UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2026

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from ____ to ____

Commission File Number: 001-43435

BlossomHill Therapeutics, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**85-1578711**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
10255 Science Center Drive	
Suite 200	
San Diego, CA	**92121**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 732-3880

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	BLSM	The Nasdaq Global Select Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☐ No ☒

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of September 16, 2026, the registrant had 31,784,909 shares of common stock, $0.0001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains express or implied forward-looking statements about us and our industry that involve substantial risks and uncertainties, within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). All statements other than statements of historical fact contained in this Quarterly Report on Form 10-Q, 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, investors 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;
- 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 or other countries where we conduct clinical development or other business operations;
- 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

- other risks and uncertainties, including those listed under the section titled “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

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 Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q, 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 Quarterly Report on Form 10-Q 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, investors should not place undue reliance on these forward-looking statements.

Investors should carefully read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed as exhibits hereto 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 Quarterly Report on Form 10-Q 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.

RISK FACTOR SUMMARY

Our business is subject to numerous risks and uncertainties, including those described in Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q. The following is a summary of the principal risks and uncertainties described in more detail in this Quarterly Report on Form 10-Q:

- 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 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.
- 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, 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, BH-30236 and BH-501284, 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.
- 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.
- 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 is likely to be volatile and you could lose all or part of your investment.

The above summary is not complete and is qualified in its entirety by the more detailed discussion of these and other risks and uncertainties set forth in Part II, Item 1A, “Risk Factors” in this Quarterly Report on Form 10-Q, which you should read carefully together with all of the other information contained in this Quarterly Report on Form 10-Q before making an investment decision.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

BLOSSOMHILL THERAPEUTICS, INC.
UNAUDITED CONDENSED BALANCE SHEETS
(in thousands, except share and par value data)

	June 30, 2026 (unaudited)	December 31, 2025
Assets		
Current Assets:		
Cash and cash equivalents	$ 95,376	$ 136,682
Prepaid expenses and other current assets	5,592	2,144
Total current assets	100,968	138,826
Property and equipment, net	1,489	1,726
Operating lease right-of-use assets	19,197	19,921
Other assets	2,477	2,495
Total assets	$ 124,131	$ 162,968
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 3,930	$ 2,314
Accrued expenses	9,194	8,431
Accrued compensation	3,539	4,730
Other current liabilities	809	-
Operating lease liability, current	1,149	5
Total current liabilities	18,621	15,480
Operating lease liability, non-current	22,222	22,393
Other long-term liabilities	1,245	-
Total liabilities	42,088	37,873
Commitments and contingencies (Note 6)		
Convertible preferred stock, $0.0001 par value; 85,552,612 shares authorized at June 30, 2026 and December 31, 2025; 18,258,960 shares issued and outstanding at June 30, 2026 and December 31, 2025; $257,153 aggregate liquidation preference at June 30, 2026 and December 31, 2025	256,823	256,823
Stockholders' deficit:		
Common stock, $0.0001 par value; 110,000,000 shares authorized at June 30, 2026 and December 31, 2025; 2,767,848 and 2,548,659 shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively.	1	1
Additional paid-in capital	5,014	3,300
Accumulated deficit	(179,795)	(135,029)
Total stockholders' deficit	(174,780)	(131,728)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 124,131	$ 162,968

The accompanying notes are an integral part of these unaudited condensed financial statements.

BLOSSOMHILL THERAPEUTICS, INC.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 21,355	$ 12,530	$ 41,256	$ 22,102
General and administrative	3,315	1,573	5,521	3,455
Total operating expenses	24,670	14,103	46,777	25,557
Loss from operations	(24,670)	(14,103)	(46,777)	(25,557)
Other income (expense), net:				
Interest income, net	915	859	2,017	1,835
Other expense, net	(3)	-	(6)	-
Total other income, net	912	859	2,011	1,835
Net loss	$ (23,758)	$ (13,244)	$ (44,766)	$ (23,722)
Net loss per share, basic and diluted	$ (8.75)	$ (5.51)	$ (16.91)	$ (9.90)
Weighted average common shares outstanding, basic and diluted	2,713,696	2,405,140	2,646,721	2,395,789

The accompanying notes are an integral part of these unaudited condensed financial statements.

BLOSSOMHILL THERAPEUTICS, INC.
UNAUDITED CONDENSED 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 March 31, 2026	18,258,960	$ 256,823	2,644,326	$ 1	$ 3,916	$ (156,037)	$ (152,120)
Exercise of stock options	-	-	107,191	-	447	-	447
Vesting of restricted common stock	-	-	16,331	-	74	-	74
Stock-based compensation expense	-	-	-	-	577	-	577
Net loss	-	-	-	-	-	(23,758)	(23,758)
Balance at June 30, 2026	18,258,960	256,823	2,767,848	1	5,014	(179,795)	(174,780)
Balance at December 31, 2025	18,258,960	$ 256,823	2,548,659	$ 1	$ 3,300	$ (135,029)	$ (131,728)
Exercise of stock options	-	-	202,858	-	740	-	740
Vesting of restricted common stock	-	-	16,331	-	74	-	74
Stock-based compensation expense	-	-	-	-	900	-	900
Net loss	-	-	-	-		(44,766)	(44,766)
Balance at June 30, 2026	18,258,960	$ 256,823	2,767,848	$ 1	$ 5,014	$ (179,795)	$ (174,780)

The accompanying notes are an integral part of these unaudited condensed financial statements.

