this offering will be passed upon for the underwriters by Latham & Watkins LLP, San Diego, California. As of the date of this prospectus, GC&H Investments, LLC, an entity comprised of partners and associates of Cooley LLP, beneficially owns an aggregate of 14,179 shares of our capital stock.

Experts

The financial statements of BlossomHill Therapeutics, Inc. as of December 31, 2024 and 2025, and for each of the two years in the period ended December 31, 2025, included in this prospectus, have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report. Such financial statements are included in reliance upon the report of such firm given their authority as experts in accounting and auditing.

Where you can find more information

We have filed with the SEC a registration statement on Form S-1, including exhibits and schedules, under the Securities Act, with respect to the shares of our common stock being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the internet at the SEC's website at www.sec.gov.

Upon the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection at the website of the SEC referred to above. We also maintain a website at www.bhtherapeutics.com, at which, following the closing of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained in or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

Index to financial statements

Audited financial statements as of and for the years ended December 31, 2024 and 2025

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Unaudited condensed financial statements as of and for the three months ended March 31, 2025 and 2026:

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of BlossomHill Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of BlossomHill Therapeutics, Inc. (the “Company”) as of December 31, 2024 and 2025, the related statements of operations, convertible preferred stock and stockholders’ deficit, and cash flows, for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2025, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Substantial doubt about the company’s ability to continue as a going concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred net losses and negative cash flows from operations since inception, has a significant accumulated deficit and expects to continue to incur net losses for the foreseeable future which are factors that raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

San Diego, California

April 24, 2026 (August 3, 2026 as to the effects of the reverse stock split as described in Note 10)

We have served as the Company’s auditor since 2024.

BlossomHill Therapeutics, Inc.

Balance sheets

(in thousands, except share and par value data)

	As of December 31,	
	2024	2025
Assets		
Current assets:		
Cash and cash equivalents	\$ 100,147	\$ 136,682
Prepaid expenses and other current assets	4,025	2,144
Total current assets	104,172	138,826
Property and equipment, net	1,100	1,726
Operating lease right-of-use assets	486	19,921
Other assets	1,017	2,495
Total assets	\$ 106,775	\$ 162,968
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 849	\$ 2,314
Accrued expenses	2,938	8,431
Accrued compensation	2,461	4,730
Operating lease liability, current	525	5
Total current liabilities	6,773	15,480
Operating lease liability, non-current	—	22,393
Total liabilities	6,773	37,873
Commitments and contingencies (Note 8)		
Convertible preferred stock, \$0.0001 par value; 63,188,793 and 85,552,612 shares authorized at December 31, 2024 and 2025, respectively; 13,485,975 and 18,258,960 shares issued and outstanding at December 31, 2024 and 2025, respectively; \$173,000 and \$257,153 aggregate liquidation preference at December 31, 2024 and December 31, 2025, respectively	172,885	256,823
Stockholders' deficit:		
Common stock, \$0.0001 par value; 79,726,375 and 110,000,000 shares authorized at December 31, 2024 and 2025, respectively; 2,381,320 and 2,548,659 shares issued and outstanding at December 31, 2024 and 2025, respectively	1	1
Additional paid-in capital	1,590	3,300
Accumulated deficit	(74,474)	(135,029)
Total stockholders' deficit	(72,883)	(131,728)
Total liabilities, convertible preferred stock and stockholders' deficit	\$ 106,775	\$ 162,968

See accompanying notes to financial statements

BlossomHill Therapeutics, Inc.

Statements of operations

(in thousands, except share and per share data)

	Year ended December 31,	
	2024	2025
Operating expenses:		
Research and development	\$ 31,810	\$ 56,138
General and administrative	4,591	7,886
Total operating expenses	36,401	64,024
Loss from operations	(36,401)	(64,024)
Other income (expense), net:		
Interest income, net	5,706	3,480
Other expense	—	(11)
Total other income, net	5,706	3,469
Net loss	\$ (30,695)	\$ (60,555)
Net loss per share, basic and diluted	\$ (13.40)	\$ (24.83)
Weighted-average common shares outstanding, basic and diluted	2,290,188	2,438,357

See accompanying notes to financial statements

BlossomHill Therapeutics, Inc.

Statements of convertible preferred stock and stockholders' deficit

(in thousands, except share data)

	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2023	12,842,229	\$ 161,545	2,240,557	\$ 1	\$ 666	\$ (43,779)	\$ (43,112)
Issuance of convertible preferred stock, net of issuance costs	643,746	11,340	—	—	—	—	—
Exercise of stock options	—	—	140,763	—	420	—	420
Stock-based compensation expense	—	—	—	—	504	—	504
Net loss	—	—	—	—	—	(30,695)	(30,695)
Balance at December 31, 2024	13,485,975	172,885	2,381,320	1	1,590	(74,474)	(72,883)
Issuance of convertible preferred stock, net of issuance costs	4,772,985	83,938	—	—	—	—	—
Exercise of stock options	—	—	167,339	—	620	—	620
Stock-based compensation expense	—	—	—	—	1,090	—	1,090
Net loss	—	—	—	—	—	(60,555)	(60,555)
Balance at December 31, 2025	18,258,960	\$ 256,823	2,548,659	\$ 1	\$ 3,300	\$ (135,029)	\$ (131,728)

See accompanying notes to financial statements

BlossomHill Therapeutics, Inc.

Statements of cash flows

(in thousands)

	Year ended December 31,	
	2024	2025
Cash flows from operating activities:		
Net loss	\$ (30,695)	\$ (60,555)
Adjustments to reconcile net loss to net cash used in operations:		
Depreciation expense	350	441
Non-cash lease expense	697	1,288
Stock-based compensation expense	504	1,090
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(4,547)	1,912
Other assets	931	(1,478)
Accounts payable	(1,138)	1,465
Accrued compensation	986	2,269
Accrued expenses	2,221	5,493
Operating lease liabilities	(725)	1,150
Net cash used in operating activities	(31,416)	(46,925)
Cash flows from investing activities:		
Purchases of property and equipment	(92)	(1,067)
Net cash used in investing activities	(92)	(1,067)
Cash flows from financing activities:		
Proceeds from the exercise of stock options	420	589
Proceeds from the issuance of convertible preferred stock, net of issuance costs	17,140	83,938
Net cash provided by financing activities	17,560	84,527
Net increase (decrease) in cash and cash equivalents	(13,948)	36,535
Cash and cash equivalents at the beginning of period	114,095	100,147
Cash and cash equivalents at the end of period	\$ 100,147	\$ 136,682
Supplemental disclosure of noncash activities:		
Right-of-use asset obtained in exchange for operating lease liability	\$ —	\$ 20,946

See accompanying notes to financial statements

BlossomHill Therapeutics, Inc.

Notes to financial statements

As of and for the years ended December 31, 2024 and 2025

1. Organization, liquidity and going concern, and basis of presentation

Organization

BlossomHill Therapeutics, Inc. (the “Company”) is a clinical-stage biopharmaceutical company applying its intentional, chemistry-based approach to develop innovative small molecule medicines that address significant unmet medical needs in cancer treatment. The Company was incorporated in the State of Delaware on June 22, 2020, and its principal operations are in San Diego, California.

From its inception to December 31, 2025, the Company has devoted substantially all of its resources to conducting research and development, staffing the Company, establishing and protecting the Company’s intellectual property portfolio, scaling up manufacturing processes and supplying product candidates and other materials for the Company’s preclinical studies and clinical trials, leasing office and laboratory space, raising capital, business planning, and providing general and administrative support for these activities. The Company’s operations to date have been funded primarily through the issuance of convertible preferred stock.

Liquidity and going concern

In accordance with Accounting Standards Codification (ASC) Topic 205-40, Going Concern, the Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year from the date that these financial statements are issued.

The Company has incurred net losses and negative cash flows from operations since inception, has a significant accumulated deficit and expects to continue to incur net losses for the foreseeable future. The Company has never generated any revenue from product sales and does not expect to generate any revenues from product sales unless and until it successfully completes development of and obtains regulatory approval for its product candidates, which will not be for several years, if ever.

As the Company continues to pursue its business plan, it expects to finance its operations through a combination of public or private equity or debt financings or other capital sources, which may include strategic collaborations and other strategic arrangements with third parties. However, there can be no assurance that any additional financing or strategic transactions will be available to the Company on acceptable terms, if at all.

As of April 24, 2026, the issuance date of the financial statements as of and for the year ended December 31, 2025, there is uncertainty about whether the Company’s cash and cash equivalents will be sufficient to fund operations beyond twelve months from the issuance date of these financial statements and therefore the Company concluded that substantial doubt exists about the Company’s ability to continue as a going concern.

The accompanying financial statements have been prepared on a going- concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

Basis of presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”) and the U.S. Securities and Exchange Commission rules under

Regulation S-X. Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the ASC and Accounting Standards Updates ("ASU") promulgated by the Financial Accounting Standards Board ("FASB").

