BlossomHill Therapeutics Reports Third Quarter 2026 Financial Results and Recent Business Highlights

November 12, 2026

Alignment with the US Food and Drug Administration (FDA) on 50 mg twice daily as the recommended Phase 2 dose for BH-30643 based on favorable PK, safety, and efficacy data to date

Announced SOLARA-2, the single-arm pivotal Phase 2 portion of the SOLARA trial, designed with registrational intent to evaluate BH-30643 in patients with EGFR C797S-positive NSCLC; expect to dose first patient in Q1 2027

Collaboration with Foundation Medicine to develop a companion diagnostic assay for the EGFR C797S resistance mutation

$224.9 million in cash and cash equivalents as of September 30, 2026

SAN DIEGO, Nov. 12, 2026 (GLOBE NEWSWIRE) -- BlossomHill Therapeutics, Inc. (Nasdaq: BLSM), a clinical-stage biopharmaceutical company applying an intentional, chemistry-based approach to design and develop innovative small molecule medicines for the treatment of cancer, today announced financial results for the third quarter 2026 and highlighted recent progress.

“We are pleased to have aligned with the FDA on a recommended Phase 2 dose of 50 mg BID based on favorable PK, safety and efficacy data in the Phase 1 portion of the SOLARA trial. We are now preparing to initiate SOLARA-2, a single arm, pivotal Phase 2 trial designed to evaluate BH-30643 in both chemotherapy-naive and chemotherapy-pretreated patients with C797S-positive NSCLC after progression on a third-generation EGFR TKI,” said J. Jean Cui, Ph.D., Founder, President and Chief Executive Officer of BlossomHill Therapeutics. “In parallel, we continue to advance the development of novel, small molecule medicines in our portfolio. We recently presented preclinical data on BH-501284, our novel, pseudo-irreversible, Switch-II pan-KRAS inhibitor, that demonstrated sustained KRAS pathway suppression and deep and durable antitumor activity across multiple *KRAS*-mutant tumor models. An IND filing is planned for the first quarter next year. We also plan to present translational data with clinical validation of BH-30236's mechanism of action at the American Society of Hematology Annual Meeting in December, reinforcing our belief in its potential to address a significant unmet need in patients with myeloid malignancies.”

Recent Business Highlights and Corporate Updates:

- Alignment with the FDA on 50 mg twice daily as the recommended Phase 2 dose based on favorable pharmacokinetic (PK), safety and efficacy data from the SOLARA Phase 1 trial
- Announced SOLARA-2, the single-arm Phase 2 portion of the SOLARA trial, in patients with EGFR C797S-positive NSCLC to potentially support an accelerated approval application
- Collaboration with Foundation Medicine to develop a companion diagnostic assay (CDx) for the *EGFR* C797S resistance mutation
- Preclinical data on BH-501284, a novel, orally bioavailable, non-covalent, pseudo-irreversible pan-KRAS inhibitor designed to overcome limitations of current KRAS-targeted therapies, presented at the American Association for Cancer Research (AACR) Conference on Pancreatic Cancer: New Frontiers in Biology and Therapeutic Development
- Abstract highlighting the upcoming presentation of translational data providing further clinical validation of BH-30236’s mechanism of action at the American Society of Hematology (ASH) Annual Meeting in December

Anticipated Upcoming Milestones:

BH-30643

- Q1 2027: First patient dosed in pivotal SOLARA-2 trial
- 1H 2027: Updated Phase 1 data, including C797S durability
- 2H 2027: Phase 1 data on TKI-naive durability and initial chemo combo cohort data

BH-501284

- Q1 2027: Investigational new drug application (IND) submission

BH-30236

- 1H 2027: Updated Phase 1 data on safety and anti-leukemic effect

Third Quarter 2026 Financial Results

Research and development (R&D) expenses for the third quarter of 2026 were $21.9 million, compared with $14.7 million for the same period in 2025. The increase of $7.3 million was primarily due to greater clinical development expenses related to BH-30643, increased personnel-related expenses driven by R&D headcount growth, and greater expenses related to IND-enabling work for BH-501284.

General and administrative (G&A) expenses for the third quarter of 2026 were $3.6 million, compared with $2.1 million for the same period in 2025. The increase of $1.5 million was primarily due to increased personnel-related expenses, greater general overhead and outside services expenses, and an increase in legal expenses.

Net loss for the third quarter of 2026 was $24.0 million, or ($1.29) per basic and diluted share, compared with $16.0 million, or ($6.54) per basic and diluted share for the same period in 2025. The increase in net loss was primarily attributable to increased operating expenses, partially offset by an increase in other income.