BLOSSOMHILL THERAPEUTICS, INC.
UNAUDITED CONDENSED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (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 March 31, 2025	13,485,975	$ 172,886	2,394,437	$ 1	$ 1,860	$ (84,952)	$ (83,091)
Exercise of stock options	-	-	16,579	-	47	-	47
Stock-based compensation expense	-	-	-	-	254	-	254
Net loss	-	-	-	-	-	(13,244)	(13,244)
Balance at June 30, 2025	13,485,975	172,886	2,411,016	1	2,161	(98,196)	(96,034)
Balance at December 31, 2024	13,485,975	$ 172,886	2,381,320	$ 1	$ 1,590	$ (74,474)	$ (72,883)
Exercise of stock options	-	-	29,696	-	86	-	86
Stock-based compensation expense	-	-	-	-	485	-	485
Net loss	-	-	-	-		(23,722)	(23,722)
Balance at June 30, 2025	13,485,975	$ 172,886	2,411,016	$ 1	$ 2,161	$ (98,196)	$ (96,034)

The accompanying notes are an integral part of these unaudited condensed financial statements.

BLOSSOMHILL THERAPEUTICS, INC.
UNAUDITED CONDENSED STATEMENTS OF CASH FLOWS
(in thousands)

	Six Months Ended June 30,	
	2026	2025
Cash flows from operating activities:		
Net loss	$ (44,766)	$ (23,722)
Adjustments to reconcile net loss to net cash used in operations		
Depreciation expense	250	187
Non-cash lease expense	724	482
Stock-based compensation expense	900	485
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(2,323)	2,251
Other assets	18	(1,484)
Accounts payable	1,616	(180)
Accrued expenses	(373)	1,341
Accrued compensation	(1,191)	471
Operating lease liabilities	971	48
Net cash used in operating activities	(44,174)	(20,121)
Cash flows from investing activities:		
Purchases of property and equipment	(13)	(997)
Net cash used in investing activities	(13)	(997)
Cash flows from financing activities:		
Proceeds from the exercise of stock options	2,881	85
Net cash provided by financing activities	2,881	85
Net increase (decrease) in cash and cash equivalents	(41,306)	(21,033)
Cash and cash equivalents at the beginning of period	136,682	100,147
Cash and cash equivalents at the end of period	$ 95,376	$ 79,114
Supplemental disclosure of noncash activities:		
Right-of-use asset obtained in exchange for operating lease liability	—	$ 20,927
Deferred financing costs included in accounts payable and accrued expenses	$ 1,136	—

The accompanying notes are an integral part of these unaudited condensed financial statements.

BLOSSOMHILL THERAPEUTICS, INC.
NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

Note 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 June 30, 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 through June 30, 2026 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.

The Company has an accumulated deficit of $179.8 million as of June 30, 2026. During the six months ended June 30, 2026, the Company used $44.2 million of cash for operating activities. As of June 30, 2026, the Company had $95.4 million in cash and cash equivalents. In August 2026, the Company closed on its Initial Public Offering (the "IPO"), in which the Company received aggregate net proceeds of $151.7 million, inclusive of the partial exercise of the underwriters' option to purchase additional shares (the "IPO Proceeds"). Management believes that the Company's existing cash resources, together with the IPO Proceeds, will be sufficient to fund operations for at least 12 months following the issuance of these unaudited condensed financial statements.

If the Company is unable to obtain additional funding before achieving sufficient profitability and positive cash flows from operations, the Company will be forced to delay, reduce or eliminate some or all of its research and development programs, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue plans to obtain additional funding before achieving sufficient profitability and positive cash flows from operations, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

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. 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 June 30, 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 June 30, 2026 has been derived from the 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 included in the Company's final prospectus dated August 7, 2026 related to its IPO filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended. 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").

Unaudited Condensed Interim Financial Information

The unaudited condensed balance sheet as of June 30, 2026, the unaudited condensed statements of operations for the three and six months ended June 30, 2026 and 2025, the unaudited condensed statements of convertible preferred stock and stockholders' deficit for the three and six months ended June 30, 2026 and 2025, and the unaudited condensed statements of cash flows for the six months ended June 30, 2026 and 2025 are unaudited. These unaudited condensed financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary to present fairly the Company's financial position, results of operations, and cash flows for the interim period presented. The financial data and the other financial information contained in these notes to the unaudited condensed financial statements related to the three and six months ended June 30, 2026 and 2025 are also unaudited. The condensed results of operations for the three and six months ended June 30, 2026 are not necessarily indicative of the results to be expected for the year ending December 31, 2026 or for any other future annual or interim period.

