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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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 September 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 001-43432

Braveheart Bio, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**99-2981994**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One Letterman Drive, Building A, Suite A4-300 San Francisco, CA	**94129**
(Address of Principal Executive Offices)	(Zip Code)

(415) 707-6312
Registrant's telephone number, including area code

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, par value $0.0001 per share	BRVE	The Nasdaq Global 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, a 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 Act).

Yes ☐ No ☒

As of November 6, 2026, there were 89,870,352 shares of registrant's common stock, $0.0001 par value per share, outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this "Quarterly Report") contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in 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 facts, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned nonclinical studies and clinical trials, results of nonclinical studies, clinical trials, research and development costs, regulatory approvals, commercial strategy, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that are in some cases beyond our control and 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.

In some cases, forward-looking statements can be identified by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "believe," "estimate," "predict," "potential," or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this Quarterly Report may include, but are not limited to, statements about:

- the initiation, timing, enrollment, progress, interim analysis and data readout results of our research and development programs, nonclinical studies and clinical trials, including LIONHEART-HCM, TRUEHEART-HCM, NOBLEHEART-HCM and HEARTSONG-LTE, and for Hengrui's ongoing Phase 3 trial of BHB-1893 in oHCM in China;
- our interpretation of data from Hengrui's Phase 2 trials of BHB-1893, including the 52-week open-label extension and other exploratory and ad hoc analyses, and the extent to which such data will be predictive of results in our ongoing and planned clinical trials;
- the ability of clinical trials to demonstrate safety and efficacy of BHB-1893 and any future product candidates, and other positive results, and the ability of our nonclinical studies to predict later clinical trial results;
- the timing, scope and likelihood of regulatory filings and approvals of BHB-1893 and any future product candidates;
- the implementation of our business model, and strategic plans for our business, programs, BHB-1893 and any future product candidates;
- our ability to obtain additional cash and the sufficiency of our existing cash and cash equivalents to fund our future operating expenses and capital expenditure requirements;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the size and growth potential of the markets for BHB-1893 and any future product candidates, and our ability to serve those markets;
- our potential and ability to successfully manufacture and supply BHB-1893 and any future product candidates for clinical trials and for commercial use, if approved;
- the scope of protection we are able to establish and maintain for intellectual property rights covering BHB-1893 and any future product candidates;
- developments relating to our competitors and our industry, including competing product candidates and therapies;
- existing regulations and regulatory developments in the U.S. and other jurisdictions;
- expectations regarding future events under collaboration and licensing agreements, including potential future payments, as well as our plans and strategies for entering into further collaboration and licensing agreements;
- general economic, industry and market conditions, including rising interest rates and inflation;
- our ability to attract and retain the continued service of our key personnel and to identify, hire and then retain additional qualified personnel;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; and
- our anticipated use of our existing cash and cash equivalents, including the proceeds from our initial public offering.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of risks, uncertainties and assumptions described in "*Risk Factors*" and elsewhere in this Quarterly Report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. No forward-looking statement is a guarantee of future performance. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this Quarterly Report, whether as a result of any new information, future events or otherwise. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures, or investments that we may make or enter into.

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, 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 you are cautioned not to unduly rely upon these statements.

This Quarterly Report includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third-parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosure contained in this Quarterly Report, and we believe that these sources are reliable; however, we have not independently verified the information contained in such publications.

SUMMARY OF MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks include, but are not limited to, the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history, have incurred significant operating losses since inception, anticipate that we will continue to incur significant operating losses for the foreseeable future, and we may never achieve or maintain profitability.
- We will need substantial additional funding. We may be unable to raise capital on acceptable terms, if at all, and, as a result, we may be required to delay, reduce or eliminate our product development or commercialization efforts.
- We are substantially dependent on the success of our only product candidate, BHB-1893, which is a cardiac myosin inhibitor being developed for the treatment of HCM. If we are unable to advance BHB-1893 into later-stage clinical development or unable to obtain regulatory approval and commercialize BHB-1893 for the treatment of HCM, or experience significant delays in doing so, our business will be materially harmed.
- We rely on clinical data generated by Hengrui from clinical trials that were not designed or conducted by us, and such data may not be adequate to support our regulatory submissions or future clinical development plans. If we are unable to confirm or replicate the results from Hengrui's clinical trials, if those trials were not conducted in accordance with applicable law, including GCPs, or if the FDA or comparable foreign regulatory authorities do not accept such data, our development programs could be materially delayed or harmed.
- We have not yet completed all testing of BHB-1893 in clinical trials. Interim, topline and preliminary results from our or Hengrui's nonclinical studies or clinical trials are not necessarily predictive of the results or analyses of such results of later clinical trials. If we cannot replicate the positive results from any nonclinical studies or clinical trials of BHB-1893 or any other potential future product candidates that have positive results, or if we suffer any other significant setbacks in our later clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize BHB-1893 or potential future product candidates.
- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain the required regulatory approval for any product candidate, our business will be substantially harmed.
- Targeting the cardiac myosin protein is novel, and there are currently no FDA-approved therapies specifically indicated for nHCM, which subjects the design and execution of our clinical development program for our sole product candidate, BHB-1893, to complexities and known and unknown risks, including those related to novel and/or subjective clinical endpoints.
- Our nonclinical studies and clinical trials may fail to demonstrate the safety and efficacy of BHB-1893 or any future product candidates, or serious or unacceptable adverse side effects or unexpected toxicology findings may be identified during the development of BHB-1893 or any future product candidates, which could prevent or delay further clinical development, regulatory approvals and commercialization, impact the product's labeling, if approved, increase our costs or necessitate the abandonment or limitation of the development of BHB-1893 or any future product candidates.
- A significant portion of our equity is held by a Chinese company and for so long as a Chinese company continues to hold a significant equity interest in us, changes in U.S. and Chinese laws and geopolitical developments may adversely affect our business, results of operations, financial condition and prospects.
- We depend on our Exclusive License Agreement with, and the comprehensiveness of the intellectual property licensed from, Hengrui in order to continue developing and, if approved, commercialize BHB-1893. Termination of the Exclusive License Agreement, and issues related to intellectual property we license from Hengrui, would have a material adverse effect on our business.
- Our business is subject to the risks associated with having a collaboration partner and third-party manufacturer based in China.
- If we or our licensors are unable to obtain, maintain and enforce intellectual property rights relating to BHB-1893 or any future product candidates, or if the scope of the protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, our ability to successfully commercialize BHB-1893 or any of our future product candidates may be adversely affected and we may not be able to compete effectively in our markets.
- We rely on Hengrui to manufacture our sole product candidate, BHB-1893, which may increase the risk that we will not have sufficient quantities of our product candidate or products or such quantities at an acceptable time and cost, which could delay, prevent or impair our development or commercialization efforts.
- We face substantial competition. Our main competitors in the HCM market hold substantial market share and have substantially greater resources than we do. We may not be able to compete successfully in this environment and, in particular, against much larger competitors.
- An active trading market for our common stock may not be sustained.
- The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could lose all or part of their investment.

The summary risk factors described above should be read together with the text of the full risk factors in the section titled "Risk Factors" and the other information set forth in this Quarterly Report, including our unaudited interim condensed financial statements and the related notes, as well as in other documents that we file with the Securities and Exchange Commission ("SEC"). The risks summarized above or described in full elsewhere in this Quarterly Report are not the only risks that we face. Additional risks and uncertainties not presently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

Part I - Financial Information

Item 1. Financial Statements

Braveheart Bio, Inc.
Condensed Balance Sheets (unaudited)
(in thousands, except share and par value data)

	As of September 30, 2026	As of December 31, 2025
Assets		
Current assets		
Cash and cash equivalents	$ 121,291	$ 89,161
Prepaid expenses and other current assets	10,302	119
Short-term investments	227,981	—
Total current assets	359,574	89,280
Property and equipment, net	20	—
Operating lease right-of-use assets	510	—
Other long-term assets	98	70
Long-term investments	154,248	—
Total assets	$ 514,450	$ 89,350
Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities		
Accounts payable (includes related party amounts of $13 and $73, respectively)	$ 1,975	$ 1,058
Accrued expenses (includes related party amounts of $1,431 and $3,272, respectively)	8,138	4,184
Other current liabilities	6,145	—
Current portion of lease liabilities	415	—
Total current liabilities	16,673	5,242
Lease liabilities, net of current portion	100	—
Other long-term liabilities	75	91
Total liabilities	16,848	5,333
Commitments and contingencies (Note 7)		
Series A redeemable convertible preferred stock, $0.0001 par value; zero and 185,000,000 shares authorized at September 30, 2026 and December 31, 2025, respectively; zero and 125,000,000 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively; $0 and $125,000 liquidation preference at September 30, 2026 and December 31, 2025, respectively	—	124,214
Nonvoting Series A redeemable convertible preferred stock, $0.0001 par value; zero and 32,500,000 shares authorized, issued and outstanding at September 30, 2026 and December 31, 2025, respectively; $0 and $32,500 liquidation preference at September 30, 2026 and December 31, 2025, respectively	—	25,675
Stockholders' equity (deficit)		
Undesignated preferred stock, $0.0001 par value; 10,000,000 and zero shares authorized at September 30, 2026 and December 31, 2025, respectively; zero shares issued and outstanding at September 30, 2026 and December 31, 2025	—	—

Common stock, $0.0001 par value; 500,000,000 and 335,500,000 (303,000,000 voting and 32,500,000 nonvoting) shares authorized at September 30, 2026 and December 31, 2025, respectively; 89,867,737 and 15,943,937 shares issued at September 30, 2026 and December 31, 2025, respectively; and 82,069,077 and 6,685,088 shares outstanding at September 30, 2026 and December 31, 2025, respectively	8	1
Accumulated other comprehensive loss	(718)	—
Additional paid-in capital	620,714	179
Accumulated deficit	(122,402)	(66,052)
Total stockholders' equity (deficit)	497,602	(65,872)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	$ 514,450	$ 89,350

See accompanying notes to condensed financial statements

Braveheart Bio, Inc.
Condensed Statements of Operations and Comprehensive Loss (unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended		Nine Months Ended	
	September 30, 2026	September 30, 2025	September 30, 2026	September 30, 2025
Operating expenses				
Research and development (includes related party amounts of $1,024 and $7,413 for the three and nine months ended September 30, 2026, respectively, and $0 for the three and nine months ended September 30, 2025)	$ 17,542	$ 9	$ 39,581	$ 9
In-process research and development (includes related party amounts of $0 for the three and nine months ended September 30, 2026 and $58,409 for the three and nine months ended September 30, 2025)	—	58,770	—	59,218
General and administrative (includes related party amounts of $84 and $159 for the three and nine months ended September 30, 2026, respectively, and nominal amounts for the three and nine months ended September 30, 2025)	12,607	508	21,499	540
Total operating expenses	30,149	59,287	61,080	59,767
Loss from operations	(30,149)	(59,287)	(61,080)	(59,767)
Other income				
Interest income	3,712	169	5,372	169
Other income (expense), net	(58)	—	(55)	—
Total other income	$ 3,654	$ 169	$ 5,317	$ 169
Net loss	$ (26,495)	$ (59,118)	$ (55,763)	$ (59,598)
Deemed dividends upon issuance of redeemable convertible preferred stock	—	—	(3,615)	—
Net loss attributable to common stockholders	$ (26,495)	$ (59,118)	$ (59,378)	$ (59,598)
Net loss per share, basic and diluted	$ (0.51)	$ (10.05)	$ (2.66)	$ (20.46)
Weighted-average shares of common stock outstanding, basic and diluted	52,095,078	5,881,011	22,285,633	2,912,682
Comprehensive loss:				
Net Loss	$ (26,495)	$ (59,118)	$ (55,763)	$ (59,598)
Other comprehensive loss:				
Unrealized loss on investments	(718)	—	(718)	—
Comprehensive loss	$ (27,213)	$ (59,118)	$ (56,481)	$ (59,598)