2. Summary of significant accounting policies

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Accounting estimates and management judgments reflected in the financial statements include: the accrual of research and development expenses, common stock valuation, stock-based compensation, and the determination of right-of-use assets under lease transactions and related lease obligations, and income tax uncertainties. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may materially differ from these estimates and assumptions.

Concentration of credit risk

Financial instruments which potentially subject the Company to significant concentration of credit risk consist of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company has not experienced any losses in such accounts, and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Segment reporting

The Company operates and manages its business as one operating segment and one reportable segment. The Company's Chief Executive Officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for allocating resources and evaluating financial performance. All long-lived assets are maintained in the United States.

Cash and cash equivalents

Cash and cash equivalents are considered to be highly liquid investments with maturities of three months or less at the date of purchase. Cash equivalents primarily represent funds invested in readily available money market accounts. As of December 31, 2025, the Company had cash and cash equivalents balances deposited at multiple major financial institutions.

Property and equipment, net

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets (generally three to seven years, or the remaining term of the lease). The Company capitalizes laboratory equipment used for research and development if it has alternative future use in research and development or otherwise. Upon retirement or sale, the cost of assets disposed and the related accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is included in the statements of operations.

Leases

At the inception of a contractual arrangement, the Company determines whether the contract contains a lease by assessing whether there is an identified asset and whether the contract conveys the right to control the use

of the identified asset in exchange for consideration over a period of time. If both criteria are met, the Company records the associated lease liability and corresponding right-of-use ("ROU") asset upon commencement of the lease. The Company additionally evaluates leases at their inception to determine if they are to be accounted for as an operating lease or a finance lease.

Operating lease assets represent a right to use an underlying asset for the lease term ("ROU assets") and operating lease liabilities represent an obligation to make lease payments arising from the lease. Operating lease liabilities with a term greater than twelve months and their corresponding ROU assets are recognized in the balance sheets at the commencement date of the lease based on the present value of lease payments over the expected lease term. The Company excludes short-term leases having initial terms of twelve months or less at lease commencement as an accounting policy election. Certain adjustments to the ROU assets may be required for items such as initial direct costs paid or incentives received. As the Company's leases do not typically provide an implicit rate, the Company utilizes the appropriate incremental borrowing rate, determined as the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term and in a similar economic environment. Lease cost is recognized on a straight-line basis over the lease term and variable lease payments are recognized as operating expenses in the period in which the obligation for those payments is incurred. Variable lease payments primarily include common area maintenance, utilities, real estate taxes, insurance and other operating costs that are passed on from the lessor in proportion to the space leased by the Company. The Company has elected the practical expedient to not separate lease and non-lease components.

Fair value of financial instruments

Cash equivalents are recognized and measured at fair value. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. A framework is used for measuring fair value utilizing a three-tier hierarchy that prioritizes the inputs to valuation techniques used to measure fair value.

Level 1—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2—Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability.

Level 3—Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

Money market funds are highly liquid investments and are classified as Level 1. The pricing information for these assets is readily available and can be independently validated as of the measurement date.

Impairment of long-lived assets

The Company reviews its long-lived assets, including property and equipment and right-of-use assets, for impairment whenever events or changes in circumstances indicate that the carrying value of the assets may not be fully recoverable. If such circumstances are determined to exist, an estimate of undiscounted future cash flows produced by the long-lived asset group, including the proceeds from the eventual disposition of the asset, is compared to the carrying value of the asset group to determine whether impairment exists. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset group, the assets

within the group are written-down to their estimated fair values. The Company has not recognized any impairment charges for the years ended December 31, 2024 and 2025.

Convertible preferred stock

The Company records convertible preferred stock at fair value on the date of issuance, net of issuance costs. Upon the occurrence of certain events that are outside the Company's control, including a deemed liquidation event, holders of the convertible preferred stock can cause redemption for cash. Therefore, convertible preferred stock is classified outside of stockholders' deficit on the balance sheets as events triggering the redemption are not solely within the Company's control. The carrying values of the convertible preferred stock are adjusted to their liquidation preferences if and when it becomes probable that such a redemption event will occur.

Research and development expenses and accrued research and development costs

Research and development expenses consist of costs to third-party contractors to perform research and development activities, internal related salaries, benefits, stock-based compensation charges for those individuals involved in research and development efforts, and associated overhead expenses. Research and development costs are expensed as incurred. Nonrefundable advance payments for goods and services, including fees for process development, are deferred and recognized as expenses in the period that the related goods are consumed or services are performed.

The Company is required to estimate expenses resulting from its obligations under contracts with vendors, consultants, and contract research organizations, in connection with conducting research and development activities. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company reflects research and development expenses in its financial statements by matching those expenses with the period in which services and efforts are expended, as measured by the timing of various aspects of the preclinical study or clinical trial or related activities. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and payments made in advance of or after the performance are reflected in the accompanying balance sheets as prepaid expenses or accrued liabilities, respectively. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the services, including the phase or completion of events, invoices received and contracted costs. The Company holds discussions with relevant employees and outside service providers as to the progress of preclinical or clinical efforts, or the services completed. Significant judgments and estimates may be made in determining the prepaid or accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. As of December 31, 2025, the Company has had no material differences between its estimates of such expenses and the amounts actually incurred.

General and administrative expenses

General and administrative expenses consist of compensation, employee benefits, stock-based compensation of employees, consulting, legal and other expenses not associated with research and development expenses.

Interest income, net

Interest income, net consists primarily of interest income earned on money market funds classified as cash and cash equivalents.

Patent costs

All patent-related costs incurred in connection with filing and prosecuting patent applications such as direct application fees, and legal and consulting expenses are expensed as incurred due to the uncertainty about the

recovery of the expenditure. Patent-related costs are classified as general and administrative expenses within the Company's statements of operations.

Stock-based compensation

Stock-based compensation is accounted for in accordance with ASC Topic 718, *Compensation—Stock Compensation*, and is measured at the grant date fair value for employee, officer, director and non-employee equity awards and is recognized on a straight-line basis over the requisite service period, which is generally the vesting period. Forfeitures are recognized as they occur. Stock-based compensation is classified in the statements of operations in the same manner in which the recipient's payroll or fees are classified.

The fair value of stock options is estimated using a Black-Scholes option pricing model on the date of grant. This method requires certain assumptions to be used as inputs, such as the fair value of the underlying common stock, expected term of the option before exercise, expected volatility of the Company's common stock, risk-free interest rate and expected dividend yield. Options granted have a maximum contractual term of ten years. The Company has limited historical stock option activity and therefore estimates the expected term of stock options granted using the simplified method, which represents the arithmetic average of the original contractual term of the stock option and its weighted-average vesting term. The expected volatility of stock options is based upon the historical volatility of a number of publicly traded companies in similar stages of clinical development, as there is no active trading market for the Company's common stock. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available. The risk-free interest rates used are based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected term of the stock options. The Company has historically not declared or paid any dividends and does not currently expect to do so in the foreseeable future, and therefore has estimated the dividend yield to be zero.

Common stock valuation

Due to the absence of an active market for the Company's common stock, the Company utilized methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants' Audit and Accounting Practice Guide: *Valuation of Privately-Held Company Equity Securities Issued as Compensation* to estimate the fair value of its common stock. In determining the exercise prices for options granted, the Company has considered the fair value of the common stock as of the grant date. The estimated fair value of the common stock has been determined based upon a variety of factors, including:

- the Company's stage of development and forecast of its financial results;
- external market conditions and trends affecting the early-stage biotech pharmaceutical industry;
- a comparison of the financial positions and market prices of similar public companies within the biotech pharmaceutical industry;
- analysis of recent acquisitions and initial public offerings of companies within the biotech pharmaceutical industry;
- the Company's financial position, including cash on hand, and its historical and forecasted performance and operating results; and
- the value implied by the Company's recent fundraising transactions.

The Company's common stock valuation was prepared using a market approach to estimate the enterprise value and an option pricing method ("OPM") to allocate value to the common stock. Under the OPM, shares are

valued by creating a series of call options with exercise prices based on the liquidation preferences and conversion terms of each equity class. The value of the common stock is inferred by analyzing these options.

Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

Commitments and contingencies

The Company recognizes a liability with regard to loss contingencies when it believes it is probable a liability has been incurred, and the amount can be reasonably estimated. If some amount within a range of loss appears at the time to be a better estimate than any other amount within the range, the Company accrues that amount. When no amount within the range is a better estimate than any other amount, the Company accrues the minimum amount in the range. The Company had not recorded any such liabilities as of December 31, 2024 or 2025.

Income taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

As of December 31, 2024 and 2025, the Company maintained full valuation allowances against its deferred tax assets as the Company concluded it had not met the “more likely than not” to be realized threshold. Changes in the valuation allowance when they are recognized in the provision for income taxes may result in a change in the estimated annual effective tax rate.

The Company records uncertain tax positions on the basis of a two-step process whereby (i) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (ii) for those tax positions that meet the more likely than not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority.