Note 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 in the Company's final prospectus dated August 7, 2026 related to its IPO filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended. Since the date of those financial statements, there have been no changes to its significant accounting policies, except where noted below.

Use of Estimates

The preparation of the Company's unaudited condensed financial statements requires the Company to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the unaudited condensed financial statements and accompanying notes. Such estimates include the estimated incremental borrowing rate for the determination of the Company's operating lease right-of-use assets, valuation of stock-based awards, fair value of common stock prior to the Company's IPO, and the accrual of research and development expenses. Management evaluates its estimates on an ongoing basis. Although estimates are based on the Company's historical experience, knowledge of current events, and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

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 prior to its IPO. 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.

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 June 30, 2026, the Company had deferred offering costs of $3.0 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. The Company has excluded 102,002 and 51,283 weighted-average shares subject to repurchase or forfeiture from the weighted-average number of shares of common stock outstanding for the three and six months ended June 30, 2026, respectively.

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. Potentially dilutive securities 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:

	Six Months Ended June 30,	
	2026	2025
Convertible preferred stock	18,258,960	13,485,975
Options to purchase common stock	1,121,232	1,178,288
Common stock subject to repurchase rights	223,098	—
Total	19,603,290	14,664,263

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 June 30, 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.

Note 3. Fair Value Measurements

The following tables show the Company's cash equivalents measured at fair value as of December 31, 2025 and June 30, 2026 (in thousands):

	June 30, 2026			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents				
Money market funds	$ 94,671	$ —	$ —	$ 94,671
Total	$ 94,671	$ —	$ —	$ 94,671

	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 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.

Note 4. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	As of June 30, 2026	As of December 31, 2025
Accrued research and development expenses	$ 7,938	$ 8,297
Other	1,256	134
Total accrued expenses	$ 9,194	$ 8,431

Note 5. Convertible Preferred Stock and Stockholders' Deficit

Stockholders' Deficit

As of June 30, 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

In 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 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.

In 2023, 2024 and 2025, the Company issued an aggregate of 10,444,753 shares of Series B convertible preferred stock at a price of $17.63 per share resulting in aggregate gross proceeds of $184.2 million and incurred $0.4 million of total issuance costs.

As of June 30, 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.

Immediately prior to the closing of the IPO in August 2026, the Company's outstanding convertible preferred stock automatically converted into 18,258,960 shares of common stock. Following the closing of the IPO, no shares of convertible preferred stock were outstanding.

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 June 30, 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 June 30, 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.

Stock Options

In June 2020, the Company adopted the 2020 Equity Incentive Plan (the "2020 Plan"). The 2020 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 2020 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.

A summary of the Company's stock option activity under the 2020 Plan is as follows:

	Options
Outstanding at December 31, 2025	1,178,288
Granted	386,564
Exercised	(219,189)
Forfeited	(1,333)
Expired	—
Outstanding at June 30, 2026	1,344,330
Exercisable at June 30, 2026	525,503
Vested and expected to vest at June 30, 2026	1,344,330

As of December 31, 2025 and June 30, 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.

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 June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Research and development	388	233	629	443
General and administrative	189	21	271	42
Total stock-based compensation expense	$ 577	$ 254	$ 900	$ 485

As of June 30, 2026, the unrecognized compensation cost related to outstanding employee and non-employee options was $6.0 million and is expected to be recognized as expense over a weighted-average period of approximately 2.9 years.

Early Exercise Liability

During the three months ended June 30, 2026, the Company amended certain stock option agreements to permit holders to exercise their stock options prior to vesting. Shares issued upon early exercise that remain unvested are subject to the Company's right to repurchase such shares at the original exercise price upon termination of the holder's service. The Company's repurchase right lapses as the underlying shares vest.

The right to repurchase shares that were exercised prior to the time the options have vested generally lapses over the four-year vesting period. As of June 30, 2026, the early exercise liability was approximately $2.1 million and is included in other current and noncurrent liabilities and reclassified to equity as the shares vest. For accounting purposes, the early exercise of options is not considered to be a substantive exercise until the underlying awards vest and are not considered to be outstanding until those shares vest.

Note 6. Commitments and Contingencies

The Company has operating leases for its office and laboratory space in San Diego, California. Rent expense was $1.3 million and $2.6 million for the three and six months ended June 30, 2026, respectively.

Note 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 June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development expenses				
BH-30643	$ 8,966	$ 3,827	$ 18,516	$ 5,608
BH-30236	1,967	1,339	3,714	2,388
BH-501284	2,045	61	2,629	61
Other projects	57	645	67	1,652
Non project specific research and development expenses	8,320	6,658	16,330	12,393
General and administrative expenses	3,315	1,573	5,521	3,455
Other income	912	859	2,011	1,835
Net loss	$ 23,758	$ 13,244	$ 44,766	$ 23,722

Note 8. Subsequent Events

For the purposes of the condensed financial statements as of June 30, 2026, and the three and six months then ended, the Company has evaluated the subsequent events through September 18, 2026, the date the condensed financial statements were issued.