See accompanying notes to condensed financial statements

Braveheart Bio, Inc.
Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) (unaudited)
(in thousands, except share data)

	Series A Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance at December 31, 2025	157,500,000	$ 149,889	6,685,088	$ 1	$ 179	$ —	$ (66,052)	$ (65,872)
Issuance costs of Series A redeemable convertible preferred stock	—	(4)	—	—	—	—	—	—
Vesting of restricted common stock	—	—	274,936	—	2	—	—	2
Stock-based compensation	—	—	—	—	1,758	—	—	1,758
Net loss	—	—	—	—	—	—	(14,280)	(14,280)
Balance at March 31, 2026	157,500,000	$ 149,885	6,960,024	$ 1	$ 1,939	$ —	$ (80,332)	$ (78,392)
Issuance of Series A redeemable convertible preferred stock, net of nominal issuance costs	60,000,000	63,635	—	—	—	—	—	—
Deemed dividends on issuance of Series A redeemable convertible preferred stock	—	—	—	—	(3,028)	—	(587)	(3,615)
Vesting of restricted common stock	—	—	575,962	—	1	—	—	1
Stock-based compensation	—	—	—	—	1,088	—	—	1,088
Net loss	—	—	—	—	—	—	(14,988)	(14,988)
Balance at June 30, 2026	217,500,000	$ 213,520	7,535,986	$ 1	$ —	$ —	$ (95,907)	$ (95,906)
Conversion of series A redeemable convertible preferred stock to common stock upon closing of the initial public offering	(217,500,000)	(213,520)	49,657,532	5	213,515	—	—	213,520
Issuance of common stock from initial public offering, net of underwriting discounts and commissions and other offering costs of $35.5 million	—	—	24,437,500	2	404,409	—	—	404,411
Vesting of restricted common stock	—	—	438,059	—	—	—	—	—
Stock-based compensation	—	—	—	—	2,790	—	—	2,790
Unrealized loss on marketable securities	—	—	—	—	—	(718)	—	(718)
Net Loss	—	—	—	—	—	—	(26,495)	(26,495)
Balance at September 30, 2026	—	$ —	82,069,077	$ 8	$ 620,714	$ (718)	$ (122,402)	$ 497,602

	Series A Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2024	—	$ —	—	$ —	$ —	$ —	$ —
Net loss	—	—	—	—	—	(99)	(99)
Balance at March 31, 2025	—	$ —	—	$ —	$ —	$ (99)	$ (99)
Issuance of founders shares	—	—	4,794,513	1	2	—	3
Net loss	—	—	—	—	—	(381)	(381)
Balance at June 30, 2025	—	$ —	4,794,513	$ 1	$ 2	$ (480)	$ (477)
Issuance of series A redeemable convertible preferred stock, net of issuance costs of $0.5 million	101,351,352	100,741	—	—	—	—	—
Issuance of Series A redeemable convertible preferred stock for acquired in-process research and development	32,500,000	25,675	—	—	—	—	—
Vesting of restricted common stock	—	—	1,653,230	—		—	—
Net Loss	—	—	—	—	—	(59,118)	(59,118)
Balance at September 30, 2025	133,851,352	$ 126,416	6,447,743	$ 1	$ 2	$ (59,598)	$ (59,595)

See accompanying notes to condensed financial statements

Braveheart Bio, Inc.
Condensed Statements of Cash Flows (unaudited)
(in thousands)

	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
Cash flows from operating activities:		
Net loss	$ (55,763)	$ (59,598)
Adjustments to reconcile net loss to net cash used in operations:		
Acquired in-process research and development	—	59,218
Depreciation and amortization	8	—
Stock-based compensation	5,636	—
Stock-based compensation – liability-classified awards	6,145	—
Accretion of discounts on available-for-sale securities	(496)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(10,155)	(11)
Other long-term assets	(28)	—
Accounts payable	1,063	73
Accrued expenses (includes related party amounts of $(1,841) and $156, respectively)	7,116	(422)
Operating lease right-of-use asset and lease liabilities	(35)	—
Net cash used in operating activities	(46,509)	(740)
Cash flows from investing activities:		
Cash paid for purchased in-process research and development (includes related party amounts of $3,000 and $32,734, respectively)	(3,000)	(32,734)
Purchase of property and equipment	(28)	—
Purchase of marketable securities	(382,450)	—
Net cash used in investing activities	(385,478)	(32,734)
Cash flows from financing activities:		
Proceeds from issuance of founders' and restricted common stock	—	6
Proceeds from issuance of Series A redeemable convertible preferred stock, net of issuance costs	59,581	101,000
Proceeds from issuance of common stock, net of commissions and underwriting discounts	409,083	—
Payments of offering costs	(4,539)	—
Repurchase of equity awards	(8)	—
Net cash provided by financing activities	464,117	101,006
Net increase in cash and cash equivalents for the period	32,130	67,532
Cash and cash equivalents at beginning of the period	89,161	—
Cash and cash equivalents at end of the period	$ 121,291	$ 67,532
Supplemental disclosure of cash flow information:		
Non-cash investing and financing activities:		
Right-of-use assets obtained in connection with operating lease obligations	$ 795	$ —
Issuance of Series A redeemable convertible preferred stock in exchange for in-process research and development, related party	$ —	$ 25,675
Issuance costs in accrued expenses	$ —	$ 267

Non-cash deemed dividends on Series A redeemable convertible preferred stock	$	3,615	$	—
Conversion of convertible preferred stock to common stock upon initial public offering	$	213,520	$	—
Offering costs in accounts payable and accrued liabilities	$	133	$	—

See accompanying notes to condensed financial statements

Braveheart Bio, Inc.

Notes to Condensed Financial Statements (unaudited)

1. Description of Business

Organization

Braveheart Bio, Inc. (the "Company") was incorporated in the state of Delaware in May 2024 and is located in San Francisco, California. The Company is a clinical-stage biopharmaceutical company dedicated to developing therapeutics to treat hypertrophic cardiomyopathy ("HCM") and related conditions by targeting overactive proteins within the heart.

On August 7, 2026, the Company completed its initial public offering ("IPO") of its common stock, par value $0.0001 per share (the "common stock") in which the Company sold 24,437,500 shares of its common stock, which includes the exercise in full of the underwriters' option to purchase an additional 3,187,500 shares of common stock, at a public offering price of $18.00 per share, resulting in aggregate gross proceeds of $439.9 million and net proceeds of approximately $404.4 million, after deducting underwriter discounts and commissions of $30.8 million and other offering costs of $4.7 million.

On July 29, 2026, in connection with the IPO, the Company effected a 1-for-4.38 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios of each series of the Company's redeemable convertible preferred stock. Accordingly, all share and per share amounts for all periods presented in the accompanying unaudited interim condensed financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustments of the redeemable convertible preferred stock conversion ratios throughout this Quarterly Report.

Immediately prior to the closing of the IPO, the Company's outstanding redeemable convertible preferred stock automatically converted into 49,657,532 shares of common stock. Following the closing of the IPO, no shares of redeemable convertible preferred stock were outstanding. In connection with the closing of the IPO, the Company's certificate of incorporation was amended and restated to authorize 500,000,000 shares of common stock, par value $0.0001 per share and 10,000,000 shares of undesignated preferred stock, par value $0.0001 per share.

Liquidity and Capital Resources

Since inception, the Company has devoted substantially all of its resources to research and development activities, business planning, establishing and maintaining its intellectual property portfolio, hiring personnel, raising capital, and providing general and administrative support for these operations. The Company has a limited operating history, and the sales and income potential of its business is unproven. The Company has incurred net losses and negative cash flows from operating activities since its inception and expects to continue to incur net losses into the foreseeable future as it continues the development of its therapeutic candidates.

As of September 30, 2026, the Company had an accumulated deficit of $122.4 million and cash, cash equivalents and investments of $503.5 million. For the nine months ended September 30, 2026 and 2025, the Company had a net loss of $55.8 million and $59.6 million, respectively, and net cash used in operating activities of $46.5 million and $0.7 million, respectively.

The Company has 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 after the date that these condensed financial statements are issued. As of November 10, 2026, the issuance date of the condensed financial statements, the Company expects that its cash, cash equivalents and investments will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next twelve months.

The Company will need additional financing to support its continuing operations and pursue its growth strategy. Until such time as the Company can generate significant revenue from product sales, if ever, the Company expects to finance its cash needs through a combination of equity offerings, debt or royalty financings, and collaborations. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaborations or other arrangements. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is

unable to obtain sufficient funding, the Company will be forced to delay, scale back or discontinue some or all of its research and development programs, product portfolio expansion efforts or commercialization efforts, which could adversely affect its business prospects. Although management continues to pursue these plans, 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.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited interim condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") and pursuant to the rules and regulations applicable to interim financial reporting. These condensed financial statements should be read in conjunction with the audited financial statements and related notes for the year ended December 31, 2025. The unaudited interim condensed financial statements reflect all adjustments that, in the opinion of management, are necessary for a fair presentation of the results for the interim periods presented. Such adjustments are of a normal recurring nature. The condensed results of operations for the nine months ended September 30, 2026, are not necessarily indicative of the results to be expected for the full year ending December 31, 2026, or for any other future period.

The condensed balance sheet as of December 31, 2025, has been derived from the audited financial statements as of that date.

Use of Estimates

The preparation of condensed financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed financial statements and the reported amounts of income and expenses during the reporting periods. Significant estimates and assumptions are used for, but not limited to, the accruals for research and development expenses, stock-based compensation expense, the determination of fair value of equity instruments, the valuation of equity and liability-classified compensation awards, the fair value of acquired in-process research and development, and income taxes. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Cash and Cash Equivalents

Cash and cash equivalents include cash in readily available operating accounts, U.S. Treasury bills, money market funds and deposits with commercial banks. Cash equivalents are defined as short-term, highly liquid investments with original maturities of 90 days or less from the date of purchase.

Available-for-Sale Securities

The Company classifies its investments in debt securities as available-for-sale. Debt securities that do not meet the definition of cash equivalents are classified as short-term or long-term investments based on their remaining maturity at each balance sheet date. Securities maturing within one year are included in short-term investments, and those maturing in more than one year are included in long-term investments. Accordingly, securities initially classified as long-term investments are reclassified to short-term investments when their remaining maturity becomes one year or less.

The Company records its available-for-sale securities at estimated fair value in the condensed balance sheets. Unrealized gains and losses, if any, are reported as a component of other comprehensive loss in the condensed statements of operations and comprehensive loss and are included in accumulated other comprehensive loss, a separate component of stockholders' equity.

Any premium arising at purchase is amortized, and any discount arising at purchase is accreted, to maturity using the effective interest method. Amortization of premiums and accretion of discounts are recorded in interest income in the condensed statements of operations and comprehensive loss.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

• Level 1—Quoted prices in active markets for identical assets or liabilities.

• Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

• Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents and marketable securities are carried at fair value, determined according to the fair value hierarchy (see Note 4). The carrying values of the Company's accounts payable and accrued expenses approximate their fair values due to the short-term nature of these liabilities.

Operating Leases

The Company accounts for leases in accordance with ASC 842, Leases. The Company entered into its first lease agreement in January 2026 (see Note 7). The Company determines if an arrangement is a lease at inception. Operating lease right-of-use ("ROU") assets represent the Company's right to use an underlying asset during the lease term, and operating lease liabilities represent the Company's obligation to make lease payments. ROU assets and lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the remaining lease term. As the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. Lease expense is recognized on a straight-line basis over the lease term.

Property and Equipment

Property and equipment, net consists of lab equipment, computer equipment, furniture and fixtures, and leasehold improvements, which are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets (three to seven years, or, for leasehold improvements, the shorter of the remaining lease term or the estimated useful life). Repairs and maintenance costs are expensed as incurred.

Deferred Offering Costs

The Company incurred certain legal, accounting, and other third party fees that were directly related to the Company's IPO that closed in August 2026. Such costs were recorded in stockholders' equity (deficit) as a reduction to the proceeds received from the IPO.

Stock-Based Compensation – Liability-Classified Awards

Restricted stock awards that include a vesting condition that is not related to service, performance or market conditions are classified as liabilities. The Company measures these awards at fair value using a Monte Carlo simulation model and remeasures them at each reporting date until they are reclassified to equity or settled. Compensation cost is recognized over the derived service period and the Company does not update the derived service period after the initial measurement date (see Note 9).

Recently Issued Accounting Standards Not Yet Adopted

In November 2024, the FASB issued ASU No. 2024-03, Income Statement—Reporting Comprehensive Income (Topic 220): Disaggregation of Income Statement Expenses. This ASU requires enhanced disaggregation of certain expense categories in the notes to the financial statements. The guidance is effective for annual periods beginning after December 15, 2026, and interim periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted, and the standard may be applied on either a prospective or retrospective basis. The Company is currently evaluating the impact of this standard on its financial statements.

In September 2025, the FASB issued ASU No. 2025-06, Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software. This ASU removes references to project stages from the guidance on internal-use software costs, clarifies the threshold for beginning to capitalize those costs, and supersedes the separate guidance for website development costs. The guidance is effective for annual periods beginning after December 15, 2027, and interim periods within those annual reporting periods, with early adoption permitted. The Company is currently evaluating the impact of this standard on its financial statements.

3. Related Party Transactions

Financial Accounting Standards Board (FASB) ASC 850, Related Party Disclosures (FASB ASC 850) requires that transactions with related parties that would make a difference in decision making shall be disclosed so that users of the financial statements can evaluate their significance.

Hengrui Pharmaceuticals Exclusive License Agreement

The Company entered into an Exclusive License Agreement (the “License Agreement”) with Jiangsu Hengrui Pharmaceuticals Co., Ltd. (“Hengrui”) in September 2025, as described in the Company’s audited financial statements for the year ended December 31, 2025. Hengrui is a related party of the Company as a result of its ownership of 7,420,091 shares of the Company’s common stock, representing approximately 8.3% of the Company’s issued common stock as of September 30, 2026. During the nine months ended September 30, 2026, the Company incurred related party expenses of $7.0 million in connection with the License Agreement for the completed manufacturing technology transfer milestone and initial echo data transfer milestone, which were recorded within research and development expense on the condensed statement of operations and comprehensive loss. The manufacturing technology transfer milestone of $6.0 million was paid as of September 30, 2026. The initial echo data transfer milestone of $1.0 million was recorded within accrued expenses on the condensed balance sheet as of September 30, 2026. During the nine months ended September 30, 2026, the Company also incurred related party expenses of $0.4 million for drug supply purchases from Hengrui, which was recorded within research and development expense on the condensed statement of operations and comprehensive loss and within accrued expenses on the condensed balance sheet. As of September 30, 2026, the accrued license milestone of $3.0 million recorded as of December 31, 2025 has been paid.

Other Related Party Transactions

During the nine months ended September 30, 2026, the Company incurred related party expenses of $0.2 million in connection with fees to certain directors, and board and committee members. These expenses are included within general and administrative expense on the condensed statement of operations and comprehensive loss. As of September 30, 2026, $0.1 million of these expenses are accounted for within accounts payable or accrued expenses on the condensed balance sheet.

4. Fair Value Measurements

Assets measured at fair value on a recurring basis are as follows (in thousands):

	As of September 30, 2026			
	(Level 1)	(Level 2)	(Level 3)	Total
Assets				
Money market funds	$ 41,579	$ —	$ —	$ 41,579
U.S. Treasury securities - cash equivalents	—	77,653	—	77,653
Total cash equivalents	$ 41,579	$ 77,653	$ —	$ 119,232
U.S. Treasury securities short-term	—	227,981	—	227,981
U.S. Treasury securities long-term	—	154,248	—	154,248
Total investments	$ —	$ 382,229	$ —	$ 382,229
Total fair value of assets	$ 41,579	$ 459,882	$ —	$ 501,461

	As of December 31, 2025			
	(Level 1)	(Level 2)	(Level 3)	Total
Assets				
Money market funds	$ 88,991	$ —	$ —	$ 88,991
Total fair value of assets	$ 88,991	$ —	$ —	$ 88,991

There have been no transfers between fair value levels during the nine months ended September 30, 2026. Money market funds are valued at the closing price reported by the fund sponsor from an actively-traded exchange. The Company obtains the fair value of its Level 2 cash equivalents and short-term investments from third-party pricing services. The pricing services utilize industry standard valuation models whereby all significant inputs, including benchmark yields, reported trades, broker/dealer quotes, issuer spreads, bids, offers, or other market-related data, are observable.

5. Marketable Securities

Marketable securities consisted of available-for-sale securities as follows (in thousands):

	As of September 30, 2026			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash equivalents:				
U.S. Treasury securities	77,662	—	(9)	77,653
Total cash equivalents	$ 77,662	$ —	$ (9)	$ 77,653
Short-term marketable securities:				
U.S. Treasury securities	228,261	—	(280)	227,981
Total short-term marketable securities	$ 228,261	$ —	$ (280)	$ 227,981
Long-term marketable securities:				
U.S. Treasury securities	154,677	—	(429)	154,248
Total long-term marketable securities	$ 154,677	$ —	$ (429)	$ 154,248
Total	$ 460,600	$ —	$ (718)	$ 459,882

During the three and nine months ended September 30, 2026, the Company purchased $227.9 million in short-term investments and $154.6 million in long-term investments. There were no sales or maturities of available-for-sale debt securities during the three and nine months ended September 30, 2026.

The Company's money market mutual fund holdings are highly liquid and invested primarily in short-term U.S. Treasury bills and obligations guaranteed by the U.S. government. The Company's portfolio of available-for-sale debt securities consists primarily of U.S. Treasury securities. These securities are classified as short-

term investments when remaining effective maturities are one year or less from the balance sheet date, and as long-term investments when maturities exceed one year from the balance sheet date. As of September 30, 2026, the Company's long-term investments had contractual maturities of less than two years.

As of September 30, 2026, the Company's available-for-sale securities had gross unrealized losses of $0.7 million. Management determined that the gross unrealized losses on the Company's available-for-sale securities as of September 30, 2026 were primarily attributable to current economic and market conditions and not credit risk. As of September 30, 2026, no allowance for credit losses was recorded for available-for-sale securities. It is neither management's intention to sell nor is it more likely than not that the Company will be required to sell any investments prior to recovery of their amortized cost basis, which is expected to be at maturity.

There were no available-for-sale securities in an unrealized loss position for greater than one year as of September 30, 2026, and the Company held no available-for-sale securities as of December 31, 2025.

Accrued interest receivable on the Company's available-for-sale securities was $1.4 million at September 30, 2026, and is included in prepaid expenses and other current assets on the condensed balance sheet.

6. Balance Sheet Details

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2026	December 31, 2025
Accrued compensation	$ 2,615	$ 315
Accrued research and development	2,312	153
Accrued clinical	1,333	—
Accrued licensing, related party	1,000	3,000
Accrued professional services	732	370
Accrued deferred offering and issuance costs	116	272
Other accrued expenses	30	74
Total accrued expenses	$ 8,138	$ 4,184

7. Commitments and Contingencies

Legal Proceedings

In the event the Company becomes subject to claims or suits arising in the ordinary course of business, the Company would accrue an estimated liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

The Company has not recorded any such liabilities as of September 30, 2026.

Hengrui License Agreement – Contingent Obligations

As described in Note 3 to our audited financial statements for the year ended December 31, 2025, the Company is obligated to make contingent cash payments to Hengrui upon the achievement of specified milestones. During the nine months ended September 30, 2026, the Company has incurred $7.0 million related to specified milestones. The Company will continue to evaluate the probability of remaining contingent milestone and royalty payments at each reporting period.

The flipping transaction provision described in Note 3 to our audited financial statements for the year ended December 31, 2025, remains in effect through March 3, 2027 (18 months from the September 3, 2025, effective date of the License Agreement). As of September 30, 2026, no flipping transaction has occurred.

Operating Lease

Effective January 2026, the Company executed a sublease agreement (the "Sublease") with Aperture Group, LLC, for office space located in San Francisco, California. The Company determined the Sublease is an operating lease. The initial term of the Sublease is approximately 24 months and the commencement date occurred in January 2026. Lease payments total approximately $0.4 million annually, exclusive of operating expenses including utilities, common area maintenance, insurance, and property taxes.

Upon commencement of the Sublease in January 2026, the Company recognized an operating lease right-of-use asset of $0.8 million and a corresponding operating lease liability of $0.8 million, based on the present value of the remaining minimum lease payments using an incremental borrowing rate of 7.65%.

Rent expense was $0.1 million and $0.3 million for the three and nine months ended September 30, 2026, respectively.

Future minimum annual obligations under the Sublease, to be recognized over a weighted-average remaining term of 1.2 years, are as follows (in thousands):

	Period Ended December 31,
2026 (remaining)	105
2027	433
Total minimum lease payments	538
Less: amount representing interest	(23)
Present value of lease liabilities	515
Less: current portion of lease liabilities	(415)
Lease liabilities, net of current portion	$ 100

8. Convertible Preferred Stock and Stockholders' Equity (Deficit)

Convertible Preferred Stock

Redeemable Convertible Preferred Stock

During the nine months ended September 30, 2026, the Company issued 60,000,000 shares of Series A redeemable convertible preferred stock at a price of $1.00 per share in a third closing under the Series A Preferred Stock Purchase Agreement, which granted certain investors the right to purchase these additional shares upon approval by the Board of Directors. This third closing occurred on April 24, 2026, and the Company received $60.0 million in gross proceeds. In connection with this additional closing, the Company recorded a deemed dividend of $3.6 million, representing the excess of the estimated fair value of the Series A redeemable convertible preferred stock issued over the $1.00 per share purchase price. The deemed dividend increased the carrying value of the Series A redeemable convertible preferred stock and increased net loss attributable to common stockholders in the computation of net loss per share (see note 10). Immediately prior to the closing of the Company's IPO, all 217,500,000 outstanding shares of Series A redeemable convertible preferred stock automatically converted into 49,657,532 shares of common stock (see note 1).