The Company recognizes interest and penalties related to unrecognized tax benefits within the provision for income taxes in the statements of operations. Any accrued interest and penalties are included within the related tax liability in the balance sheets. As of December 31, 2025, the Company had no accrued interest or penalties.

Comprehensive loss

The Company is required to report all components of comprehensive loss, including net loss, in the accompanying financial statements in the period in which they are recognized. Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net loss and comprehensive loss were the same for all periods presented.

Net loss per share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock and common stock equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. The Company's potentially dilutive securities include outstanding convertible preferred stock, as well as outstanding stock options under the Company's 2020 Equity Incentive Plan and have been excluded from the computation of diluted net loss per share as their inclusion would be anti-dilutive. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

The following table summarizes the outstanding potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because their inclusion in the calculation would be anti-dilutive:

	As of December 31,	
	2024	2025
Convertible preferred stock	13,485,975	18,258,960
Outstanding options under the Company's 2020 Equity Incentive Plan	736,017	1,178,237
Total	14,221,992	19,437,197

Emerging growth company status

The Company is an "emerging growth company," as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"), and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. The Company may take advantage of these exemptions up until the last day of the fiscal year following the fifth anniversary of an offering or such earlier time that the Company is no longer an "emerging growth company." Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. The Company has elected to use the extended transition period for complying with new or revised accounting standards and as a result of this election, its financial statements may not be comparable to companies that comply with public company effective dates. However, the Company may elect to early adopt any new or revised accounting standards whenever such early adoption is permitted for non-public companies. The Company may take advantage of these exemptions up until the time that it is no longer an emerging growth company.

Recently adopted accounting pronouncements

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280)—Improvements to Reportable Segment Disclosures* ("ASU 2023-07"). The update requires entities to disclose their significant segment expense categories and amounts for each reportable segment. Significance is assessed using both quantitative and qualitative factors depending on the facts and circumstances. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods in fiscal years beginning after December 15, 2024. The Company adopted this standard for the fiscal year 2025 annual financial statements and interim financial statements thereafter and has applied this standard retrospectively for all prior periods presented in the financial statements. See Note 9 for further details on segment information.

Issued accounting pronouncements not yet adopted

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"). The amendments in ASU No. 2023-09 address investor requests for enhanced

income tax information primarily through changes to disclosure regarding rate reconciliation and income taxes paid both in the United States and foreign jurisdictions. This guidance is effective for fiscal years beginning after December 15, 2025, on a prospective basis, with the options to apply the standard retrospectively, and early adoption is permitted. The Company is currently evaluating this guidance to determine the impact it may have on its financial statements.

In November 2024, the FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"). In January 2025, the FASB issued ASU 2025-01, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date*, to clarify the effective date of ASU 2024-03. These amendments are intended to provide more information about certain costs and expenses on an interim and annual basis. The amendments are effective for annual periods beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The new standards are expected to be applied prospectively, but retrospective application is permitted. The Company is currently evaluating the impact on its financial statements and related disclosures.

In December 2025, the FASB issued ASU No. 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements* ("ASU 2025-11"), which clarifies interim disclosure requirements and the applicability of Topic 270. The objective of the amendments is to provide further clarity about the current interim disclosure requirements. ASU 2025-11 is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027. Adoption of this ASU can be applied using either a prospective or a retrospective approach. Early adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2025-11 and does not expect the adoption of this guidance to have a material impact on its financial statements.

3. Fair value measurements

The following tables show the Company's cash equivalents measured at fair value as of December 31, 2024 and 2025 (in thousands):

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents				
Money market funds	\$ 99,582	\$ —	\$ —	\$ 99,582
Total	\$ 99,582	\$ —	\$ —	\$ 99,582
December 31, 2025				
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents				
Money market funds	\$ 135,227	\$ —	\$ —	\$ 135,227
Total	\$ 135,227	\$ —	\$ —	\$ 135,227

The carrying amounts of the Company's accounts payable, accrued expenses and accrued compensation approximate fair value due to their short maturities. None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis. There were no transfers between Levels 1, 2 or 3 for any of the periods presented.

4. Property and equipment, net

Property and equipment, net consisted of the following (in thousands):

	As of December 31,	
	2024	2025
Laboratory equipment	\$1,563	\$ 1,580
Computer equipment	180	496
Office furniture and equipment	124	544
Leasehold improvements	103	268
Software	89	89
	2,059	2,977
Less: accumulated depreciation and amortization	(959)	(1,251)
Property and equipment, net	\$1,100	\$ 1,726

The Company recognized depreciation and amortization expense of \$0.4 million during each of the years ended December 31, 2024 and 2025.

5. Accrued expenses

Accrued expenses consisted of the following (in thousands):

	As of December 31,	
	2024	2025
Accrued research and development expenses	\$ 2,610	\$ 8,297
Other	328	134
Total accrued expenses	\$ 2,938	\$ 8,431

6. Convertible preferred stock and stockholders' deficit

Stockholders' deficit

Under the Company's amended and restated certificate of incorporation, the Company had a total of 195,552,612 shares of capital stock authorized for issuance, consisting of 110,000,000 shares of common stock, par value of \$0.0001 per share, and 85,552,612 shares of convertible preferred stock, par value of \$0.0001 per share, as of December 31, 2025.

Convertible preferred stock

As of December 31, 2024, issued and outstanding convertible preferred stock consisted of the following (in thousands, except share amounts and per share amounts):

Series	Shares authorized	Shares outstanding	Original issue price	Liquidation preference	Carrying value
Series Angel	10,000,000	2,134,242	\$ 0.9371	\$ 2,000	\$ 2,000
Series A	26,613,546	5,679,965	12.5000	71,000	70,981
Series B	26,575,247	5,671,768	17.6311	100,000	99,904
Total	63,188,793	13,485,975		\$ 173,000	\$ 172,885

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As of December 31, 2025, issued and outstanding convertible preferred stock consisted of the following (in thousands, except share amounts and per share amounts):

Series	Shares authorized	Shares outstanding	Original issue price	Liquidation preference	Carrying value
Series Angel	10,000,000	2,134,242	\$ 0.9371	\$ 2,000	\$ 2,000
Series A	26,613,546	5,679,965	12.5000	71,000	70,981
Series B	48,939,066	10,444,753	17.6311	184,153	183,842
Total	85,552,612	18,258,960		\$ 257,153	\$ 256,823

In December 2020, the Company issued 2,134,242 shares of its Series Angel convertible preferred stock at a price of \$0.94 per share, resulting in aggregate gross proceeds of \$2.0 million, and incurred immaterial issuance costs.

In March 2021, the Company issued 5,679,965 shares of its Series A convertible preferred stock at a price of approximately \$12.50 per share, resulting in aggregate gross proceeds of \$71.0 million, and incurred immaterial issuance costs.

The Company entered into the Series B Preferred Stock Purchase Agreement dated December 28, 2023, whereby the Company agreed to issue and sell, and certain investors agreed to purchase an aggregate of 5,671,768 shares of the Company's Series B convertible preferred stock, in one or more closings. In December 2023, the Company issued 5,028,022 shares of its Series B convertible preferred stock at a price of approximately \$17.63 per share, resulting in aggregate gross proceeds of \$88.7 million, and incurred immaterial issuance costs. Through December 31, 2023, the Company received \$82.8 million in proceeds and recorded a receivable for the remaining \$5.8 million. Cash proceeds related to this receivable were received in 2024. In January 2024, the Company issued 643,746 shares of its Series B convertible preferred stock at a price of approximately \$17.63 per share, resulting in aggregate gross proceeds of \$11.3 million, and incurred immaterial issuance costs.

The Company entered into a subsequent Series B Preferred Stock Purchase Agreement dated November 25, 2025, whereby the Company agreed to issue and sell, and certain investors agreed to purchase an aggregate of 4,772,985 shares of the Company's Series B convertible preferred stock. Between November and December 2025, the Company issued 4,772,985 shares of its Series B convertible preferred stock at a price of approximately \$17.63 per share, resulting in aggregate gross proceeds of \$84.2 million, and incurred \$0.1 million of issuance costs.

As of December 31, 2025, the Company's Series Angel, Series A and Series B convertible preferred stock has been classified as temporary equity in the accompanying balance sheets given that the holders of the convertible preferred stock could cause certain events to occur that are outside of the Company's control whereby the Company could be obligated to redeem the convertible preferred stock. The carrying value of the convertible preferred stock is not adjusted to the redemption value until the contingent redemption events are considered to be probable of occurring.

The Company's convertible preferred stock has the following rights, preferences and privileges:

Dividends

The Company shall not declare or pay any dividends on shares of any class of capital stock of the Company unless the holders of the Series Angel, Series A or Series B convertible preferred stock shall first receive, or simultaneously receive, a dividend on each outstanding share of such convertible preferred stock equal to an amount as defined in the Company's amended and restated certificate of incorporation. No such dividends have been declared or paid through December 31, 2025.