On July 31, 2026, the Company effected a 1-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. These accompanying condensed financial statements and notes to the condensed financial statements give retroactive effect to the reverse stock split for all periods presented.

On August 10, 2026, the Company completed its IPO, pursuant to which it issued and sold 9,375,000 shares of common stock at a public offering price of $16.00 per share (the "IPO Price"). The aggregate gross proceeds of the IPO were $150.0 million before deducting underwriting discounts, commissions, and offering expenses of $15.3 million, for aggregate net proceeds from the IPO of $134.7 million. In addition, the Company granted the underwriters an option for a period of 30 days to purchase up to 1,406,250 additional shares of common stock. On August 25, 2026 the underwriters partially exercised their 30-day option and purchased an additional 1,141,240 shares of the Company's common stock at the IPO Price, upon which the Company received net proceeds of approximately $17.0 million. All underwriting discounts, commissions, and offering expenses, including the previously deferred offering costs as disclosed previously in this Quarterly Report, will be charged to additional paid in capital as recorded against the gross proceeds.

In connection with the closing of the IPO, the Company's outstanding convertible preferred stock automatically converted into 18,258,960 shares of common stock.

In connection with the closing of the IPO, the Company's board of directors adopted the 2026 Equity Incentive Plan (the "2026 Plan"), a successor to and continuation of the 2020 Plan (as defined in Note 5), and the 2026 Employee Stock Purchase Plan (the "2026 ESPP"). Upon the effectiveness of the 2026 Plan, 5,280,528 shares of common stock were authorized for issuance which consists of (1) 3,781,612 new shares of common stock, and (2) 1,498,916 shares available for issuance under the 2020 Plan. Furthermore, upon effectiveness of the 2026 Plan, no further grants will be made under the 2020 Plan. Upon the effectiveness of the 2026 ESPP, 302,529 shares of common stock were authorized for issuance.

Item 2. 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 Quarterly Report on Form 10-Q. 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 Quarterly Report on Form 10-Q. 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-naive settings, including a cohort with C797S resistance, a population with no currently approved targeted therapy, as well as in combination with carboplatin and pemetrexed. In September 2026, we presented updated data from the ongoing Phase 1/2 SOLARA trial in patients with EGFR C797S-positive NSCLC.

BH-30643 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-positive NSCLC (with or without T790M). 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.

In August 2026, the FDA granted Fast Track designation to BH-30643 for the treatment of adult patients with advanced or metastatic EGFR C797S-positive NSCLC after prior treatment with a third-generation EGFR TKI. 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 *EGFR*-mutant C797S-positive NSCLC is planned 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 updated Phase 1 data on durability of response in the C797S population in the first half of 2027, initial Phase 1 data on a chemotherapy combination cohort in the second half of 2027, and updated Phase 1 data on durability of response in TKI-naive patients in the second half of 2027.

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 AML patients. We also plan to explore the effect of BH-30236 in additional myeloid malignancies, including R/R myelofibrosis, as well as study the safety and antileukemic effect of BH-30236 with venetoclax plus azacitidine for the treatment of AML, with initial studies planned in R/R AML. We expect to report updated data on safety and anti-leukemic effects from the BH-30236 Phase 1 trial in the first half of 2027.

We are also advancing our pan-KRAS program, 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. 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 Investigational New Drug Application (IND) enabling studies of BH-501284 and plan to submit an IND in the first quarter of 2027.

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 June 30, 2026, we have raised aggregate gross proceeds of $257.2 million. Additionally, on August 10, 2026, we closed on our IPO, in which we issued and sold 9,375,000 shares of common stock at a public offering price of $16.00 per share. We also sold an additional 1,141,240 shares of common stock upon the partial exercise of the underwriters' option to purchase additional shares. The aggregate net proceeds of the IPO, inclusive of the partial exercise of the underwriters' option to purchase additional shares and after deducting underwriting discounts, commissions and offering expenses, was $151.7 million (IPO Proceeds). As of June 30, 2026, we had cash and cash equivalents of $95.4 million. Based on our current operating plan, we estimate that our existing cash and cash equivalents as of June 30, 2026, together with the IPO Proceeds, will be sufficient to fund our projected operating expenses and capital expenditures into the second 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 enough product revenue 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 $23.8 million and $13.2 million for the three months ended June 30, 2026 and 2025, respectively. As of June 30, 2026, we had an accumulated deficit of $179.8 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, 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 one or more of 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 any 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 the IPO, 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

Comparison of the three months ended June 30, 2026 and 2025

The following table summarizes our results of operations for each of the periods indicated (in thousands):

	Three Months Ended June 30,		
	2026	2025	Change
Operating expenses:			
Research and development	$ 21,355	$ 12,530	8,825
General and administrative	3,315	1,573	1,742
Total operating expenses	24,670	14,103	10,567
Loss from operations	(24,670)	(14,103)	(10,567)
Other income (expense), net:			
Interest income, net	915	859	56
Other expense, net	(3)	-	(3)
Total other income, net	912	859	53
Net loss	$ (23,758)	$ (13,244)	(10,514)