Common Stock

As of September 30, 2026, the Company was authorized to issue 500,000,000 shares of $0.0001 par value common stock. As of September 30, 2026, 89,867,737 shares of common stock were issued and 82,069,077 shares of common stock were outstanding. The difference represents 7,798,660 shares of unvested restricted common stock, which are issued but not outstanding for accounting purposes until vested.

Common stock reserved for future issuance consisted of the following:

	September 30, 2026
Common stock options granted and outstanding	5,680,186
Shares available for issuance under the 2026 equity incentive plan	7,628,506
Shares available for issuance under the 2026 employee stock purchase plan	894,100
Total common stock reserved for issuance	14,202,792

9. Equity Incentive Plan and Stock-Based Compensation

Stock Options

On May 5, 2026, the Company entered into an amendment to the 2025 Stock Option and Grant Plan (the "2025 Plan"), pursuant to which the number of shares of common stock available for issuance thereunder was increased to 14,576,068 shares, representing an increase of 2,191,781 shares. On June 24, 2026, the Company's board of directors adopted, and the Company's stockholders approved, the 2026 Stock Option and Incentive Plan (the "2026 Plan") and the 2026 Employee Stock Purchase Plan (the "2026 ESPP") (together, the "Stock Plans"), which became effective on August 4, 2026 in connection with the Company's IPO. The Company initially reserved 10,761,900 and 894,100 shares of common stock for issuance under the 2026 Plan and the 2026 ESPP, respectively. The 2026 Plan has replaced the 2025 Plan and the shares reserved for future issuance under the 2025 Plan ceased to be available for issuance at the time the 2026 Plan became effective. The 2025 Plan will continue to govern outstanding equity awards granted thereunder and any shares underlying outstanding stock awards granted under the 2025 Plan that subsequently expire or are repurchased, forfeited, cancelled, or withheld will return to the 2026 Plan and be reserved and available for issuance.

A summary of the Company's stock option activity for the nine months ended September 30, 2026, under the 2025 Plan and 2026 Plan is as follows (in thousands, except share and per share data and years):

	Options Outstanding	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at December 31, 2025	320,773	$ 0.05		
Granted	5,572,643	12.43		
Exercised	—	—		
Forfeited	(213,230)	1.71		
Balance at September 30, 2026	5,680,186	$ 12.13	9.2	$ 48,229
Vested and exercisable at September 30, 2026	107,397	$ 16.17	8.7	$ 433

Exercisable options reflect the number of options vested as of the date reported. The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of the Company's common stock for all options that were in-the-money as of September 30, 2026.

The weighted-average grant date fair value of options granted during the nine months ended September 30, 2026, was $8.56 per share. There were no options granted during the nine months ended September 30, 2025.

The Company recorded stock-based compensation expense related to stock options as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2026	September 30, 2025	September 30, 2026	September 30, 2025
Research and development	$ 998	$ —	$ 1,233	$ —
General and administrative	1,047	—	1,093	—
Total stock-based compensation expense	$ 2,045	$ —	$ 2,326	$ —

As of September 30, 2026, the unrecognized compensation cost related to outstanding stock options was $45.4 million and is expected to be recognized as expense over a weighted-average period of approximately 3.7 years.

The assumptions used in the Black-Scholes option pricing model to determine the fair value of the option grants issued for the nine months ended September 30, 2026, were as follows:

	September 30, 2026
Risk-free rate of interest	3.77% - 4.63%
Expected term (years)	3.52 - 6.08
Expected stock price volatility	78.27% - 82.67%
Dividend yield	— %

Restricted Stock Awards

As of September 30, 2026, the Company recorded $0.1 million in other long-term liabilities on the condensed balance sheet related to unvested awards that the Company has the option to repurchase.

A summary of the Company's restricted stock activity under the 2025 Plan for the nine months ended September 30, 2026, is as follows:

	Number of Shares Outstanding	Weighted-Average Grant Date Fair Value
Balance at December 31, 2025	8,442,641	$ 0.92
Issuance of unvested restricted stock awards	—	—
Share Vesting	(1,243,295)	0.89
Forfeited	(171,232)	—
Balance at September 30, 2026	7,028,114	$ 0.90

Restricted Stock Award Modification

In July 2026, the Company's board of directors modified the vesting criteria for 1.7 million shares of restricted stock awards for an executive officer with certain market-based conditions. Under the modified terms, subject to the executive's continued employment through the vesting dates, the awards vest in two equal tranches upon the achievement of stock price hurdles, set as specified multiples of the original issuance price of the Series A redeemable convertible preferred stock, within specified periods following the Company's public listing. In addition, vesting cannot occur before the later of a specified period following the Company's public listing and the public disclosure of top-line results from a Phase 3 clinical study conducted by Hengrui. If the shares underlying the award have not vested by the tenth anniversary of the closing of the Company's Series A financing, the Company has the right, but not the obligation, to repurchase such shares at the original per share purchase price.

Because vesting also depends on the timing of the public disclosure of clinical results from a study conducted by a third party, which is not a service, performance or market condition, the awards were classified as liabilities as of the modification date. No compensation cost was recognized for the original awards because the change-in-control condition was not considered probable. No compensation cost was recognized at the modification date because vesting of the modified awards also required the Company's public listing, which was not considered probable until the Company completed its initial public offering on August 7, 2026. The fair value of the awards, determined using a Monte Carlo simulation model, was $25.2 million at the modification date and $28.1 million as of September 30, 2026. Significant assumptions used in the model were expected volatility of 98.4% at the modification date and 89.1% as of September 30, 2026, based on the historical volatility of a group of comparable publicly traded entities; risk-free interest rates of 4.31% and 4.88%, respectively; an expected dividend yield of zero; and vesting end terms through the end of each tranche's market condition period in September 2028 and September 2029. The awards are remeasured to fair value at each reporting date until they are reclassified to equity or settled, and compensation expense is recognized on a straight-line basis over the derived service period of each tranche, approximately 0.8 and 1.0 years from the modification date.

Other Restricted Stock Awards

In addition to grants under the 2025 Plan, the Company has also granted RSAs outside of the 2025 Plan. The shares were issued under the terms of restricted stock purchase agreements, and unvested shares are subject to repurchase by the Company upon the holder's termination of his or her relationship with the Company at the original purchase price per share.

A summary of the Company's restricted stock activity outside of the 2025 Plan for the nine months ended September 30, 2026, is as follows:

	Number of Shares Outstanding	Weighted-Average Grant Date Fair Value
Balance at December 31, 2025	816,208	$ 0.17
Issuance of unvested restricted stock awards	—	—
Share vesting	(45,662)	0.07
Balance at September 30, 2026	770,546	$ 0.19

The total fair value of all RSAs vested during the nine months ended September 30, 2026, was $1.2 million.

The Company recorded stock-based compensation expense related to RSAs as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2026	September 30, 2025	September 30, 2026	September 30, 2025
Research and development	$ 120	$ —	$ 424	$ —
General and administrative	6,770	—	9,032	—
Total stock-based compensation expense	$ 6,890	$ —	$ 9,456	$ —

Stock-based compensation expense for RSAs for the three and nine months ended September 30, 2026 includes $6.1 million related to the modified RSAs described above. This expense is included in general and administrative expense in the condensed statements of operations and comprehensive loss, and the related share-based liability of $6.1 million is included in other current liabilities on the condensed balance sheet.

As of September 30, 2026, the unrecognized compensation cost related to all outstanding RSAs was $6.4 million and is expected to be recognized over a weighted-average period of approximately 2.9 years, in addition to $21.9 million of total unrecognized stock-based compensation expense related to the modified executive RSAs, which we expect to recognize over a remaining weighted-average period of 0.8 years. No stock-based compensation expense related to RSAs was recorded for the three and nine months ended September 30, 2025.

2026 Employee Stock Purchase Plan

No offerings have been authorized to date under the 2026 ESPP.

10. Net loss per share

The following table sets forth the computation of basic and diluted net loss per share (in thousands, except share and per share data):

	Three Months Ended		Nine Months Ended	
	September 30, 2026	September 30, 2025	September 30, 2026	September 30, 2025
Numerator:				
Net loss	$ (26,495)	$ (59,118)	$ (55,763)	$ (59,598)
Less: deemed dividend to preferred stockholders	—	—	(3,615)	—
Net loss attributable to common stockholders	$ (26,495)	$ (59,118)	$ (59,378)	$ (59,598)
Denominator:				
Weighted-average common shares issued	60,238,452	10,558,925	30,873,417	4,489,122
Less: Weighted-average common shares subject to repurchase and vesting conditions	(8,143,374)	(4,677,914)	(8,587,784)	(1,576,440)
Weighted-average shares used to compute net loss per share, basic and diluted	52,095,078	5,881,011	22,285,633	2,912,682
Net loss per share attributable to common stockholders, basic and diluted	$ (0.51)	$ (10.05)	$ (2.66)	$ (20.46)

The potential shares of common stock that were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive are as follows:

	As of September 30, 2026	As of September 30, 2025
Common stock options outstanding[1]	5,669,484	—
Unvested restricted common stock	7,798,660	7,470,359
Common stock issuable upon conversion of Series A redeemable convertible preferred stock	—	30,559,669
Total	13,468,144	38,030,028

(1) As of September 30, 2026, excluded from this amount are 10,702 shares underlying vested common stock options with a weighted average exercise price of $0.04, which have been included in the computation of basic and diluted net loss per share on the date all necessary conditions have been satisfied for issuance, which is the date any service based vesting conditions have been met, as they represent shares issuable for little or no cash consideration upon the satisfaction of certain conditions pursuant to ASC 260-10-45-13.

11. Income Taxes

As of September 30, 2026, there have been no material changes to the Company's uncertain tax positions or its assessment regarding the realizability of its deferred tax assets as compared to December 31, 2025. The Company continues to maintain a full valuation allowance on its net deferred tax assets as it has determined that it is more likely than not that these deferred tax assets will not be realized. For the three and nine months ended September 30, 2026, the Company's effective tax rate differed from the U.S. federal statutory rate of 21% primarily due to the full valuation allowance maintained against its deferred tax assets.

12. Segment Reporting

The Company operates and manages its business as one reportable and operating segment, which is the business of developing therapeutics to treat hypertrophic cardiomyopathy. The Company's chief operating decision maker ("CODM") is the chief executive officer, who assesses performance of the segment based on net loss, which includes evaluating the progress of ongoing research and development. 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		Nine Months Ended	
	September 30, 2026	September 30, 2025	September 30, 2026	September 30, 2025
Revenue	$ —	$ —	$ —	$ —
Less:				
External research and development	11,393	9	22,018	9
License milestones	1,000	—	7,000	—
In-process research and development	—	58,770	—	59,218
Personnel-related	14,794	130	24,927	130
Facilities	119	—	354	—
Other[a]	2,843	378	6,781	410
Interest income	3,712	169	5,372	169
Other income (expense), net	(58)	—	(55)	—
Net loss	$ (26,495)	$ (59,118)	$ (55,763)	$ (59,598)

(a) Other primarily includes consultants, legal, insurance expenses and subscriptions.