Preferences on liquidation

The holders of the Series A and Series B convertible preferred stock are entitled to receive liquidation preferences, in the event of a change in control, liquidation, dissolution or winding up, at an amount per share equal to the greater of (i) the original issuance price, plus any dividends declared but unpaid or (ii) the amount per share that would be payable had the share been converted to shares of common stock immediately prior to the liquidation event. Liquidation payments to the holders of the Series A and Series B convertible preferred stock have priority and are made in preference to any payments to the holders of Series Angel convertible preferred stock and common stock. If assets available to be distributed are insufficient to pay Series A and Series B convertible preferred stock holders, amounts available will be distributed on a pro-rata basis.

After full payment of the liquidation preference to the holders of the Series A and Series B convertible preferred stock, the remaining assets, if any, will be distributed to the holders of the Series Angel convertible preferred stock. The holders of the Series Angel convertible preferred stock are entitled to receive liquidation preferences, in the event of a change in control, liquidation, dissolution, or winding up, at an amount per share equal to the greater of (i) the original issuance price, plus any dividends declared but unpaid or (ii) the amount per share that would be payable had the share been converted to shares of common stock immediately prior to the liquidation event. Liquidation payments to the holders of the Series Angel convertible preferred stock have priority and are made in preference to any payments to the holders of common stock. If assets available to be distributed are insufficient to pay Series Angel convertible preferred stockholders, amounts available will be distributed on a pro-rata basis.

After full payment of the liquidation preference to the holders of the Series Angel, Series A and Series B convertible preferred stock, the remaining assets, if any, will be distributed to the holders of common stock, pro rata based on the number of shares held by each holder.

Conversion rights

The shares of Series Angel, Series A, and Series B convertible preferred stock are convertible into common stock at the option of the holder. The conversion rate for the convertible preferred stock is determined by dividing the original issue price by the conversion price. The conversion price is initially the original issue price, but is subject to adjustment for dividends, stock splits, and other distributions. The conversion rate on December 31, 2025, for the Series Angel, Series A, and Series B convertible preferred stock was 1:1.

Each share of Series Angel, Series A, and Series B convertible preferred stock will be automatically converted into common stock at the then effective conversion rate upon: (i) the closing of the sale of common stock to the public (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the common stock), in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least \$50.0 million of gross proceeds to the Company; or (ii) the date and time, or the occurrence of an event, specified by vote or written consent of the majority of holders of the outstanding shares of Series Angel, Series A and Series B convertible preferred stock.

Voting

The holders of Series Angel convertible preferred stock shall be entitled to cast the number of votes equal to ten times the number of shares of Common Stock into which the shares of Series Angel convertible preferred stock held by such holder are then convertible. The holders of Series A and Series B convertible preferred stock shall be entitled to cast the number of votes equal to the number of shares of common stock into which the shares of Series A and Series B convertible preferred stock held by such holder are then convertible. The holders of Series Angel, Series A and Series B convertible preferred stock generally vote together with the

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shares of common stock as a single class, but also have class vote approval rights as provided by the Company's amended and restated certificate of incorporation or as required by applicable law.

The holders of shares of Series Angel convertible preferred stock, exclusively and as a separate class, shall be entitled to elect one member of the board of directors. The holders of shares of Series A convertible preferred stock, exclusively and as a separate class, shall be entitled to elect three members of the board of directors. The holders of shares of Series B convertible preferred stock, exclusively and as a separate class, shall be entitled to elect two members of the board of directors. The holders of shares of common stock, exclusively and as a separate class, shall be entitled to elect at least one member of the board of directors. The holders of Series Angel, Series A and Series B convertible preferred stock voting together as a single class, shall be entitled to elect all remaining members of the board of directors.

Common stock

The voting, dividend, and liquidation rights of the holders of the common stock are subject to, and qualified by, the rights, preferences and privileges of the holders of the Series Angel, Series A and Series B convertible preferred stock. The holders of the common stock are entitled to one vote for each share of common stock held at all meetings of stockholders.

Common stock reserved for future issuance consisted of the following:

	As of December 31,	
	2024	2025
Common stock options granted and outstanding	736,017	1,178,237
Shares available for issuance under the 2020 equity incentive plan	412,140	328,821
Total common stock reserved for future issuance	1,148,157	1,507,058

Stock options

In June 2020, the Company adopted the 2020 Equity Incentive Plan (the "2020 Plan"). The Plan provides for the grant of incentive stock options ("ISO"), non-statutory stock options ("NSO"), stock bonus awards, and restricted stock awards. A total of 320,137 shares of common stock were initially reserved for issuance under the 2020 Plan. The 2020 Plan was subsequently amended in February 2021, July 2023 and, March 2025 to increase the total number of shares available under the 2020 Plan to 691,495, 1,395,279, and 1,921,534, respectively.

Options granted under the Plan are exercisable at various dates as determined upon grant and will expire no more than ten years from their date of grant. The exercise price of each option shall be determined by the board of directors based on the estimated fair value of the Company's stock on the date of the option grant. The exercise price shall not be less than 100% of the fair market value of the Company's common stock at the time the option is granted. The stock option awards generally include service condition vesting terms of four years, with 25% of the award vesting one year from the vesting commencement date and then ratably over the following 36 months, though some vest over shorter periods, vesting monthly from grant date.

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A summary of the Company's stock option activity under the 2020 Plan is as follows:

	Options	Weighted-average exercise price	Weighted- average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2024	736,017	\$ 4.04	8.7	\$ 1,167
Granted	707,199	\$ 6.02		
Exercised	(167,339)	\$ 3.71		
Forfeited	(97,640)	\$ 4.22		
Expired	—	\$ —		
Outstanding at December 31, 2025	1,178,237	\$ 5.26	8.6	\$ 2,526
Exercisable at December 31, 2025	204,392	\$ 3.87	7.4	\$ 723
Vested and expected to vest at December 31, 2025	1,178,237	\$ 5.26	8.6	\$ 2,526

The weighted-average grant date fair value of options granted for the years ended December 31, 2024 and 2025, was \$4.05 and \$4.39 per share, respectively. As of December 31, 2025, the Company recorded a receivable for amounts related to option exercises, of approximately \$31 thousand. These amounts were received in 2026. The total intrinsic value of options exercised during the years ended December 31, 2024 and 2025 was \$0.3 million and \$0.4 million, respectively.

Stock-based compensation expense

Stock-based compensation expense recognized for all equity awards has been included in the statements of operations as follows (in thousands):

	Year ended December 31,	
	2024	2025
Research and development	428	859
General and administrative	76	231
Total stock-based compensation expense	\$ 504	\$ 1,090

The fair value of stock options granted during the year ended December 31, 2024 and 2025 was estimated using the following assumptions:

	Year ended December 31,	
	2024	2025
Risk-free interest rate	3.48% - 4.32%	3.74% - 4.41%
Expected term (years)	5.04 - 6.12	5.04 - 6.12
Expected stock price volatility	80.90% - 81.74%	82.39% - 83.69%
Expected dividend yield	—	—

As of December 31, 2025, the unrecognized compensation cost related to outstanding employee and non-employee options was \$3.4 million and is expected to be recognized as expense over a weighted-average period of approximately 3.1 years.

7. Income taxes

The following is a reconciliation between the provision for income taxes and income taxes computed using the U.S. federal statutory corporate tax rate for the years ended December 31, 2024 and 2025 (in thousands):

	Year ended December 31,	
	2024	2025
Income tax benefit at statutory federal rate	\$ (6,446)	\$ (12,716)
State and local taxes, net of federal benefit ⁽¹⁾	(37)	(265)
Research and development credits	(868)	(3,038)
Changes in valuation allowance	9,326	16,674
Nontaxable or nondeductible items:		
Stock-based compensation	104	207
Other adjustments:		
Return to provision	(2,144)	(664)
Other	65	(198)
Provision for income taxes	\$ —	\$ —

A reconciliation of the Company's effective tax rate and federal statutory rate is comprised of permanent and temporary differences. The Company's effective tax rate differs from the statutory rate due to current research and development credits, return to provision adjustments, and changes in the valuation allowance.

The Company did not record any income tax expense or benefit during the years ended December 31, 2024 and 2025 and no income taxes were paid. The Company's pretax loss is all domestic. Deferred income taxes reflect the net tax effects of loss and credit carryforwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred income taxes are as follows (in thousands):

	Year ended December 31,	
	2024	2025
Deferred tax assets:		
Net operating losses	\$ 5,354	\$ 16,798
Section 174 research and experimentation capitalized costs	11,127	11,645
Lease liability	111	4,797
Accrued liabilities	443	926
Tax credits	1,632	5,334
Others	17	28
Total deferred tax assets	18,684	39,528
Valuation allowance	(18,523)	(35,198)
Total deferred tax assets net of valuation allowance	161	4,330
Deferred tax liabilities:		
Right-of-use assets, operating	(102)	(4,266)
Plant and equipment	(59)	(64)
Total deferred tax liabilities	(161)	(4,330)
Net deferred tax asset (liability)	\$ —	\$ —

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A valuation allowance of 100% has been established with respect to the net deferred income tax assets due to the uncertainty of the Company's realization of such deferred tax assets for U.S. Federal and State on the Company's balance sheets as of December 31, 2024 and 2025. The increase in the valuation allowance is approximately \$9.3 million and \$16.7 million for the year ended December 31, 2024 and 2025, respectively.