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 each of the periods indicated (in thousands):

	Three Months Ended June 30,		
	2026	2025	Change
External research and development expense:			
BH-30643	$ 8,966	$ 3,827	$ 5,139
BH-30236	1,967	1,339	628
BH-501284	2,045	61	1,984
Other programs and discovery	998	1,387	(389)
Internal research and development expense:			
Personnel-related	5,679	4,911	768
Facilities, overhead and other	1,700	1,005	695
Total research and development expense	$ 21,355	$ 12,530	$ 8,825

Research and development expenses were $21.4 million for the three months ended June 30, 2026 compared to $12.5 million for the three months ended June 30, 2025. The increase of $8.8 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 $9.0 million for the three months ended June 30, 2026 compared to $3.8 million for the three months ended June 30, 2025. The increase of approximately $5.1 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 $2.0 million for the three months ended June 30, 2026 compared to $1.3 million for the three months ended June 30, 2025. The increase of approximately $0.6 million was primarily due to the advancement of our ongoing clinical trial. For BH-501284, external costs were $2.0 million for the three months ended June 30, 2026 compared to $61 thousand for the three months ended June 30, 2025. The increase of $2.0 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 $0.4 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 $7.4 million for the three months ended June 30, 2026 compared to $5.9 million for the three months ended June 30, 2025. The increase of approximately $1.5 million was due to a $0.8 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 $0.7 million in facilities, overhead and other expenses.

General and administrative expenses. General and administrative expenses were $3.3 million for the three months ended June 30, 2026 compared to $1.6 million for the three months ended June 30, 2025. The increase of $1.7 million was comprised of a $0.6 million increase in personnel-related expenses, a $0.7 million increase in legal expenses, and an increase in general overhead and outside services expense of $0.4 million.

Interest income, net. Interest income, net was $0.9 million for each of the three months ended June 30, 2026 and 2025.

Comparison of the six months ended June 30, 2026 and 2025

The following table summarizes our results of operations for each of the periods indicated (in thousands):

	Six Months Ended June 30,		
	2026	2025	Change
Operating expenses:			
Research and development	$ 41,256	$ 22,102	19,154
General and administrative	5,521	3,455	2,066
Total operating expenses	46,777	25,557	21,220
Loss from operations	(46,777)	(25,557)	(21,220)
Other income (expense), net:			
Interest income, net	2,017	1,835	182
Other expense, net	(6)	-	(6)
Total other income, net	2,011	1,835	176
Net loss	$ (44,766)	$ (23,722)	(21,044)

Research and Development Expenses

The following table summarizes our research and development expenses by program for each of the periods indicated (in thousands):

	Six Months Ended June 30,		
	2026	2025	Change
External research and development expense:			
BH-30643	$ 18,516	$ 5,608	$ 12,908
BH-30236	3,714	2,388	1,326
BH-501284	2,629	61	2,568
Other programs and discovery	2,009	3,229	(1,220)
Internal research and development expense:			
Personnel-related	11,114	9,113	2,001
Facilities, overhead and other	3,274	1,703	1,571
Total research and development expense	$ 41,256	$ 22,102	$ 19,154

Research and development expenses were $41.3 million for the six months ended June 30, 2026 compared to $22.1 million for the six months ended June 30, 2025. The increase of $19.2 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 $18.5 million for the six months ended June 30, 2026 compared to $5.6 million for the six months ended June 30, 2025. The increase of approximately $12.9 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 $3.7 million for the six months ended June 30, 2026 compared to $2.4 million for the six months ended June 30, 2025. The increase of approximately $1.3 million was primarily due to the advancement of our ongoing clinical trial. For BH-501284, external costs were $2.6 million for the six months ended June 30, 2026 compared to $61 thousand for the six months ended June 30, 2025. The increase of $2.6 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 $1.2 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 $14.4 million for the six months ended June 30, 2026 compared to $10.8 million for the six months ended June 30, 2025. The increase of approximately $3.6 million was due to a $2.0 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 $1.6 million in facilities, overhead and other expenses.

General and administrative expenses. General and administrative expenses were $5.5 million for the six months ended June 30, 2026 compared to $3.5 million for the six months ended June 30, 2025. The increase of $2.1 million was comprised of a $1.0 million increase in personnel-related expenses, a $0.5 million increase in legal expenses, and an increase in general overhead and outside services expense of $0.6 million.

Interest income, net. Interest income, net was $2.0 million and $1.8 million for the six months ended June 30, 2026 and 2025, respectively.

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 June 30, 2026, we have raised aggregate gross proceeds of $257.2 million to fund our operations, comprised primarily from our issuance of convertible preferred stock. Additionally, in August 2026, we closed on our IPO, in which we received the IPO Proceeds. As of June 30, 2026, we had cash and cash equivalents of $95.4 million and an accumulated deficit of $179.8 million. Based on our current operating plans, we expect the IPO Proceeds, together with our existing cash and cash equivalents, will be sufficient to fund our planned operating expenses and capital expenditure requirements into the second quarter of 2028. Our total future capital requirements will depend on many factors and are subject to the risks and uncertainties set forth in the section titled “Risk Factors.”