13. Subsequent Events

The Company has evaluated subsequent events through the date the condensed financial statements were issued. No subsequent events occurring after the balance sheet date were identified that require recognition or disclosure in the financial statements.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our unaudited interim condensed financial statements and related notes and other financial information appearing elsewhere in this Quarterly Report and with our audited financial statements and related notes for the year ended December 31, 2025 included in our IPO final prospectus dated August 5, 2026 *filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the "Securities Act"). References to the "Company," "Braveheart," "Braveheart Bio," "we," "our," "us," or similar terms refer to Braveheart Bio, Inc. This discussion and analysis and other parts of this Quarterly Report contains forward-looking statements based upon our current plans and strategy for our business that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and beliefs. Our actual results and the timing of events could differ materially from those described in, anticipated in or implied by these forward-looking statements as a result of various factors, including those set forth under the headings "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors" elsewhere in this Quarterly Report.*

Overview

Braveheart Bio, Inc. is a clinical-stage biopharmaceutical company focused on developing therapies for patients with hypertrophic cardiomyopathy ("HCM") and other serious cardiovascular diseases. Our lead product candidate, BHB-1893, is a next-generation oral small-molecule cardiac myosin inhibitor ("CMI") that we are developing for the treatment of obstructive HCM ("oHCM") and non-obstructive HCM ("nHCM"). Our goal is to improve the treatment options for these patients by enhancing speed of onset, depth of gradient response, systolic safety, and reversibility, and reducing prescribing complexity.

Cardiac myosin inhibition is a clinically validated therapeutic approach in symptomatic oHCM. However, currently approved therapies require complex dose titration and frequent echocardiographic monitoring, which can create operational burden and limit adoption. Based on nonclinical and clinical data generated to date, we believe BHB-1893 has the potential to offer a differentiated product profile, including rapid onset of action, predictable pharmacokinetics, limited drug-drug interactions, and a low left ventricular ejection fraction cost.

We plan to advance BHB-1893 through global Phase 3 development in both oHCM and nHCM. We have initiated LIONHEART-HCM, a Phase 3, multi-region, multi-center, randomized, double-blind, active-comparator-controlled trial to evaluate the efficacy and safety of BHB-1893 compared to metoprolol in adults with symptomatic obstructive hypertrophic cardiomyopathy. LIONHEART-HCM is currently enrolling patients, and we expect to conduct an interim analysis in the second half of 2027. We also plan to initiate TRUEHEART-HCM to evaluate a fixed 40 mg twice-daily dose of BHB-1893, with no titration visits, on top of standard of care in patients with symptomatic oHCM in the U.S. in the first half of 2027. We plan to initiate NOBLEHEART-HCM, a global Phase 3 trial in nHCM in the first half of 2027. Participants from our global studies will be candidates to enroll in HEARTSONG-LTE, our planned long-term extension study. We hold exclusive rights to develop, manufacture and commercialize BHB-1893 worldwide, excluding Mainland China, Hong Kong, Macau and Taiwan, under an exclusive license agreement (the "Exclusive License Agreement") with Jiangsu Hengrui Pharmaceuticals Co., Ltd. ("Hengrui").

Since inception, we have devoted substantially all of our resources to organizing our company, hiring personnel, business planning, acquiring rights to BHB-1893, conducting research and development activities, advancing clinical trials, and establishing our operational infrastructure. We do not have any products approved for sale and have not generated any revenue from product sales. We expect to continue to incur significant and increasing expenses and increasing substantial losses for the foreseeable future as we continue our development of and seek regulatory approvals for BHB-1893, seek to commercialize BHB-1893, if approved, seek to expand our product pipeline, and invest in our organization. Our ability to achieve and sustain profitability will depend on our ability to successfully develop, obtain regulatory approval for, and commercialize our product candidate. There can be no assurance that we will ever earn revenues or achieve profitability, or if achieved, that the revenues or profitability will be sustained on a continuing basis.

To date, we have primarily funded our operations with proceeds from sales of shares of our common stock and redeemable convertible preferred stock in private placements and from our initial public offering ("IPO"), which closed in August 2026. As of September 30, 2026, we had $503.5 million in cash, cash equivalents, and investments.

We have incurred significant operating losses and negative cash flows from operations since our inception. Our net loss for the nine months ended September 30, 2026 and 2025, was $55.8 million and $59.6 million, respectively. As of September 30, 2026, we had an accumulated deficit of $122.4 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and, to a lesser extent, from general and administrative costs associated with our operations. Our net losses and operating losses may fluctuate from quarter to quarter and year to year depending primarily on the timing of acquisition of any new product candidates, the timing of our nonclinical studies and clinical trials, our other research and development expenses, and the timing and amount of any milestone or royalty payments due under the Exclusive License Agreement with Hengrui (as defined below) and future license agreements. In addition, we expect to incur additional costs associated with operating as a public company, including significant legal, audit, accounting, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer liability insurance costs, investor and public relations costs, and other expenses that we did not incur as a private company. We anticipate that our expenses will increase significantly in connection with our ongoing activities, particularly if and as we:

- continue to progress the development of BHB-1893 into later stage clinical development;
- explore additional indications for our existing product candidate;
- hire additional clinical, quality control, and scientific personnel;
- obtain, maintain, expand, and protect our intellectual property rights, including defending against any claims by third parties that we have infringed, misappropriated, or otherwise violated any intellectual property of any such third party;
- make royalty, milestone, or other payments under the Exclusive License Agreement, and any future, license or collaboration agreement;
- seek to identify, acquire, or in-license new technologies or product candidates;
- seek regulatory and marketing approvals for any of our current or future product candidates that successfully complete clinical trials, if any;
- procure manufacturing and supply chain capacity for our current or future product candidates, including commercial manufacturing readiness and scale-up;
- experience any delays, challenges, or other issues associated with the clinical development of our current or future product candidates, including with respect to our regulatory strategies;
- establish a sales, marketing, and distribution infrastructure to commercialize any product candidates for which we obtain marketing approval; and
- add operational, legal, financial, and management information systems and personnel to support our product development, clinical execution, and planned future commercialization efforts.

Because of the numerous risks and uncertainties associated with therapeutic product development, we may never achieve or sustain profitability and, unless and until we are able to develop and commercialize our current or future product candidates, we will need to continue to raise additional capital. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through public or private equity or debt financings, or potentially other capital sources, such as collaboration or licensing arrangements with third parties or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing to support our business plans when needed on acceptable 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 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. If we are unable to raise capital as and when needed, or on attractive terms, we may have to significantly delay, reduce, or discontinue the development and commercialization of our current or future product candidates or scale back or terminate our pursuit of new in-licenses and acquisitions.

As of September 30, 2026, we had $503.5 million in cash, cash equivalents and investments. Based on our current operating plan, we believe that our existing cash, cash equivalents and investments will be sufficient to fund our projected operating expenses and capital expenditure requirements into 2029. We have based this estimate on our current assumptions, which may prove to be wrong, and we may exhaust our available capital resources sooner than we expect.

We currently have no sales, marketing, or commercialization capabilities. However, we intend to build the necessary sales, marketing, and commercialization capabilities and infrastructure over time as our product candidate advances through clinical development. We expect to spend a significant amount in development and marketing costs prior to obtaining regulatory and marketing approval of our current or future product candidates. We expect that our expenses and capital requirements will increase substantially in the near- to mid-term as we continue our late-stage development efforts for BHB-1893; and add clinical, scientific, sales and marketing, operational, and financial personnel, including personnel to support our product development and potential future commercialization activity.

Recent Developments

AHA Scientific Sessions 2026 Presentations

On November 6, 2026, we and Hengrui presented clinical and preclinical data for BHB-1893 at the American Heart Association (“AHA”) Scientific Sessions 2026.

52-Week Open-Label Extension in oHCM. Results from the 52-week open-label extension (“OLE”) of Hengrui’s Phase 2 trial of BHB-1893 in patients with symptomatic oHCM (NCT06516068) were presented in a late-breaking oral presentation. All 42 patients from the 12-week core period rolled over into the OLE following a washout period. In the OLE, the planned starting dose for all patients was 40 mg twice-daily (“BID”), with the option to titrate to 60 mg or 80 mg BID based on Valsalva left ventricular outflow tract gradient (“LVOT-G”) and left ventricular ejection fraction (“LVEF”) criteria. By Week 1, prior to any dose titration, 67% of patients achieved a Valsalva LVOT-G below 30 mmHg, and 90% reached this threshold at one or more visits during the 52-week treatment period, with 79% (33/42) reaching the threshold at Week 52. At Week 52, 57% of patients were maintained on a 40 mg BID dose. From OLE baseline to Week 52, mean peak oxygen uptake (“pVO2”) improved by 2.7 mL/kg/min and mean Kansas City Cardiomyopathy Questionnaire Clinical Summary Score (“KCCQ-CSS”) improved by 17.3 points. In an exploratory, unadjusted post hoc comparison at similar plasma drug concentrations, LVOT-G and NT-proBNP measured after the post-treatment washout following 52 weeks of treatment were lower than those measured after the washout following the 12-week core period. We believe this is consistent with potential reverse remodeling. BHB-1893 was generally well tolerated, with no severe or serious treatment-emergent adverse events while patients were receiving study drug. Two patients experienced a transient site-measured LVEF below 50% and resumed treatment at a lower dose. As of the data cutoff, no new cases of LVEF below 50% had been observed.

Mechanistic and Diastolic Function Data in nHCM. We also presented nonclinical mechanistic data from engineered heart tissue models and an ad hoc pooled analysis of Hengrui's randomized, double-blind, placebo-controlled Phase 2 trial of BHB-1893 in 84 patients with nHCM (NCT06816251). In these analyses, BHB-1893 improved indices of diastolic function while preserving systolic performance, both in vitro and in patients. At Week 12, a majority of BHB-1893-treated patients had normal septal and lateral e′ velocities (59% and 57%, respectively, compared with 14% and 18% of placebo-treated patients). LVEF below 50% was observed in four of 56 BHB-1893-treated patients, each of whom returned to an LVEF of 50% or greater following dose reduction. We expect 52-week data from the OLE of this trial to be available in the first half of 2027.

Hengrui Pharmaceuticals Exclusive License Agreement

In September 2025, we entered into an Exclusive License Agreement (the "Exclusive License Agreement") with Hengrui under which Hengrui granted us an exclusive, royalty-bearing and sublicensable license to develop, commercialize, manufacture, and otherwise exploit products containing Hengrui's cardiac myosin inhibitor HRS-1893 and other related compounds (the "Licensed Products") for any and all uses worldwide outside of Mainland China, Hong Kong, Macau and Taiwan (the "Territory") and a non-exclusive, royalty-bearing and sublicensable license to develop and manufacture the Licensed Products outside of the Territory solely for the development or commercialization of such Licensed Products in the Territory.

Pursuant to the terms of the Exclusive License Agreement, Hengrui received a $32.5 million upfront payment and 32,500,000 shares of non-voting Series A redeemable convertible preferred stock as consideration at an original price of $1.00 per share. We separately calculated the fair value of the non-voting Series A redeemable convertible preferred stock and the corresponding fair value of the non-voting Series A redeemable convertible preferred stock issued was $0.79 per share, representing total equity consideration of $25.7 million. Hengrui is also potentially eligible to receive additional payments (i) up to $23.0 million upon achievement of certain technology transfer and development milestones and (ii) up to $1.0 billion upon achievement of certain commercial milestones, in addition to tiered royalties on a Licensed Product-by-Licensed Product basis and country-by-country basis ranging from 5% to 10%, on total annual net sales of each such Licensed Product and will be compensated for ongoing program expenses. We will assume full responsibility for future development and commercialization expenses.