As of December 31, 2025, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$72.3 million, which will not expire but can only be used to offset 80% of future taxable income. As of December 31, 2025, the Company had net operating loss carryforwards for state income tax purposes of approximately \$23.5 million, which expire beginning in the year 2040.

As of December 31, 2025, the Company had research and development tax credit carryforwards for federal income tax purposes of approximately \$4.8 million which expire beginning in the year 2041. As of December 31, 2025, the Company had research and development tax credit carryforwards for state income tax purposes of approximately \$2.6 million which expire beginning in the year 2039.

Under Section 382 of the Internal Revenue Code, as amended ("IRC"), substantial changes in the Company's ownership may limit the amount of net operating loss carryover that could be used annually in the future to offset taxable income. The tax benefits related to future utilization of federal and state net operating loss carryforward may be limited or lost if cumulative changes in ownership exceed 50% within any three-year period. The Company has not completed an IRC Section 382 analysis regarding the limitation of net operating loss, and therefore, the ability of the Company to utilize its net operating loss carryover may be limited.

The Company is subject to taxation in the United States and in various states. The Company's U.S. federal income tax returns remain subject to examination by the Internal Revenue Service. The Company's state income tax returns remain subject to examination by the state authorities. Due to net operating losses, research and development credits and other tax credit carryforwards that may be utilized in future years, all U.S. federal and state tax years are open to examination. The Company is not currently under examination by any tax authority.

The following table summarizes the changes to the Company's gross unrecognized tax benefits for the years ended December 31, 2024 and 2025, respectively (in thousands):

	Year ended December 31,	
	2024	2025
Gross unrecognized tax benefits at the beginning of the year	\$ —	\$ 706
Increases (decreases) related to current year positions	435	710
Increases (decreases) related to prior year positions	271	283
Expiration of unrecognized tax benefits	—	—
Gross unrecognized tax benefits at the end of the year	\$ 706	\$ 1,699

Due to the existence of the valuation allowance, future changes in unrecognized tax benefits would have no effect on the Company's effective tax rate. The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. For the year ended December 31, 2025, the Company has not recorded any interest and penalties related to income tax matters. The Company does not foresee any material changes to unrecognized tax benefits within the next twelve months.

On July 4, 2025, the U.S. President signed into law H.R. 1, the legislation commonly known as the One Big Beautiful Bill Act (the "OBBBA"). This legislation extended, modified, or made permanent many of the tax provisions which were initially enacted as part of the Tax Cuts and Jobs Act of 2017. The OBBBA contains a number of tax provisions including, but not limited to, immediate expensing of domestic research and experimental expenditures, modifications to the limitation on business interest, bonus depreciation

modifications, as well as international tax provision modifications. The Company has reflected the effect of OBBBA within the provision for income taxes and the deferred taxes as of December 31, 2025.

Cash amounts paid for income taxes, net of refunds received, were immaterial in both 2024 and 2025.

8. Commitments and contingencies

The Company has operating leases for its office and laboratory space in San Diego, California.

In March 2021, the Company entered into a lease agreement for 10,867 square feet of office and laboratory space in San Diego, California (the "JHC Lease"). The JHC Lease commenced on March 9, 2021, with an initial term of five years and included aggregate monthly payments to the lessor of approximately \$0.1 million. The JHC Lease provided for rent abatements and scheduled increases in base rent. In June 2024, the JHC Lease was amended to reduce the remaining lease term by approximately two years, in connection with the Company's entry into a new facility lease. As a result of the modification, the Company reduced the right-of-use asset and corresponding lease liability by \$0.7 million, assuming a modified remaining lease term of 15 months and a modified discount rate of 7.6%, based on the Company's incremental borrowing rate at the date of the lease modification. The JHC Lease expired in July 2025.

In June 2024, the Company entered into a lease agreement for approximately 46,353 square feet of office and laboratory space in San Diego, California (the "Science Center Lease"). The construction and design of the space was the primary responsibility of the lessor. The Science Center Lease is accounted for as an operating lease and commenced in June 2025, with a ten-year initial term through June 2035. The Science Center Lease includes aggregate monthly rent payments to the lessor of approximately \$0.3 million, with a rent escalation clause providing for annual increases in base rent of 3%, and a free rent period for the first 12 months following the lease commencement date. Additionally, the Company is obligated to remit to the lessor its allocable portion of real estate taxes, maintenance costs, and other operating expenses attributable to the leased premises, which are variable in nature. The Company shall remain fully liable for such costs throughout the duration of any free rent period. The Company paid a cash security deposit of \$0.9 million, which is refundable at the end of the lease term and is included in other long-term assets in the Company's balance sheet as of December 31, 2025. The Science Center Lease includes one option to renew for either five or two additional years, at the Company's election, at fair market value. The Company has not yet determined whether it will exercise the renewal option.

Cash paid for amounts included in the measurement of lease liabilities was \$0.8 million and \$0.5 million for the years ended December 31, 2024 and 2025, respectively.

The components of lease expense include operating and variable lease costs. Amortization is recorded within research and development and general and administrative expenses in the statements of operations. Components of lease cost for the years ended December 31, 2024 and 2025, respectively, were as follows (in thousands):

	Year ended December 31,	
	2024	2025
Operating lease cost	\$ 781	\$ 2,703
Short-term lease cost	301	146
Variable lease cost	380	373
Total lease cost	\$ 1,462	\$ 3,222

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Maturities of lease liabilities, weighted-average remaining term and weighted-average discount rate were as follows (in thousands):

Year ending December 31,	
2026	\$ 2,289
2027	3,910
2028	4,024
2029	4,141
2030	4,265
Thereafter	20,577
Total future minimum lease payments	39,206
Less: amount representing interest	(16,808)
Present value of operating lease liabilities	22,398
Less: operating lease liabilities, current	(5)
Operating lease liabilities, non-current	\$ 22,393

	As of December 31,	
	2024	2025
Weighted-average remaining lease term (years)	0.7	9.5
Weighted-average incremental borrowing rate	7.60%	11.80%

9. Segment information

The Company operates and manages its business as one reportable and operating segment, which is the business of designing and developing novel small molecule product candidates. The Company's chief operating decision maker is the Chief Executive Officer, who assesses performance of the segment based on net loss, which includes evaluating the progress of ongoing clinical trials. The measure of segment assets is reported on the balance sheet as total assets. All long-lived assets are maintained in the United States. The following table contains information on segment profit or loss, including significant segment expenses (in thousands):

	Year ended December 31,	
	2024	2025
Operating expenses:		
Research and development expenses		
BH-30643	\$ 5,958	\$ 20,648
BH-30236	3,841	6,829
BH-501284	—	891
Other projects	2,829	1,764
Nonproject specific research and development expenses	19,182	26,006
General and administrative expense	4,591	7,886
Other income	5,706	3,469
Net loss	\$ 30,695	\$ 60,555

10. Subsequent events

Management has reviewed and evaluated material subsequent events through April 24, 2026, which is the date the financial statements were available for issuance. No material subsequent events were identified that require adjustment to or disclosure in these financial statements, other than as described herein.

Stock option issuance

During the period from December 31, 2025 to the date that these financial statements were issued, the Company granted stock options to employees to purchase an aggregate of 204,781 shares of common stock at a weighted-average exercise price of \$10.82 per share under the 2020 Plan.

Reverse stock split

On July 31, 2026, the Company effected a one-for-4.6855 reverse stock split of its common stock and convertible preferred stock. The par value and the authorized shares of the common stock and convertible preferred stock were not adjusted as a result of the reverse stock split. The accompanying financial statements and notes to the financial statements give retroactive effect to the reverse stock split for all periods presented.