Cash and cash equivalents totaled $224.9 million as of September 30, 2026. BlossomHill completed its IPO in August 2026 in which it sold 10,516,240 shares of its common stock, including partial exercise of the over-allotment option, for gross proceeds of $168.3 million. BlossomHill believes that its cash and cash equivalents as of September 30, 2026, will be sufficient to fund its operations into the second quarter of 2028.

About BH-30643
BH-30643 is an investigational, novel, orally bioavailable, non-covalent, macrocyclic, brain active, mutant-selective, OMNI-EGFR™ inhibitor for the treatment of *EGFR*-mutant NSCLC. BH-30643 was designed to overcome the limitations of currently approved EGFR inhibitors, which were discovered over a decade ago without the current, modern understanding of the structure and protein dynamics of mutant EGFRs. In preclinical studies, BH-30643 demonstrated potent inhibitory activity across diverse *EGFR* mutation categories — classical mutations, on-target resistance mutations such as C797S with or without T790M, atypical mutations and exon 20 insertions — while maintaining marked selectivity over wild-type EGFR. BH-30643 has received Fast Track designation and is being evaluated in SOLARA, a global Phase 1/2, first-in-human clinical trial with ongoing Phase 1 dose expansion cohorts enrolling in both TKI-pretreated and TKI-naive settings, including a C797S resistance cohort. SOLARA-2, a global Phase 2 pivotal study in C797S-Positive NSCLC is scheduled to dose the first patient in the first quarter of 2027. For additional information on SOLARA, including a list of study sites and how to enroll, please visit clinicaltrials.gov (NCT06706076).

About BH-30236
BH-30236 is an investigational orally bioavailable, macrocyclic inhibitor of the CDC-like kinase (CLK) family. BH-30236 was intentionally designed to potently inhibit CLK, leading to modulation of aberrant alternative splicing in cancerous tissue, targeting the same aberrant splicing machinery that drives relapsed or refractory (R/R) acute myeloid leukemia (AML) and higher-risk myelodysplastic syndromes (HR-MDS) disease biology and that cancer cells exploit to develop resistance to venetoclax, FLT3 inhibitors and cytarabine. BH-30236 is being evaluated in a Phase 1/1b multicenter, open-label, first-in-human dose escalation and expansion trial in adults with R/R AML and HR-MDS. The U.S. Food and Drug Administration (FDA) has granted orphan drug designation to BH-30236 for the treatment of AML. For additional information on this trial, including a list of study sites and how to enroll, please visit clinicaltrials.gov (NCT06501196).

About BH-501284
BH-501284 is an investigational, orally bioavailable, pan-KRAS inhibitor, which utilizes a novel Switch-II chemical scaffold to achieve prolonged, potent and selective inhibition of KRAS mutations. We believe this molecule, which uses a non-covalent scaffold, is unique in its potential to achieve tight and durable binding, a feature described as “pseudo-irreversible” binding. In preclinical studies, BH-501284 demonstrated sustained blocking of KRAS signaling leading to deeper and more durable antitumor activities in KRAS mutant cells and tumor models at low dose levels.

About BlossomHill Therapeutics
BlossomHill Therapeutics, Inc. is a clinical-stage biopharmaceutical company applying an intentional, chemistry-based approach to design and develop innovative small molecule medicines that address significant unmet medical needs in cancer treatment. Founded and led by industry veteran J. Jean Cui, Ph.D., with her proven track record in oncology drug design and development – including three FDA-approved drugs – BlossomHill Therapeutics applies cutting-edge science with a goal to address key oncogenic drivers and improve patient outcomes in difficult-to-treat cancers. The company’s lead clinical program is BH-30643, an investigational, novel, orally bioavailable, non-covalent, macrocyclic, brain active, mutant-selective OMNI-EGFR™ inhibitor for the treatment of EGFR-mutant non-small cell lung cancer (NSCLC), has received Fast Track designation for the C797S resistance population after 3rd generation EGFR TKI treatment. The company is also conducting clinical development of BH-30236, an investigational macrocyclic CDC-like kinase (CLK) inhibitor initially being studied in a clinical trial for the treatment of relapsed or refractory acute myeloid leukemia (R/R AML) and higher-risk myelodysplastic syndromes (HR-MDS). The company’s pipeline also includes BH-501284, a preclinical, non-covalent, selective, pan-KRAS Switch-II inhibitor for potential future development in diverse KRAS-mutant tumors.