The acquisition of the exclusive license pursuant to the Exclusive License Agreement was accounted for as an in-process research and development asset acquisition. As the acquired technology did not have an alternative use, the total consideration of $58.2 million was recorded as in-process research and development expense in the statement of operations and comprehensive loss at the inception of the license agreements. Milestone payments are contingent consideration and are recognized in the period the obligation is resolved. Royalties will be recognized as cost of sales when products are sold and royalties are payable. The technology transfer milestone for $3.0 million was completed in December 2025, and recorded within accrued expenses and other current liabilities in the balance sheet as of December 31, 2025. As of September 30, 2026, this milestone has been paid. The manufacturing technology transfer milestone for $6.0 million was completed in March 2026, and has been paid as of September 30, 2026. The initial echo data transfer milestone for $1.0 million was completed in August 2026, and was recorded within accrued expenses on the condensed balance sheet as of September 30, 2026. For a more detailed description of the Exclusive License Agreement, see the section titled "*Business—Hengrui License Agreement*," included in our IPO final prospectus dated August 5, 2026 filed with the SEC.

Reverse Stock Split

In connection with our IPO, on July 29, 2026, we effected a 1-for-4.38 reverse stock split of our issued and outstanding shares of common stock. Accordingly, all share and per share amounts for all periods presented in this section have been adjusted retroactively, where applicable, to reflect this reverse stock split.

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

Research and development expenses consist of external and internal costs primarily related to acquiring our product candidate pipeline and technologies, and clinical development of our product candidate.

External costs include:

- costs associated with acquiring technology and intellectual property licenses that have no alternative future uses and costs incurred under in-license or assignment agreements, including milestone payments;
- costs incurred in connection with the clinical development of our product candidate, including under agreements with CROs, CMOs, and other third parties that conduct clinical trials and manufacture clinical supplies, product candidates, and components on our behalf; and
- costs for third-party professional research and development consulting services.

Internal costs include:

- research and development personnel-related costs, including salaries, benefits, travel and meals expenses, and stock-based compensation expense; and
- allocated facilities and other overhead costs, including software, computer supplies and accessories, and other miscellaneous expenses.

We expense research and development costs as incurred. Costs of certain activities are recognized based on an evaluation of the progress to completion of specific tasks. However, payments made prior to the receipt of goods or services that will be used or rendered for future research and development activities are deferred and capitalized as prepaid expenses and other current assets on our balance sheets. The capitalized amounts are recognized as expense as the goods are delivered or as related services are performed. Since our inception and through September 30, 2026, substantially all of our third-party expenses were related to the development of BHB-1893. We use internal resources primarily for managing our process development, manufacturing, and clinical development activities. We deploy our personnel across all of our research and development activities and, as our employees work across multiple programs, we do not currently track our costs by product candidate indication.

We expect our research and development expenses to increase substantially for the foreseeable future as we advance our product candidate through Phase 3 clinical trials, pursue regulatory approval of our product candidate, build our operational and commercial capabilities for supplying and marketing our products, if approved, and expand our pipeline of product candidates. We expect to incur significant manufacturing costs as our CMOs develop scaled commercial manufacturing processes. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our current or future product candidates may be affected by a variety of factors, including the safety and efficacy of such product candidates, clinical data, investment in our clinical programs, competition, manufacturing capability, and commercial viability. We may never succeed in achieving regulatory approval for any of our current or future product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion of costs of our research and development projects or if, when, and to what extent we will generate revenue from the commercialization and sale of our current or future product candidates, if approved by the FDA and other applicable regulatory authorities.

Our future research and development costs may vary significantly based on factors such as:

- the scope, timing, progress, costs, and results of our ongoing development of BHB-1893 as well as for potential discovery, nonclinical, and clinical development activities for future product candidates;
- the amount and timing of any milestone payment due under the Exclusive License Agreement with Hengrui, or any future license or collaboration agreement;
- the number of patients that participate in our clinical trials, and per participant clinical trial costs;
- the number and duration of clinical trials required for approval of our product candidate;

- the number of sites included in our clinical trials, and the locations of those sites;
- delays or difficulties in adding trial sites and enrolling participants in our clinical trials;
- patient drop-out or discontinuation rates;
- potential additional safety monitoring requested by regulatory authorities;
- the phase of development of our product candidate;
- the efficacy and safety profile of our product candidate;
- the timing, receipt, and terms of any approvals from applicable regulatory authorities including the FDA and non-U.S. regulators, including whether we are permitted to accelerate the development of BHB-1893 for patients with HCM and related conditions;
- maintaining a continued acceptable safety profile of our product candidate following approval, if approved;
- changes in the competitive outlook;
- the extent to which we establish additional strategic collaborations or other arrangements; and
- the impact of any interruptions to our operations or to those of the third parties with whom we work.

A change in the outcome of any of these variables with respect to the development of our product candidate could significantly change the costs and timing associated with the development of the product candidate.

General and Administrative

Our general and administrative expenses consist primarily of personnel-related costs, legal and consulting services, including those relating to intellectual property and corporate matters, and allocated overhead, including software, computer supplies and accessories, insurance, and other miscellaneous expenses. Personnel-related costs include salaries, annual bonuses, benefits, recruiting fees, travel and meal expenses, and stock-based compensation for our general and administrative personnel, including expenses related to the executive modified restricted stock award.

We expect that our general and administrative expenses will increase substantially in the future as a result of expanding our operations, including hiring personnel, preparing for potential commercialization of our product candidate, and facility occupancy costs, as well as various incremental costs associated with operating as a public company. We expect that our costs will increase related to legal, audit, accounting, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements as well as director and officer insurance costs, investor and public relations costs, and other expenses that we did not incur as a private company. We also expect to increase the size of our administrative function to support the growth of our business.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income and gains or losses from exchange rate changes on transactions denominated in currencies other than the U.S. dollar. Interest income consists of interest earned on money market funds and U.S. Treasury securities.

Deemed Dividends Upon Issuance of Redeemable Convertible Preferred Stock

Deemed dividends upon issuance of redeemable convertible preferred stock consists of the amount by which the estimated fair value of the issued shares exceeded the per share purchase price.

Income taxes

As of December 31, 2025, we recorded a full valuation allowance of our deferred tax asset position of $13.8 million as we believe it was more likely than not that we would not be able to utilize our deferred tax assets.

As of December 31, 2025, we had federal net operating loss carryforwards of $4.3 million, and no state net operating loss carryforward. All of our federal net operating loss carryforwards can be carried forward indefinitely, but are limited to 80% utilization against future taxable income each year.

As of September 30, 2026, there have been no material changes to our tax positions as compared to December 31, 2025.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2026 and 2025

The following table summarizes our results of operations for the three and nine months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2026	September 30, 2025	September 30, 2026	September 30, 2025
	(unaudited)			
Operating expenses				
Research and development	$ 17,542	$ 9	$ 39,581	$ 9
In-process research and development	—	58,770	—	59,218
General and administrative	12,607	508	21,499	540
Total operating expenses	30,149	59,287	61,080	59,767
Loss from operations	(30,149)	(59,287)	(61,080)	(59,767)
Other income				
Interest income	3,712	169	5,372	169
Other income (expense), net	(58)	—	(55)	—
Total other income	$ 3,654	$ 169	$ 5,317	$ 169
Net loss	$ (26,495)	$ (59,118)	$ (55,763)	$ (59,598)
Deemed dividends upon issuance of redeemable convertible preferred stock	$ —	$ —	$ (3,615)	$ —
Net loss attributable to common stockholders	$ (26,495)	$ (59,118)	$ (59,378)	$ (59,598)

Research and Development Expenses

The following table summarizes our research and development expenses for the three and nine months ended September 30, 2026, and 2025 (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30, 2026	September 30, 2025	September 30, 2026	September 30, 2025
	(unaudited)			
External research and development expense:				
Clinical trial expenses	$ 7,248	$ —	$ 11,951	$ —
Manufacturing expenses	2,249	—	5,207	—
Outside research and development services	1,896	9	4,860	9
License milestone expenses	1,000	—	7,000	—
Internal research and development expense:				
Personnel-related costs	4,842	—	9,885	—
Facilities	79	—	226	—
Other	$ 228	$ —	$ 452	$ —
Total research and development expense	$ 17,542	$ 9	$ 39,581	$ 9

Research and development expense for the three and nine months ended September 30, 2026 was $17.5 million and $39.6 million, respectively. The nine-month expense was comprised of $17.2 million in clinical and manufacturing expenses to support BHB-1893 oHCM Phase 3 study start-up activities, $9.9 million in

personnel-related costs, $7.0 million in Hengrui license milestone expenses, $4.9 million in outside research and development support services, and $0.6 million in other research and development expenses primarily related to allocated rent, software subscriptions and other IT-related matters. The three-month expense was comprised of $9.5 million in clinical and manufacturing expenses to support BHB-1893 oHCM Phase 3 study start-up activities, $4.8 million in personnel-related costs, $1.9 million in outside research and development support services, $1.0 million in Hengrui license milestone expenses, and $0.3 million in other research and development expenses primarily related to allocated rent, software subscriptions and other IT-related matters. There was nominal research and development expense incurred during the three and nine months ended September 30, 2025, as the Company's research and development efforts did not begin until late 2025.

In-Process Research and Development Expenses

In-process research and development expense was zero for the three and nine months ended September 30, 2026, as the Hengrui license acquisition occurred in 2025. In-process research and development expense was $58.8 million and $59.2 million for the three and nine months ended September 30, 2025, respectively, which related to $32.5 million of cash consideration and $0.2 million in VAT taxes, $25.7 million in non-cash consideration, and transaction costs incurred in connection with that license.

General and Administrative Expenses

General and administrative expense for the three and nine months ended September 30, 2026 was $12.6 million and $21.5 million, respectively. During both the three and nine months ended September 30, 2026, expenses were comprised primarily of personnel-related costs, consultant costs to support the Company's increased operations and business development, legal costs for general counsel and patent services, and other general and administrative expenses primarily related to allocated rent, insurance and software subscriptions. General and administrative expense for the three and nine months ended September 30, 2026 included stock-based compensation expense of $7.8 million and $10.1 million, respectively, of which $6.1 million in each period related to the liability-classified modified executive restricted stock awards described in Note 9 to our unaudited interim condensed financial statements. Because this award is remeasured to fair value at each reporting date until it vests or is settled, the related expense will fluctuate with the trading price of our common stock and may cause general and administrative expense to vary significantly from period to period. General and administrative expense for the three and nine months ended September 30, 2025 was $0.5 million, primarily related to legal costs and nominal personnel and consultant costs, as the Company's operations did not begin until late 2025.

Total Other Income (Expense), Net

Total other income for the three and nine months ended September 30, 2026 was $3.7 million and $5.3 million, respectively, from the recognition of interest income from our cash invested in money market funds and US treasuries, increasing from the total other income for the three and nine months ended September 30, 2025 of $0.2 million, as the accounts were opened during the three months ended September 30, 2025.

Liquidity, Capital Resources and Capital Requirements

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. From inception, we have primarily funded our operations from sales of shares of our common stock and redeemable convertible preferred stock in private placements and through our IPO.