BlossomHill Therapeutics, Inc.
Condensed balance sheets (unaudited)
(in thousands, except share and par value data)

	December 31, 2025	March 31, 2026
Assets		
Current assets:		
Cash and cash equivalents	\$ 136,682	\$ 116,003
Prepaid expenses and other current assets	2,144	3,720
Total current assets	138,826	119,723
Property and equipment, net	1,726	1,614
Operating lease right-of-use assets	19,921	19,596
Other assets	2,495	2,477
Total assets	\$ 162,968	\$ 143,410
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 2,314	\$ 5,380
Accrued expenses	8,431	8,180
Accrued compensation	4,730	2,125
Operating lease liability, current	5	493
Total current liabilities	15,480	16,178
Operating lease liability, non-current	22,393	22,529
Total liabilities	37,873	38,707
Commitments and contingencies (Note 6)		
Convertible preferred stock, \$0.0001 par value; 85,552,612 shares authorized at December 31, 2025 and March 31, 2026; 18,258,960 shares issued and outstanding at December 31, 2025 and March 31, 2026; \$257,153 aggregate liquidation preference at December 31, 2025 and March 31, 2026	256,823	256,823
Stockholders' deficit:		
Common stock, \$0.0001 par value; 110,000,000 shares authorized at December 31, 2025 and March 31, 2026; 2,548,659 and 2,644,326 shares issued and outstanding as of December 31, 2025 and March 31, 2026, respectively	1	1
Additional paid-in capital	3,300	3,916
Accumulated deficit	(135,029)	(156,037)
Total stockholders' deficit	(131,728)	(152,120)
Total liabilities, convertible preferred stock and stockholders' deficit	\$ 162,968	\$ 143,410

See accompanying notes to unaudited condensed financial statements

BlossomHill Therapeutics, Inc.
Condensed statements of operations (unaudited)
(in thousands, except share and per share data)

	Three months ended March 31,	
	2025	2026
Operating expenses:		
Research and development	\$ 9,572	\$ 19,901
General and administrative	1,882	2,206
Total operating expenses	11,454	22,107
Loss from operations	(11,454)	(22,107)
Other income (expense), net:		
Interest income, net	976	1,102
Other expense	—	(3)
Total other income, net	976	1,099
Net loss	\$ (10,478)	\$ (21,008)
Net loss per share, basic and diluted	\$ (4.39)	\$ (8.14)
Weighted-average common shares outstanding, basic and diluted	2,386,501	2,580,106

See accompanying notes to unaudited condensed financial statements

BlossomHill Therapeutics, Inc.

Condensed statements of convertible preferred stock and stockholders' deficit (unaudited)

(in thousands, except share data)

	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2024	13,485,975	\$ 172,885	2,381,320	\$ 1	\$ 1,590	\$ (74,474)	\$ (72,883)
Exercise of stock options	—	—	13,117	—	39	—	39
Stock-based compensation expense	—	—	—	—	231	—	231
Net loss	—	—	—	—	—	(10,478)	(10,478)
Balance at March 31, 2025	13,485,975	\$ 172,885	2,394,437	\$ 1	\$ 1,860	\$ (84,952)	\$ (83,091)

	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2025	18,258,960	\$ 256,823	2,548,659	\$ 1	\$ 3,300	\$ (135,029)	\$ (131,728)
Exercise of stock options	—	—	95,667	—	293	—	293
Stock-based compensation expense	—	—	—	—	323	—	323
Net loss	—	—	—	—	—	(21,008)	(21,008)
Balance at March 31, 2026	18,258,960	\$ 256,823	2,644,326	\$ 1	\$ 3,916	\$ (156,037)	\$ (152,120)

See accompanying notes to unaudited condensed financial statements

BlossomHill Therapeutics, Inc.
Condensed statements of cash flows (unaudited)
(in thousands)

	Three months ended March 31,	
	2025	2026
Cash flows from operating activities:		
Net loss	\$ (10,478)	\$ (21,008)
Adjustments to reconcile net loss to net cash used in operations		
Depreciation expense	85	125
Non-cash lease expense	179	325
Stock-based compensation expense	231	323
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,766	(1,106)
Other assets	(1,566)	18
Accounts payable	654	3,066
Accrued compensation	(895)	(2,605)
Accrued expenses	(762)	(702)
Operating lease liabilities	(193)	624
Net cash used in operating activities	(10,979)	(20,940)
Cash flows from investing activities:		
Purchases of property and equipment	(402)	(13)
Net cash used in investing activities	(402)	(13)
Cash flows from financing activities:		
Proceeds from the exercise of stock options	39	274
Net cash provided by financing activities	39	274
Net increase (decrease) in cash and cash equivalents	(11,342)	(20,679)
Cash and cash equivalents at the beginning of period	100,147	136,682
Cash and cash equivalents at the end of period	\$ 88,805	\$ 116,003
Supplemental disclosure of noncash activities:		
Deferred offering costs in accounts payable and accrued expenses	\$ —	\$ (451)

See accompanying notes to unaudited condensed financial statements

BlossomHill Therapeutics, Inc.

Notes to condensed financial statements (unaudited)

1. Organization, liquidity and going concern and basis of presentation

Organization

BlossomHill Therapeutics, Inc. (the “Company”) is a clinical-stage biopharmaceutical company applying its intentional, chemistry-based approach to develop innovative small molecule medicines that address significant unmet medical needs in cancer treatment. The Company was incorporated in the State of Delaware on June 22, 2020, and its principal operations are in San Diego, California.

From its inception to March 31, 2026, the Company has devoted substantially all of its resources to conducting research and development, staffing the Company, establishing and protecting the Company’s intellectual property portfolio, scaling up manufacturing processes and supplying product candidates and other materials for the Company’s preclinical studies and clinical trials, leasing office and laboratory space, raising capital, business planning and providing general and administrative support for these activities. The Company’s operations to date have been funded primarily through the issuance of convertible preferred stock.

Liquidity and going concern

In accordance with Accounting Standards Codification (“ASC”) Topic 205-40, *Going Concern*, the Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year from the date that these financial statements are issued.

The Company has incurred net losses and negative cash flows from operations since inception, has a significant accumulated deficit and expects to continue to incur net losses for the foreseeable future. The Company has never generated any revenue from product sales and does not expect to generate any revenues from product sales unless and until it successfully completes development of and obtains regulatory approval for its product candidates, which will not be for several years, if ever.

As the Company continues to pursue its business plan, it expects to finance its operations through a combination of public or private equity or debt financings or other capital sources, which may include strategic collaborations and other strategic arrangements with third parties. However, there can be no assurance that any additional financing or strategic transactions will be available to the Company on acceptable terms, if at all.

As of June 11, 2026, the issuance date of the financial statements as of and for the three months ended March 31, 2026, there is uncertainty about whether the Company’s cash and cash equivalents will be sufficient to fund operations beyond twelve months from the issuance date of these financial statements and therefore the Company concluded that substantial doubt exists about the Company’s ability to continue as a going concern.

The accompanying financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

Basis of presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) and pursuant to rules and regulations of

the Securities and Exchange Commission for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. These unaudited condensed financial statements include only normal and recurring adjustments that the Company believes are necessary to fairly state the Company's financial position and the results of its operations and cash flows. The results for the three months ended March 31, 2026 are not necessarily indicative of the results expected for the full fiscal year or any subsequent interim period. The unaudited condensed balance sheet as of December 31, 2025 has been derived from the audited financial statements as of that date but does not include all disclosures required by GAAP for complete financial statements. As all of the disclosures required by GAAP for complete financial statements are not included herein, these unaudited condensed financial statements and the notes accompanying herein should be read in conjunction with the Company's audited financial statements as of and for the years ended December 31, 2024 and 2025. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the ASC and Accounting Standards Updates ("ASU") promulgated by the Financial Accounting Standards Board ("FASB").

2. Summary of significant accounting policies

The Company's significant accounting policies are disclosed in the audited financial statements as of and for the years ended December 31, 2024 and 2025, included elsewhere in this prospectus. Since the date of those financial statements, there have been no changes to its significant accounting policies, except where noted below.

Common stock valuation

Due to the absence of an active market for the Company's common stock, the Company utilized methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants' Audit and Accounting Practice Guide: *Valuation of Privately-Held Company Equity Securities Issued as Compensation* to estimate the fair value of its common stock. In determining the exercise prices for options granted, the Company has considered the fair value of the common stock as of the grant date. The estimated fair value of the common stock has been determined based upon a variety of factors, including:

- the prices at which the Company sold shares of its convertible preferred stock and the superior rights, preferences and privileges of the convertible preferred stock relative to the Company's common stock at the time of each grant;
- the progress of the Company's research and development programs;
- the Company's stage of development and its business strategy;
- external market conditions affecting the biotechnology industry and trends within the biotechnology industry;
- the Company's financial position, including cash on hand, and its historical and forecasted performance and operating results;
- the lack of an active public market for the Company's common stock and its convertible preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering or sale of the Company in light of prevailing market conditions; and
- the analysis of IPOs and the valuations and market performance of similar companies in the biotechnology industry.

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Based on the Company's early stage of development and other relevant factors, options granted prior to February 11, 2026, were valued using an option pricing method ("OPM") as an OPM was the most appropriate method for allocating the enterprise value to determine the estimated fair value of the common stock. For options granted after February 11, 2026, the Company determined that a hybrid method that combines both OPM and probability-weighted expected return method ("PWERM") was the most appropriate method to determine the estimated fair value of the Company's common stock.

Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

Deferred offering costs

The Company capitalizes costs that are directly associated with in-process equity financings until such financings are consummated, at which time such costs are recorded against the gross proceeds of the offering. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the statements of operations. As of March 31, 2026, the Company had deferred offering costs of \$0.5 million, recorded as a component of prepaid expenses and other current assets. There were no deferred offering costs as of December 31, 2025.