Cash Flows

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

	Six Months Ended June 30,		
	2026	2025	Change
Net cash provided by (used in):			
Operating activities	$ (44,174)	$ (20,121)	$ (24,053)
Investing activities	(13)	(997)	984
Financing activities	2,881	85	2,796
Net decrease in cash	$ (41,306)	$ (21,033)	$ (20,273)

Operating Activities

Net cash used in operating activities was $44.2 million and $20.1 million for the six months ended June 30, 2026 and 2025, respectively. The net cash used in operating activities during the six months ended June 30, 2026 consisted primarily of our net loss of $44.8 million, adjusted for $1.9 million in non-cash charges, primarily related to non-cash lease expense, stock-based compensation expense, and depreciation, as well as $1.3 million in net changes in operating assets and liabilities. The net cash used in operating activities during the six months ended June 30, 2025 consisted primarily of our net loss of $23.7 million, adjusted for $1.2 million in non-cash charges, primarily related to non-cash lease expense, stock-based compensation expense, and depreciation, as well as $2.5 million in net changes in operating assets and liabilities. The increase in cash used in operations during the six months ended June 30, 2026 in comparison to the six months ended June 30, 2025 was primarily attributable to increased research and development activities.

Investing Activities

Net cash used in investing activities was $13 thousand and $1.0 million for the six months ended June 30, 2026 and 2025, respectively, consisting primarily of purchases of property and equipment.

Financing Activities

Net cash provided by financing activities was $2.9 million and $85 thousand for the six months ended June 30, 2026 and 2025, respectively, consisting of proceeds from the exercise of stock options.

Future Funding Requirements

As of June 30, 2026, we had cash and cash equivalents of $95.4 million. Based upon our current operating plans, we believe that our existing cash, cash equivalents, and IPO Proceeds will be sufficient to fund our projected operations into the second quarter of 2028. However, our forecast of the period of time through which our financial resources will be adequate to support our operations 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. Additionally, the process of conducting preclinical studies, manufacturing and testing product candidates in clinical trials is costly, and the timing of progress and expenses in these studies and trials is uncertain.

We have incurred significant losses and negative cash flows from operations since our inception. As of June 30, 2026, we had an accumulated deficit of $179.8 million.

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;
- 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 June 30, 2026.

As of June 30, 2026, we have future remaining operating lease payments of $38.8 million relating to leases we have recognized in the balance sheet. These obligations are further described in Note 6 to our unaudited condensed financial statements appearing elsewhere in this Quarterly Report.

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.

There have been no significant changes to our critical accounting estimates from those described in Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies and Significant Estimates and Judgments and our audited financial statements as of and for the year ended December 31, 2025 as included in the Company's final prospectus dated August 7, 2026 related to its IPO filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended.

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 Quarterly Report.

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 completion of our initial public 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 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 the completion of our initial public 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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report, the effectiveness of our disclosure controls and procedures. Based on that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this Quarterly Report, our disclosure controls and procedures were effective at the reasonable assurance level. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by such company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2026, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our business, financial condition or results of operations. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 1A. 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 Quarterly Report on Form 10-Q, including our financial statements and their related notes included elsewhere in this Quarterly Report on Form 10-Q 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 six months ended June 30, 2026, our net loss was $44.8 million. As of June 30, 2026, we had an accumulated deficit of approximately $179.8 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.

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, 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 June 30, 2026, we had $95.4 million in cash and cash equivalents. In August 2026, we received aggregate net proceeds of approximately $151.7 million from our initial public offering (IPO), inclusive of the partial exercise of the underwriters' option to purchase additional shares (IPO Proceeds). Based on our current operating plan, we estimate that our existing cash and cash equivalents as of June 30, 2026, together with the IPO Proceeds, will be sufficient to fund our projected operating expenses and capital expenditure requirements into the second 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;
- 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 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.

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;
- 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 related or unrelated 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.

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;
- 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 instances of high-grade EGFR wild-type toxicity (mucositis, rash, diarrhea), liver function test abnormalities (bilirubin, ALT, AST) and pneumonitis. In our ongoing Phase 1 trial of BH-30236, TRAEs were observed, including instances of high-grade diarrhea and grade 2 differentiation syndrome. 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 are planning to evaluate the use of BH-30236 as a combination therapy with venetoclax and azacitidine in patients with R/R AML. We are also currently evaluating the use of BH-30643 as a combination therapy with carboplatin and pemetrexed in adults with locally advanced or metastatic NSCLC harboring EGFR 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 is 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.

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.

Although we have received Fast Track designation for BH-30643 for the treatment of adult patients with advanced or metastatic epidermal growth factor receptor (EGFR) C797S-positive non-small cell lung cancer (NSCLC) after prior treatment with a third generation EGFR tyrosine kinase inhibitor (TKI), we may be unable to obtain or maintain the benefits associated with such designation.