As of September 30, 2026, we had $503.5 million in cash, cash equivalents and investments. Based on our current operating plan, we estimate that our existing cash, cash equivalents, and investments will be sufficient to fund our projected operating expenses and capital expenditure requirements into 2029. We have based this estimate on our current assumptions which may prove to be wrong, and we may exhaust our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with therapeutic product development, we may never achieve or maintain profitability and, unless and until we are able to commercialize our product candidate, if ever, we will continue to be dependent upon equity financing, debt financing, and other forms of capital raises. If we are unable to raise capital as and when needed or on attractive terms, we may have to significantly delay, reduce, or discontinue the development and

commercialization of our product candidate or scale back or terminate our pursuit of new in-licenses and acquisitions.

Future Funding Requirements

Our primary uses of cash are to fund our operations, which consist primarily of research and development expenditures related to our product candidate, and to a lesser extent, general and administrative expenditures. We anticipate that we will continue to incur significant and increasing expenses for the foreseeable future as we continue to advance our product candidate, expand our corporate infrastructure, including the costs associated with being a public company, further our research and development initiatives for our current or future product candidates, and incur costs associated with potential commercialization. We are subject to all of the risks typically related to the development of new drug candidates, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business.

Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses, and prepaid expenses.

Our future funding requirements will depend on many factors, including the following:

- the timing, scope, progress, and results of our nonclinical studies and clinical trials for our current or future product candidates;
- the number, scope, and duration of clinical trials required for regulatory approval of our current or future product candidates;
- the outcome, timing, and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities for our current or future product candidates, including any requirement to conduct more studies or generate additional data beyond that which we currently expect would be required to support a new drug application;
- the cost of manufacturing clinical and commercial supplies as well as scale up of our current or future product candidates;
- the increase in the number of our employees and expansion of our physical facilities to support growth initiatives;
- our ability to maintain existing, and establish new, strategic collaborations, licensing, or other arrangements, including the Exclusive License Agreement with Hengrui, 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 cost of filing and prosecuting our patent applications, and maintaining and enforcing our patents and other intellectual property rights;
- the extent to which we acquire or in-license other product candidates and technologies;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against our current or future product candidates;
- the effect of competing technological and market developments;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our current or future product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our current or future product candidates, should any candidates receive marketing approval;
- our implementation of various computerized informational systems and efforts to enhance operational systems;
- the costs associated with being a public company; and
- the impact of economic uncertainty and geopolitical tensions, which may exacerbate the magnitude of the factors discussed above.

Furthermore, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development expenditures.

Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through public or private equity or debt financings, or potentially other capital sources, such as collaboration or licensing arrangements with third parties or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing to support our business plans when needed on acceptable 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 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. If we are unable to raise capital as and when needed or on attractive terms, we may have to significantly delay, reduce, or discontinue the development and commercialization of our product candidate or scale back or terminate our pursuit of new in-licenses and acquisitions.

Cash Flows

Comparison of the Nine Months Ended September 30, 2026 and 2025

The following summarizes our cash flows for the periods indicated (in thousands):

	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
	(unaudited)	
Net cash provided by (used in):		
Operating activities	$ (46,509)	$ (740)
Investing activities	(385,478)	(32,734)
Financing activities	464,117	101,006
Net increase in cash and cash equivalents	$ 32,130	$ 67,532

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2026 of $46.5 million was primarily due to our net loss for the period of $55.8 million and $2.0 million of changes in operating assets and liabilities, partially offset by $11.3 million in net non-cash items. Non-cash items include $6.1 million of non-cash stock-based compensation expense related to the liability-classified awards and $5.6 million of non-cash stock-based compensation expense, partially offset by $0.5 million of accretion on investments. The changes in operating assets and liabilities include a $10.2 million increase in prepaid expenses and other current assets, primarily reflecting prepayments to our CROs and CDMOs for LIONHEART-HCM, partially offset by a $7.1 million increase in accrued expenses and a $1.1 million increase in accounts payable. The operating cash activity during the nine months ended September 30, 2025 was comprised of a $59.6 million net loss and a $0.3 million net decrease in operating liabilities, partially offset by $59.2 million in non-cash in-process research and development expense.

Investing Activities

Cash used in investing activities for the nine months ended September 30, 2026 was $385.5 million, $382.5 million from the purchases of investments and $3.0 million from the cash payment of the Hengrui license technology transfer milestone that had been accrued as of December 31, 2025. Cash used in investing activities for the nine months ended September 30, 2025 consisted of $32.7 million from the purchase of the license from Hengrui.

Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2026 was $464.1 million, primarily related to net cash proceeds received in the period from our IPO of $404.5 million, and net proceeds from our Series A redeemable convertible preferred stock financing of $59.6 million. Cash provided by financing activities for the nine months ended September 30, 2025 was $101.0 million, from net proceeds of our Series A redeemable convertible preferred stock financing.

Contractual Obligations and Commitments

We enter into contracts in the normal course of business with suppliers, CROs, CMOs, clinical trial sites, and the like. These agreements provide for termination at the request of either party generally with less than one-year notice and, therefore, we believe that our non-cancelable obligations under these agreements are not material. We do not currently expect any of these agreements to be terminated and did not have any non-cancelable obligations under these agreements as of September 30, 2026 and December 31, 2025.

We have milestones, royalties, and/or other payments due under our Exclusive License Agreement with Hengrui. See Note 3 to our unaudited interim condensed financial statements. The technology transfer milestone for $3.0 million was completed in 2025 and recorded within accrued expenses and other current liabilities in the balance sheet as of December 31, 2025, and was paid as of September 30, 2026. The manufacturing technology transfer milestone for $6.0 million was completed in March 2026, and has been paid as of September 30, 2026. The initial echo data transfer milestone for $1.0 million was completed in August 2026, and was recorded within accrued expenses on the condensed balance sheet as of September 30, 2026.

Leases

As of December 31, 2025, we had no lease obligations. As of September 30, 2026, we have one operating lease agreement for subleased office space located in San Francisco, California. The sublease, which commenced in January 2026, has a term of 24 months, and our total remaining rent commitments under the sublease agreement are $0.5 million throughout the lease term. In addition to base rent, we pay our share of operating expenses and taxes.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations, or cash flows is disclosed in Note 2 to our unaudited interim condensed financial statements.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including but not limited to those related to accrued research and development costs, the fair value of redeemable convertible preferred stock and common stock and stock-based compensation expense, the valuation of deferred tax assets, and uncertain income tax positions. These estimates and assumptions are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates and assumptions could occur in the future. Our estimates are based on our historical experience 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 value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ from these estimates under different assumptions or conditions.

Although our significant accounting policies are described in more detail in Note 2 to our unaudited interim condensed financial statements, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses, including those related to clinical trials and product candidate manufacturing. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the services when we have not yet been invoiced or otherwise notified of actual costs. Our service providers invoice us in arrears or require prepayments for services performed, as well as on a pre-determined schedule or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors in connection with preclinical and clinical development activities;
- CROs in connection with clinical trials; and
- CMOs in connection with the process development and scale-up activities and the production of nonclinical and clinical trial materials.

Costs for clinical trials and manufacturing activities are recognized based on an evaluation of our vendors' progress towards completion of specific tasks, using data such as participant enrollment, clinical site activations or information provided to us by our vendors regarding their actual costs incurred. Payments for these activities are based on the terms of individual contracts and payment timing may differ significantly from the period in which the services were performed. We determine accrual estimates through reports from and discussions with applicable personnel and outside service providers as to the progress or state of completion of studies, or the services completed. Our estimates of accrued expenses as of each balance sheet date are based on the facts and circumstances known at the time. Costs that are paid in advance of performance are deferred as a prepaid expense and amortized over the service period as the services are provided.

Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses. However, due to the nature of estimates, we cannot assure that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials and other research activities.

Asset Acquisitions and Acquired In-Process Research and Development Expenses

We measure and recognize asset acquisitions that are not deemed to be business combinations based on the cost to acquire the asset or group of assets, which includes transaction costs. Goodwill is not recognized in asset acquisitions. In an asset acquisition, the cost allocated to acquire in-process research and development ("IPR&D") with no alternative future use is recognized as expense on the acquisition date.

Contingent consideration in asset acquisitions payable in the form of cash is recognized in the period the obligation is resolved. Such amounts are expensed or capitalized based on the nature of the associated asset at the date the related contingency is resolved.

We concluded that the exclusive license acquired from Hengrui in September 2025 represented an asset acquisition of IPR&D assets with no alternative future use. We further concluded that the arrangement did not qualify as a business combination because substantially all of the fair value of the assets acquired was concentrated in a single asset.

Stock-Based Compensation Expense

Stock-based compensation expense related to the stock-based awards granted to employees, consultants and Board members is measured at the grant date based on the fair value of the award. Compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period. We use the straight-line method to record the expense of awards with service-based vesting conditions. We

account for forfeitures of stock-based awards as they occur rather than applying an estimated forfeiture rate to stock-based compensation expense. We recognize share-based compensation expense for awards with performance conditions when it is probable that the condition will be met, and the award will vest. For the three and nine months ended September 30, 2026, the majority of our stock-based compensation expense related to restricted stock awards, primarily due to the executive restricted stock awards modified in July 2026. These awards are liability-classified, valued using a Monte Carlo simulation model, and remeasured to fair value at each reporting date until reclassified to equity or settled.

We estimate the fair value of each option award on the date of grant using the Black-Scholes option pricing model. Restricted stock awards are valued at the difference between the common stock price and price paid for the restricted stock award. This model requires the use of highly subjective assumptions to determine the fair value of each stock-based award, including:

- Fair value of common stock. Prior to our IPO, the fair value of our common stock was determined as described in the subsection titled "— *Determination of Fair Value of Common Stock*" below. Following our IPO, the fair value of our common stock is based on its quoted market price.
- Expected term. The expected term represents the period that the stock-based awards are expected to be outstanding. The expected term for our stock options was calculated based on the weighted-average vesting term of the awards and the contract period, or simplified method.
- Expected volatility. Because we have limited trading history for our common stock, the expected volatility was estimated based on the average historical volatilities of common stock of comparable publicly traded entities over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their size, stage of their life cycle, or area of specialty. We will continue to apply this process until enough historical information regarding the volatility of our stock price becomes available.
- Risk-free interest rate. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected term of the awards.
- Expected dividend yield. We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

See Note 9 to our unaudited interim condensed financial statements for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted in the periods presented.

Stock-based compensation expense for employees and non-employees is reflected in the statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025
	(unaudited)			
Options	$ 2,045	$ —	$ 2,326	$ —
RSAs	6,890	—	9,456	—
Total	$ 8,935	$ —	$ 11,782	$ —

As of September 30, 2026 there was $45.4 million of total unrecognized stock-based compensation expense related to our granted options, which we expect to recognize over a remaining weighted-average period of 3.7 years. As of September 30, 2026 there was $6.4 million, of total unrecognized stock-based compensation expense related to outstanding RSAs, which we expect to recognize over a remaining weighted-average period of 2.9 years, in addition to $21.9 million of total unrecognized stock-based compensation expense related to the modified executive RSAs, which we expect to recognize over a remaining weighted-average period of 0.8 years. We expect to continue to grant equity-based awards in the future, and to the extent that we do, our stock-based compensation expense recognized in future periods will likely increase.

Determination of Fair Value of Common Stock

As there had been no public market for our common stock prior to the IPO, the estimated fair value of our common stock underlying our stock-based awards has been determined by our board of directors as of each option grant date with input from management, considering our most recently available third-party valuations of common stock and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation (the Practice Aid).