Net loss per share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock and common stock equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. The Company's potentially dilutive securities include outstanding convertible preferred stock, as well as outstanding stock options under the Company's 2020 Equity Incentive Plan and have been excluded from the computation of diluted net loss per share as their inclusion would be anti-dilutive. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

The following table summarizes the outstanding potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because their inclusion in the calculation would be anti-dilutive:

	As of March 31,	
	2025	2026
Convertible preferred stock	13,485,975	18,258,960
Outstanding options under the Company's 2020 Equity Incentive Plan	989,678	1,128,299
Total	14,475,653	19,387,259

Emerging growth company status

The Company is an "emerging growth company," as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"), and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. The Company may take advantage of these exemptions up until the last day of the fiscal year following the fifth anniversary of an offering or such earlier time that the Company is no longer an "emerging growth company." Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. The Company has elected to use the extended transition period for complying with new or revised accounting standards and as a result of this election, its financial statements may not be comparable to companies that comply with public company effective dates. However, the Company may elect to early adopt any new or revised accounting

standards whenever such early adoption is permitted for non-public companies. The Company may take advantage of these exemptions up until the time that it is no longer an emerging growth company.

Recently issued accounting pronouncements

There were no significant updates not already disclosed in the Company's audited financial statements for the years ended December 31, 2024 and 2025 to the recently issued accounting standards for the three months ended March 31, 2026. Although there are several other new accounting pronouncements issued by the FASB, the Company does not believe any of those accounting pronouncements have had or will have a material impact on its financial position or operating results.

3. Fair value measurements

The following tables show the Company's cash equivalents measured at fair value as of December 31, 2025 and March 31, 2026 (in thousands):

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents				
Money market funds	\$ 135,227	\$ —	\$ —	\$ 135,227
Total	\$ 135,227	\$ —	\$ —	\$ 135,227

	March 31, 2026			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents				
Money market funds	\$ 113,729	\$ —	\$ —	\$ 113,729
Total	\$ 113,729	\$ —	\$ —	\$ 113,729

The carrying amounts of the Company's accounts payable, accrued expenses and accrued compensation approximate fair value due to their short maturities. None of the Company's non-financial assets or liabilities are measured at fair value on a non-recurring basis. There were no transfers between Levels 1, 2 or 3 for any of the periods presented.

4. Accrued expenses

Accrued expenses consisted of the following (in thousands):

	As of December 31, 2025	As of March 31, 2026
Accrued research and development expenses	\$ 8,297	\$ 7,614
Other	134	566
Total accrued expenses	\$ 8,431	\$ 8,180

5. Convertible preferred stock and stockholders' deficit

Stockholders' deficit

As of March 31, 2026, under the Company's Amended and Restated Certificate of Incorporation, the Company had a total of 195,552,612 shares of capital stock authorized for issuance, consisting of 110,000,000 shares of common stock, par value of \$0.0001 per share, and 85,552,612 shares of convertible preferred stock, par value of \$0.0001 per share.

Convertible preferred stock

As of December 31, 2025 and March 31, 2026, issued and outstanding convertible preferred stock consisted of the following (in thousands, except share and per share amounts):

Series	Shares authorized	Shares outstanding	Original issue price	Liquidation preference	Carrying value
Series Angel	10,000,000	2,134,242	\$ 0.9371	\$ 2,000	\$ 2,000
Series A	26,613,546	5,679,965	12.5000	71,000	70,981
Series B	48,939,066	10,444,753	17.6311	184,153	183,842
Total	85,552,612	18,258,960		\$ 257,153	\$ 256,823

In December 2020, the Company issued 2,134,242 shares of its Series Angel convertible preferred stock at a price of \$0.94 per share, resulting in aggregate gross proceeds of \$2.0 million, and incurred immaterial issuance costs.

In March 2021, the Company issued 5,679,965 shares of its Series A convertible preferred stock at a price of approximately \$12.50 per share, resulting in aggregate gross proceeds of \$71.0 million, and incurred immaterial issuance costs.

The Company entered into the Series B Preferred Stock Purchase Agreement dated December 28, 2023, whereby the Company agreed to issue and sell, and certain investors agreed to purchase an aggregate of 5,671,768 shares of the Company's Series B convertible preferred stock, in one or more closings. In December 2023, the Company issued 5,028,022 shares of its Series B convertible preferred stock at a price of approximately \$17.63 per share, resulting in aggregate gross proceeds of \$88.7 million, and incurred immaterial issuance costs. Through December 31, 2023, the Company received \$82.8 million in proceeds and recorded a receivable for the remaining \$5.8 million. Cash proceeds related to this receivable were received in 2024. In January 2024, the Company issued 643,746 shares of its Series B convertible preferred stock at a price of approximately \$17.63 per share, resulting in aggregate gross proceeds of \$11.3 million, and incurred immaterial issuance costs.

The Company entered into a subsequent Series B Preferred Stock Purchase Agreement dated November 25, 2025, whereby the Company agreed to issue and sell, and certain investors agreed to purchase an aggregate of 4,772,985 shares of the Company's Series B convertible preferred stock. Between November and December 2025, the Company issued 4,772,985 shares of its Series B convertible preferred stock at a price of approximately \$17.63 per share, resulting in aggregate gross proceeds of \$84.2 million, and incurred \$0.1 million of issuance costs.

As of March 31, 2026, the Company's Series Angel, Series A and Series B convertible preferred stock have been classified as temporary equity in the accompanying balance sheets given that the holders of the convertible preferred stock could cause certain events to occur that are outside of the Company's control whereby the Company could be obligated to redeem the convertible preferred stock. The carrying value of the convertible

preferred stock is not adjusted to the redemption value until the contingent redemption events are considered to be probable of occurring.

The Company's convertible preferred stock has the following rights, preferences and privileges:

Dividends

The Company shall not declare or pay any dividends on shares of any class of capital stock of the Company unless the holders of the Series Angel, Series A or Series B convertible preferred stock shall first receive, or simultaneously receive, a dividend on each outstanding share of such convertible preferred stock equal to an amount as defined in the Company's Amended and Restated Certificate of Incorporation. No such dividends have been declared or paid through March 31, 2026.

Preferences on liquidation

The holders of the Series A and Series B convertible preferred stock are entitled to receive liquidation preferences, in the event of a change in control, liquidation, dissolution or winding up, at an amount per share equal to the greater of (i) the original issuance price, plus any dividends declared but unpaid or (ii) the amount per share that would be payable had the share been converted to shares of common stock immediately prior to the liquidation event. Liquidation payments to the holders of the Series A and Series B convertible preferred stock have priority and are made in preference to any payments to the holders of Series Angel convertible preferred stock and common stock. If assets available to be distributed are insufficient to pay Series A and Series B convertible preferred stockholders, amounts available will be distributed on a pro-rata basis.

After full payment of the liquidation preference to the holders of the Series A and Series B convertible preferred stock, the remaining assets, if any, will be distributed to the holders of the Series Angel convertible preferred stock. The holders of the Series Angel convertible preferred stock are entitled to receive liquidation preferences, in the event of a change in control, liquidation, dissolution or winding up, at an amount per share equal to the greater of (i) the original issuance price, plus any dividends declared but unpaid or (ii) the amount per share that would be payable had the share been converted to shares of common stock immediately prior to the liquidation event. Liquidation payments to the holders of the Series Angel convertible preferred stock have priority and are made in preference to any payments to the holders of common stock. If assets available to be distributed are insufficient to pay Series Angel convertible preferred stockholders, amounts available will be distributed on a pro-rata basis.

After full payment of the liquidation preference to the holders of the Series Angel, Series A and Series B convertible preferred stock, the remaining assets, if any, will be distributed to the holders of common stock, pro rata based on the number of shares held by each holder.

Conversion rights

The shares of Series Angel, Series A and Series B convertible preferred stock are convertible into common stock at the option of the holder. The conversion rate for the convertible preferred stock is determined by dividing the original issue price by the conversion price. The conversion price is initially the original issue price, but is subject to adjustment for dividends, stock splits and other distributions. The conversion rate on March 31, 2026, for the Series Angel, Series A and Series B convertible preferred stock was 1:1.

Each share of Series Angel, Series A and Series B convertible preferred stock will be automatically converted into common stock at the then effective conversion rate upon: (i) the closing of the sale of common stock to the public (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the common stock), in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at

least \$50.0 million of gross proceeds to the Company; or (ii) the date and time, or the occurrence of an event, specified by vote or written consent of the majority of holders of the outstanding shares of Series Angel, Series A and Series B convertible preferred stock.

Voting

The holders of Series Angel convertible preferred stock shall be entitled to cast the number of votes equal to ten times the number of shares of Common Stock into which the shares of Series Angel convertible preferred stock held by such holder are then convertible. The holders of Series A and Series B convertible preferred stock shall be entitled to cast the number of votes equal to the number of shares of common stock into which the shares of Series A and Series B convertible preferred stock held by such holder are then convertible. The holders of Series Angel, Series A and Series B convertible preferred stock generally vote together with the shares of common stock as a single class, but also have class vote approval rights as provided by the Company's amended and restated certificate of incorporation or as required by applicable law.