In August 2026, we were granted FDA Fast Track designation for BH-30643 for the above referenced indication. If a drug is intended for the treatment of a serious or life-threatening condition and demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for FDA Fast Track designation for a particular indication. NDAs submitted for Fast Track designated drugs may qualify for priority review, accelerated approval and rolling submission under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. In addition, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide assurance of ultimate FDA approval.

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 June 30, 2026, we had 69 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 (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, 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 (RYBREVANT) 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 is currently one approved pan-RAS tricomplex inhibitor, Daraxonrasib (RASONQUE), marketed by Revolution Medicines, which was approved for the treatment of adult patients with metastatic pancreatic adenocarcinoma. We are aware of numerous companies developing pan-RAS tricomplex inhibitors, such as Adlai Nortye, Betta Pharmaceuticals, Erasca 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 are 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 Quarterly Report on Form 10-Q.

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 ownership of our common stock

An active and liquid trading market for our common stock may not 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 price you paid, if at all.

Prior to our IPO in August 2026, there was no public market for shares of our common stock. Although our common stock is currently listed on the Nasdaq Global Select Market, we cannot assure you that an active trading market for our shares will be sustained. 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 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 is likely to be volatile and you could lose all or part of your investment.

The trading price of our common stock could be highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. 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 price you paid for the shares. 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;
- 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 Quarterly Report on Form 10-Q.

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. As a result of this volatility, 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. These fluctuations may be even more pronounced in the trading market for our stock.

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

Our directors and executive officers, holders of 5% or more of our capital stock and their respective affiliates beneficially own a significant percentage of our outstanding common stock. 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, including without limitation, 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. 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. In connection with our IPO, our directors and executive officers and substantially all of our pre-IPO securityholders entered into lock-up agreements with the representatives of the underwriters pursuant to which they may not, with limited exceptions, through February 2, 2027, offer, sell or otherwise transfer or dispose of any of our securities, without the prior written consent of the representatives of the underwriters. The underwriters may permit our officers, directors and other securityholders who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up agreements at any time in their sole discretion. Sales of these shares, or perceptions that they will be sold, could cause the trading price of our common stock to decline. After the lock-up agreements expire, these shares of common stock will be eligible for sale in the public market, except that shares held by directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended (Securities Act).

Moreover, certain holders of shares of our common stock 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, or until the rights terminate pursuant to the terms of the stockholder agreements between us and such holders. 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 registered 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 and such shares 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.

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 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 our annual report on Form 10-K.

We could be an emerging growth company for up to five years following our IPO, 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 our IPO, (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 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 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 Equity Incentive Plan (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 2026 Employee Stock Purchase Plan, 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.

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.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws 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 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 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.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and any appellate court therefrom are 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 provides 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 further provides 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 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 have incurred and will continue to incur increased costs and are subject to additional regulations and requirements as a result of being a public company, and our management is 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 have incurred and will continue to 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 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 IPO, 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.

We are 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, a material 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

(a) Unregistered Sales of Equity Securities

During the three months ended June 30, 2026, we granted stock options to purchase an aggregate of 339,506 shares of our common stock at a weighted-average exercise price of $12.78 per share to certain of our employees, directors and consultants pursuant to our 2020 Equity Incentive Plan.

During the three months ended June 30, 2026, we issued an aggregate of 346,620 shares of our common stock upon the exercise of stock options granted under the 2020 Equity Incentive Plan, for aggregate consideration of approximately $2.6 million. A portion of such shares were issued upon exercise of options prior to vesting and remain subject to our right to repurchase such shares at the original exercise price upon termination of the holder's service.

The issuances of the securities described above were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 promulgated under the Securities Act as transactions under compensatory benefit plans and contracts relating to compensation, or under Section 4(a)(2) of the Securities Act as transactions by an issuer not involving a public offering. The recipients of such securities were our employees, directors or bona fide consultants and received the securities under our 2020 Equity Incentive Plan. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

On August 10, 2026, we filed a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding options and all shares of our common stock otherwise issuable pursuant to our equity compensation plans.

(b) Use of Proceeds from Initial Public Offering

On August 10, 2026, we completed our IPO, in which we issued and sold 9,375,000 shares of our common stock at a price to the public of $16.00 per share. On August 25, 2026, we issued and sold an additional 1,141,240 shares of our common stock upon partial exercise of the underwriters' option to purchase additional shares, resulting in an aggregate of 10,516,240 shares of our common stock issued and sold in the offering. J.P. Morgan Securities LLC, Leerink Partners LLC and Guggenheim Securities, LLC acted as lead book-running managers for the offering, and LifeSci Capital LLC and H.C. Wainwright & Co., LLC acted as joint book-running managers.

The offer and sale of our common stock were registered under the Securities Act pursuant to our registration statement on Form S-1 (File No. 333-297512) and our registration statement on Form S-1MEF (File No. 333-298097), both of which became effective on August 6, 2026. The offering terminated upon expiration of the underwriters' option to purchase additional shares, before the sale of all of the securities registered under such registration statements.