BlossomHill Therapeutics is headquartered in San Diego, California. For more information, visit www.bhtherapeutics.com and follow us on LinkedIn and X.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995,

as amended, and other federal securities laws, including, without limitation, statements regarding: the planned launch of the SOLARA-2 trial and expected timing thereof; the planned IND filing for BH-501284 and expected timing thereof; the potential of BH-30236 to address significant unmet need in patients with myeloid malignancies; the expected implications of the End-of-Phase 1 meeting with the FDA regarding BH-30643, including potential for accelerated approval; the expected timing and achievement of development and regulatory milestones; the period over which the company estimates its existing cash and cash equivalents will be sufficient to fund its current operating plan; statements by the company's management; and the company's development plans and continued advancement of its pipeline. The words "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "upcoming," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially, including, without limitation: the company's limited operating history, history of significant losses and the early stage of development of its product candidates; the risk that preliminary and interim clinical data are subject to further analysis and may not be predictive of, may be inconsistent with, or may be more favorable than, data generated as clinical trials continue or data from future clinical trials; uncertainties inherent in the initiation, timing, design and enrollment of clinical trials, and the availability and timing of data from ongoing and future trials; the company's ability to successfully demonstrate the safety and efficacy of its product candidates and to obtain and maintain regulatory approvals; the timing and outcome of planned interactions with, and submissions to, the FDA and other regulatory authorities, including whether an accelerated approval pathway will be available to the company; the risk that regulatory designations, including Fast Track and orphan drug designation, may not result in a faster development, review or approval process, may not increase the likelihood of regulatory approval, and may be withdrawn; competition from third parties that are developing products for similar indications; the prior success of the company's management team may not be indicative of future success; the company's reliance on third parties, including contract research organizations and contract manufacturing organizations; the company's ability to obtain, maintain and protect its intellectual property; and the company's need for additional financing and its estimates regarding operating expenses and capital requirements. These and other risks are described in greater detail under the heading "Risk Factors" in the company's filings with the Securities and Exchange Commission (the "SEC"), its Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, filed with the SEC on September 18, 2026, in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2026, which will be filed with the SEC later today, as well as in the company's subsequent filings with the SEC. Any forward-looking statements represent the company's views only as of the date of this press release, and the company expressly disclaims any obligation to update any forward-looking statements, except as required by law.

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

	September 30, 2026	December 31, 2025
	(unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	$ 224,905	$ 136,682
Prepaid expenses and other current assets	4,321	2,144
Total current assets	229,226	138,826
Property and equipment, net	1,366	1,726
Operating lease right-of-use assets	18,912	19,921
Other assets	2,477	2,495
Total assets	$ 251,981	$ 162,968
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 3,459	$ 2,314
Accrued expenses	7,366	8,431
Accrued compensation	5,091	4,730
Other current liabilities	755	-
Operating lease liability, current	1,211	5

Total current liabilities	17,882	15,480
Operating lease liability, non-current	21,887	22,393
Other long-term liabilities	1,129	-
Total liabilities	40,898	37,873
Convertible preferred stock, $0.0001 par value; 10,000,000 and 85,552,612 shares authorized at September 30, 2026 and December 31, 2025, respectively; 0 shares and 18,258,960 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively; $0 and $257,153 aggregate liquidation preference at September 30, 2026 and December 31, 2025, respectively	-	256,823
Stockholders' equity (deficit):		
Common stock, $0.0001 par value; 700,000,000 and 110,000,000 shares authorized at September 30, 2026 and December 31, 2025, respectively; 31,584,753 and 2,548,659 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	3	1
Additional paid-in capital	414,888	3,300
Accumulated deficit	(203,808)	(135,029)
Total stockholders' equity (deficit)	211,083	(131,728)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 251,981	$ 162,968

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 21,927	$ 14,673	$ 63,183	$ 36,776
General and administrative	3,552	2,055	9,073	5,509
Total operating expenses	25,479	16,728	72,256	42,285
Loss from operations	(25,479)	(16,728)	(72,256)	(42,285)
Other income (expense), net:				
Interest income, net	1,463	759	3,480	2,595
Other income (expense), net	3	(7)	(3)	(8)
Total other income, net	1,466	752	3,477	2,587
Net loss	$ (24,013)	$ (15,976)	$ (68,779)	$ (39,698)
Net loss per share, basic and diluted	$ (1.29)	$ (6.54)	$ (8.59)	$ (16.46)
Weighted average common shares outstanding, basic and diluted	18,555,673	2,441,855	8,007,980	2,411,313