The holders of shares of Series Angel convertible preferred stock, exclusively and as a separate class, shall be entitled to elect one member of the board of directors. The holders of shares of Series A convertible preferred stock, exclusively and as a separate class, shall be entitled to elect three members of the board of directors. The holders of shares of Series B convertible preferred stock, exclusively and as a separate class, shall be entitled to elect two members of the board of directors. The holders of shares of common stock, exclusively and as a separate class, shall be entitled to elect at least one member of the board of directors. The holders of Series Angel, Series A and Series B convertible preferred stock voting together as a single class, shall be entitled to elect all remaining members of the board of directors.

Common stock

The voting, dividend and liquidation rights of the holders of the common stock are subject to, and qualified by, the rights, preferences and privileges of the holders of the Series Angel, Series A and Series B convertible preferred stock. The holders of the common stock are entitled to one vote for each share of common stock held at all meetings of stockholders.

Common stock reserved for future issuance consisted of the following:

	As of December 31, 2025	As of March 31, 2026
Common stock options granted and outstanding	1,178,237	1,128,299
Shares available for issuance under the 2020 equity incentive plan	328,821	283,095
Total common stock reserved for future issuance	1,507,058	1,411,394

Stock options

In June 2020, the Company adopted the 2020 Equity Incentive Plan (the "2020 Plan"). The Plan provides for the grant of incentive stock options ("ISO"), non-statutory stock options ("NSO"), stock bonus awards and restricted stock awards. A total of 320,137 shares of common stock were initially reserved for issuance under the 2020 Plan. The 2020 Plan was subsequently amended in February 2021, July 2023 and March 2025 to increase the total number of shares available under the 2020 Plan to 691,495, 1,395,279, and 1,921,534, respectively.

Options granted under the Plan are exercisable at various dates as determined upon grant and will expire no more than ten years from their date of grant. The exercise price of each option shall be determined by the board of directors based on the estimated fair value of the Company's stock on the date of the option grant. The

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exercise price shall not be less than 100% of the fair market value of the Company's common stock at the time the option is granted. The stock option awards generally include service condition vesting terms of four years, with 25% of the award vesting one year from the vesting commencement date and then ratably over the following 36 months, though some vest over shorter periods, vesting monthly from grant date.

A summary of the Company's stock option activity under the 2020 Plan is as follows:

	Options	Weighted-average exercise price	Weighted- average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2025	1,178,237	\$ 5.26	8.6	\$ 2,526
Granted	47,057	\$ 7.40		
Exercised	(95,667)	\$ 3.07		
Forfeited	(1,328)	\$ 2.91		
Expired	—	\$ —		
Outstanding at March 31, 2026	1,128,299	\$ 5.54	8.6	\$ 2,105
Exercisable at March 31, 2026	320,241	\$ 4.84	8.1	\$ 812
Vested and expected to vest at March 31, 2026	1,128,299	\$ 5.54	8.6	\$ 2,105

The weighted-average grant date fair value of options granted for the three months ended March 31, 2025 and 2026, was \$4.09 and \$5.37 per share, respectively. As of December 31, 2025 and March 31, 2026, the Company recorded receivables for amounts related to option exercises of approximately \$31 thousand and \$19 thousand, respectively. These amounts were received subsequent to the respective period end. The total intrinsic value of options exercised during the three months ended March 31, 2025 and 2026 was less than \$0.1 million and \$0.4 million, respectively.

Stock-based compensation expense

Stock-based compensation expense recognized for all equity awards has been included in the statements of operations as follows (in thousands):

	Three months ended March 31,	
	2025	2026
Research and development	210	241
General and administrative	21	82
Total stock-based compensation expense	\$ 231	\$ 323

The fair value of stock options granted during the three months ended March 31, 2025 and 2026 was estimated using the following assumptions:

	Three months ended March 31,	
	2025	2026
Risk-free interest rate	4.23% - 4.41%	3.85% - 3.85%
Expected term (years)	6.00	5.96 - 5.98
Expected stock price volatility	82.39% - 83.30%	83.29% - 83.31%
Expected dividend yield	—	—

As of March 31, 2026, the unrecognized compensation cost related to outstanding employee and non-employee options was \$3.3 million and is expected to be recognized as expense over a weighted-average period of approximately 2.8 years.

6. Commitments and contingencies

The Company has operating leases for its office and laboratory space in San Diego, California.

In March 2021, the Company entered into a lease agreement for 10,867 square feet of office and laboratory space in San Diego, California (the "JHC Lease"). The JHC Lease commenced on March 9, 2021, with an initial term of five years and included aggregate monthly payments of approximately \$0.1 million. The JHC Lease provided for rent abatements and scheduled increases in base rent. In June 2024, the JHC Lease was amended to reduce the remaining lease term by approximately two years, in connection with the Company's entry into a new facility lease. As a result of the modification, the Company reduced the right-of-use asset and corresponding lease liability by \$0.7 million, assuming a modified remaining lease term of 15 months and a modified discount rate of 7.6%, based on the Company's incremental borrowing rate at the date of the lease modification. The JHC Lease expired in July 2025.

In June 2024, the Company entered into a lease agreement for approximately 46,353 square feet of office and laboratory space in San Diego, California (the "Science Center Lease"). The construction and design of the space was the primary responsibility of the lessor. The Science Center Lease is accounted for as an operating lease and commenced in June 2025, with a ten-year initial term through June 2035. The Science Center Lease includes aggregate monthly rent payments of approximately \$0.3 million, with a rent escalation clause providing for annual increases in base rent of 3%, and a free rent period for the first 12 months following the lease commencement date. Additionally, the Company is obligated to remit to the lessor its allocable portion of real estate taxes, maintenance costs, and other operating expenses attributable to the leased premises, which are variable in nature. The Company shall remain fully liable for such costs throughout the duration of any free rent period. The Company paid a cash security deposit of \$0.9 million, which is refundable at the end of the lease term and is included in other long-term assets in the Company's balance sheet as of March 31, 2026. The Science Center Lease includes one option to renew for either five or two additional years, at the Company's election, at fair market value. The Company has not yet determined whether it will exercise the renewal option.

Cash paid for amounts included in the measurement of lease liabilities was \$0.2 million and \$29 thousand for the three months ended March 31, 2025 and 2026, respectively.

The components of lease expense include operating and variable lease costs. Amortization is recorded within research and development and general and administrative expenses in the statements of operations. Components of lease cost for the three months ended March 31, 2025 and 2026, respectively, were as follows (in thousands):

	Three months ended March 31,	
	2025	2026
Operating lease cost	\$ 188	\$ 990
Short-term lease cost	77	1
Variable lease cost	27	353
Total lease cost	\$ 292	\$ 1,344

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Maturities of lease liabilities, weighted-average remaining term and weighted-average discount rate were as follows (in thousands):

Year ending December 31,	
2026 (remaining nine months)	\$ 2,256
2027	3,903
2028	4,020
2029	4,141
2030	4,265
Thereafter	20,577
Total future minimum lease payments	39,162
Less: amount representing interest	(16,140)
Present value of operating lease liabilities	23,022
Less: operating lease liabilities, current	(493)
Operating lease liabilities, non-current	\$ 22,529

	As of December 31, 2025	As of March 31, 2026
Weighted-average remaining lease term (years)	9.5	9.3
Weighted-average incremental borrowing rate	11.80%	11.80%

7. Segment information

The Company operates and manages its business as one reportable and operating segment, which is the business of designing and developing novel small molecule product candidates. The Company's chief operating decision maker is its Chief Executive Officer, who assesses performance of the segment based on net loss, which includes evaluating the progress of ongoing clinical trials. The measure of segment assets is reported on the balance sheet as total assets. All long-lived assets are maintained in the United States. The following table contains information on segment profit or loss, including significant segment expenses (in thousands):

	Three months ended March 31,	
	2025	2026
Operating expenses:		
Research and development expenses:		
BH-30643	\$ 1,782	\$ 9,550
BH-30236	1,048	1,747
BH-501284	—	585
Other projects	1,007	10
Non project specific research and development expenses	5,735	8,009
General and administrative expenses	1,882	2,206
Other income	976	1,099
Net loss	\$ 10,478	\$ 21,008

8. Subsequent events

Management has reviewed and evaluated material subsequent events through July 16, 2026, which is the date the financial statements were available for issuance. During the period from March 31, 2026 to the date that these financial statements were available for issuance, the Company granted stock options to employees and consultants to purchase an aggregate of 339,502 shares of common stock at a weighted-average exercise price of \$12.78 per share under the 2020 Plan.

On July 31, 2026, the Company effected a one-for-4.6855 reverse stock split of its common stock and convertible preferred stock. The par value and the authorized shares of the common stock and convertible preferred stock were not adjusted as a result of the reverse stock split. The accompanying financial statements and notes to the financial statements give retroactive effect to the reverse stock split for all periods presented.

9,375,000 shares



Common stock

Prospectus

J.P. Morgan

Leerink Partners

Guggenheim Securities

LifeSci Capital

H.C. Wainwright & Co.

August 6, 2026