We received aggregate gross proceeds from our IPO of approximately $168.3 million. We incurred underwriting discounts and commissions of approximately $11.8 million and other offering expenses of approximately $4.8 million, for total expenses of approximately $16.6 million, resulting in net proceeds to us of approximately $151.7 million. No payments for such expenses were made directly or indirectly to (i) any of our directors or officers or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

There has been no material change in the planned use of proceeds from our IPO as described in the final prospectus filed with the SEC on August 7, 2026 pursuant to Rule 424(b)(4) under the Securities Act. Pending such uses, we have invested the net proceeds in interest-bearing, investment-grade securities.

(c) Issuer Repurchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Rule 10b5-1 Trading Arrangements

From time to time, our officers (as defined in Rule 16a–1(f)) and directors may enter into Rule 10b5-1 or non-Rule 10b5-1 trading arrangements (as each such term is defined in Item 408 of Regulation S-K). During the quarter ended June 30, 2026, none of our officers or directors adopted or terminated any such trading arrangements.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of BlossomHill Therapeutics, Inc. (incorporated herein by reference to Exhibit 3.1 to the Registrant's Form 8-K (File No. 001-43435), filed with the Commission on August 10, 2026).
3.2	Amended and Restated Bylaws of BlossomHill Therapeutics, Inc. (incorporated herein by reference to Exhibit 3.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-297512), filed with the Commission on July 17, 2026).
4.1	Form of Common Stock Certificate (incorporated herein by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1/A (File No. 333-297512), filed with the Commission on August 3, 2026).
4.2^+	Third Amended and Restated Investor Rights Agreement, dated December 28, 2023, by and among the Registrant and the investors named therein (incorporated herein by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-297512), filed with the Commission on July 17, 2026).
10.1	Form of Indemnification Agreement, by and between the Registrant and each of its directors and executive officers (incorporated herein by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-297512), filed with the Commission on July 17, 2026).
10.2‡	BlossomHill Therapeutics, Inc. 2026 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-297512), filed with the Commission on July 17, 2026).
10.3‡	Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the BlossomHill Therapeutics, Inc. 2026 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-297512), filed with the Commission on July 17, 2026).
10.4‡	BlossomHill Therapeutics, Inc. 2026 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-297512), filed with the Commission on July 17, 2026).
10.5‡	Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1/A (File No. 333-297512), filed with the Commission on August 3, 2026).
10.6‡	BlossomHill Therapeutics, Inc. Severance Plan (incorporated herein by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-297512), filed with the Commission on July 17, 2026).
10.7‡	Executive Employment Agreement, dated July 31, 2026, between the Registrant and J. Jean Cui (incorporated herein by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1/A (File No. 333-297512), filed with the Commission on August 3, 2026).
10.8‡	Executive Employment Agreement, dated July 31, 2026, between the Registrant and Y. Peter Li (incorporated herein by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1/A (File No. 333-297512), filed with the Commission on August 3, 2026).
10.9‡	Executive Employment Agreement, dated July 31, 2026, between the Registrant and Jason Keyes (incorporated herein by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1/A (File No. 333-297512), filed with the Commission on August 3, 2026).
10.10‡	Executive Employment Agreement, dated July 31, 2026, between the Registrant and Vincent Liptak (incorporated herein by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1/A (File No. 333-297512), filed with the Commission on August 3, 2026).
10.11‡^	Executive Employment Agreement, dated July 31, 2026, between the Registrant and Geoffrey Oxnard (incorporated herein by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1/A (File No. 333-297512), filed with the Commission on August 3, 2026).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) Under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*#	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*#	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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* Filed herewith.

‡ Indicates a management contract or any compensatory plan, contract or arrangement.

^ Pursuant to Item 601(b)(10)(iv) of Regulation S-K promulgated by the SEC, certain portions of this exhibit have been redacted because they are both not material and are the type that the Registrant treats as private or confidential. The Registrant hereby agrees to furnish supplementally to the SEC, upon its request, an unredacted copy of this exhibit.

+ Certain schedules or exhibits to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350 and are not being filed for purposes of Section 18 of the Securities Exchange Act and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

BlossomHill Therapeutics, Inc.

Date: September 18, 2026

By: /s/ J. Jean Cui, Ph.D.
J. Jean Cui, Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: September 18, 2026

By: /s/ Jason Keyes, MBA
Jason Keyes, MBA
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, J. Jean Cui, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2026 of BlossomHill Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 18, 2026

By: /s/ J. Jean Cui, Ph.D.
J. Jean Cui, Ph.D.
President, Chief Executive Officer and Director
(*Principal Executive Officer*)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jason Keyes, MBA, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2026 of BlossomHill Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 18, 2026

By: /s/ Jason Keyes, MBA
Jason Keyes, MBA
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of BlossomHill Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: September 18, 2026

By: /s/ J. Jean Cui, Ph.D.
J. Jean Cui, Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of BlossomHill Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: September 18, 2026

By: /s/ Jason Keyes, MBA
Jason Keyes, MBA
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)