In accordance with the Practice Aid, we determined the hybrid method was the most appropriate method for determining the fair value of our common stock based on our stage of development and other relevant factors. A hybrid of the scenario-based method (SBM) and the OPM, where the OPM is used to allocate value in one or more scenarios. The hybrid method utilized considered two scenarios using a weighting between the OPM scenario and a common stock equivalent (CSE) scenario. The CSE method values each class of equity on an as-converted basis, considering the number of common stock equivalents represented by each class. This method may also be referred to as the fully-diluted method or as-converted method, and ties to the fully diluted (post-money) equity value for the business based on the most recent financing round. The CSE method assumes that there is a de minimis likelihood of an equity value at exit that results in a payoff to the liquidation preferences for the preferred stock; that is, it assumes that the only possible exit scenarios result in either a value (a) $0 for all equity holders or (b) all equity holders receiving the same amount per share on an as converted basis. The OPM is a forward-looking method that considers the current equity value and then allocates that value to the various classes of equity considering a continuous distribution of outcomes, rather than focusing on distinct future scenarios. The current value of the common stock under each scenario is then probability weighted to arrive at an indication of value for the common stock. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock.

We had a third-party valuation performed as of September 3, 2025, which resulted in a valuation of our common stock of $1.93 per share. Given our recent financing transactions and progress at the time toward an IPO, we further utilized a hybrid approach to value our equity on January 15, 2026, February 25, 2026 and May 27, 2026, which resulted in valuations of our common stock of $2.28 per share, $2.41 per share, and $3.07 per share, respectively. All per share values presented reflect the 1-for-4.38 reverse stock split of our issued and outstanding shares of common stock effected on July 29, 2026.

In addition to considering the results of independent third party valuations prior to our IPO, our board of directors considered various objective and subjective factors to determine the fair value of common stock as of each grant date, including:

- the prices at which we sold shares of our preferred stock and the superior rights, preferences and privileges of our preferred stock relative to those of our common stock at the time of each grant;
- the progress of our research and development programs, including the status of nonclinical studies and clinical trials for our product candidate;
- our stage of development and our business strategy, and material risks related to our business;
- external market conditions affecting the biotechnology industry and trends within the biotechnology industry;
- the competitive landscape for our product candidate;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering or a sale of our company, given prevailing market conditions; and
- the economy in general.

We also performed a retrospective review of common stock fair value when preparing for our financial statements audits and considered the amount of time between the independent third-party valuation dates and the grant dates. We performed an interpolation of the fair value between the two valuation dates if we concluded that a significant change in valuation had occurred between the previous valuation and the grant date due to significant business or market events. The incremental stock-based compensation expense recorded as a result of the retrospective review was insignificant.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could be materially different.

Following our IPO, the fair value of our common stock is based on the quoted market price of our common stock.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Emerging Growth Company Status and Smaller Reporting Company Status

We qualify as an "emerging growth company," as defined in the Jumpstart Our Business Startup Act of 2012 (the "JOBS Act"). As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include: (i) being permitted to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosures; (ii) reduced disclosure about our executive compensation arrangements; (iii) not being required to hold advisory votes on executive compensation or to obtain stockholder approval of any golden parachute arrangements not previously approved; (iv) an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002; and (v) an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of the IPO; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in our unaudited interim condensed financial statements. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. Additionally, 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 allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, while we are an emerging growth company we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies. As a result of this election, our financial statements may not be comparable to those of other public companies that comply with new or revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

We are also a “smaller reporting company” as defined in the Securities Exchange Act of 1934, as amended (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, including an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, and will be able to take advantage of these scaled disclosures for so long as our 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 our common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter. 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. We may continue to be a smaller reporting company until the end of the fiscal year following the determination that we no longer meet the requirements necessary to be considered a smaller reporting company.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and are not required to provide the information under this item.

Item 4. Controls and Procedures

Management's Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Our 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 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.

In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. As required by Rule 13a-15(b) or Rule 15d-15(b) promulgated by the SEC under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 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 become involved in litigation or legal proceedings relating to claims arising from the ordinary course of business. We are not currently a party to any material legal proceedings that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should consider and read carefully all of the risks and uncertainties described below, as well as the other information in this Quarterly Report, including our unaudited interim condensed financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited financial statements and related notes for the year ended December 31, 2025 included in our IPO final prospectus dated August 5, 2026 *filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act, before deciding whether to invest in our common stock. The risks described below are not the only ones facing us. The following risks or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the trading price of our common stock could decline, and you may lose all or part of your investment.*

This Quarterly Report also contains forward-looking statements and estimates that involve risks and uncertainties not presently known to us or that we currently deem immaterial which could impair our business operations. Our actual results could differ materially from those anticipated in our forward-looking statements as a result of specific factors, including the risks and uncertainties described below. See the section titled "Cautionary Note Regarding Forward-Looking Statements" appearing elsewhere in this Quarterly Report.

Risks Related to Our Limited Operating History, Financial Condition and Need for Additional Capital

We are a clinical-stage biopharmaceutical company with a limited operating history, have incurred significant operating losses since inception and anticipate that we will continue to incur significant operating losses for the foreseeable future and we may never achieve or maintain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history. Our current product candidate was initially discovered and initially developed by Jiangsu Hengrui Pharmaceuticals Co., Ltd. ("Hengrui") in China, which we licensed pursuant to an exclusive license agreement with Hengrui (the "Exclusive License Agreement") in September 2025. We have not yet demonstrated an ability to complete large-scale clinical trials, obtain regulatory approvals, generate revenues, manufacture any product on a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization.

Since our inception in 2024, we have devoted substantially all of our efforts and financial resources to the development of BHB-1893, the commencement of new clinical trials and ongoing manufacturing to support BHB-1893 and any future product candidates. We have incurred operating losses in each year since our inception. Our net losses were $55.8 million and $59.6 million for the nine months ended September 30, 2026 and 2025, respectively. We had an accumulated deficit of $122.4 million as of September 30, 2026. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity (deficit) and working capital.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have not yet demonstrated an ability to conduct clinical trials, obtain regulatory approval, manufacture any product on a commercial scale or conduct sales and marketing activities necessary for successful product commercialization, and there is no assurance that we will accomplish any of these abilities in the future. Our limited operating history makes any assessment of our future success and viability subject to significant uncertainty. In addition, if we obtain marketing approval for BHB-1893 or any future product candidates, we will incur significant sales, marketing and manufacturing expenses. We will also continue to incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

The amount of our future losses is uncertain, and our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline. Our operating losses may fluctuate significantly from quarter to quarter and from year to year. We anticipate that our expenses will increase substantially as we:

- continue to advance clinical development of BHB-1893 and any future product candidates, including conducting our planned clinical trials;
- continue to advance our research and nonclinical activities relating to BHB-1893 and potentially seek to discover and develop additional product candidates in the future;
- continue to utilize third parties to manufacture BHB-1893 or any future product candidates and ensure sufficient supply of our manufacturing of drug substances and drug products;
- continue to develop, maintain, expand and protect our intellectual property portfolio (including intellectual property obtained through license agreements) and provide reimbursement of third-party expenses related to our patent portfolio;
- make potential milestone, royalty or other payments due under the Exclusive License Agreement and any future license or collaboration agreements;
- attract, hire and retain additional qualified personnel;
- seek regulatory approvals for BHB-1893 or any future product candidates that successfully complete clinical trials;
- undertake any pre-commercial activities and scale up external commercial-scale manufacturing capabilities;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize BHB-1893 or any future product candidates for which we may obtain regulatory approval;
- add additional operational, financial, clinical, quality and management information systems; and
- incur additional audit, legal, regulatory, tax and other expenses with being a public company.

We may 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.

Given the numerous risks and uncertainties associated with pharmaceutical product development, it is not certain if BHB-1893 or any future product candidates will advance through late-stage development or be approved for commercial sale; therefore, we are unable to predict if or when we will generate product revenue or achieve or maintain profitability.

Even if we successfully complete development and obtain the necessary regulatory approval for commercialization of BHB-1893 or any future product candidates, we anticipate incurring significant costs associated with launching and commercializing such products. If we fail to become profitable or do not sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or cease operations.

We will need substantial additional funding. We may be unable to raise capital on acceptable terms, if at all, and, as a result, we may be required to delay, reduce or eliminate our product development or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. Identifying potential product candidates and conducting nonclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approvals and achieve product sales. We expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future as we initiate and conduct clinical trials of BHB-1893 and any future product candidates, scale-up and manufacture BHB-1893 or any future product candidates, identify other potential product candidates and conduct nonclinical testing, seek marketing and regulatory approvals for any product candidates that successfully complete clinical trials and commercialize our products, if approved. Because the outcome of any clinical trial or nonclinical study is highly uncertain, we cannot reliably estimate the actual amount of financing necessary to successfully complete the development and commercialization of BHB-1893 or any future product candidates.

We believe that our existing cash, cash equivalents and investments will be sufficient to fund our operating expenses and capital requirements into 2029. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including but not limited to changes in progress of our development activities, acquisitions of additional product candidates and changes in regulation. Our future capital requirements will depend on many factors, including:

- the scope, timing, progress, costs, complexity and results of discovery, nonclinical development and clinical trials for our small molecule therapeutic candidate, BHB-1893 for treatment of hypertrophic cardiomyopathy (“HCM”), and any future product candidates;
- the number of clinical trials required for regulatory approvals of BHB-1893 or any future product candidates;
- the extent to which we may in the future develop, in-license or acquire other product candidates;
- the costs and timing of process development and manufacturing scale-up activities associated with BHB-1893 or any future product candidates and other programs as we advance them through preclinical and clinical development and, if approved, commercialization;
- the development requirements of BHB-1893 and any product candidates that we may pursue in the future;
- the timing and amount of milestone, royalty or other payments we must make to Hengrui and any other third parties, including the achievement of milestones that trigger payments to Hengrui and the royalty payments due to Hengrui under the Exclusive License Agreement;
- the costs, timing and outcome of regulatory review of BHB-1893 or any future product candidates;
- our headcount growth and associated costs as we expand our research and development capabilities and establish a commercial infrastructure;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for BHB-1893 or any future product candidates for which we receive marketing approval;
- 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;

- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors (or patients' willingness to pay out-of-pocket for any approved products in the absence of such coverage) and adequate market share and revenue for any approved products;
- the revenue, if any, received from commercial sales of BHB-1893 or any future product candidates for which we receive marketing approval;
- the effect of macroeconomic trends including inflation and interest rates;
- potential supply chain interruptions or delays; and
- the costs of operating as a public company.

We will require additional capital to achieve our business objectives. 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 implementing our long-term business strategy. Further, our ability to raise additional capital may be adversely impacted by potentially worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States ("U.S."). If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain, more costly and more dilutive. If we are unable to raise sufficient additional capital, we could be forced to curtail our planned operations and the pursuit of our growth strategy, or even cease operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to BHB-1893 or any future product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, such as grants, collaborations, licenses or other similar arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

If we raise additional funds through grants, collaborations, licenses or other similar arrangements with third parties, we may be required to relinquish valuable rights to our future revenue streams, intellectual property or product candidates, grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock or commit us to future payment streams. If we are unable to raise additional funds through equity or debt financings when needed or on terms acceptable to us, we may 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, or on less favorable terms than we would otherwise choose.

We maintain the majority of our cash and cash equivalents in accounts with major U.S. and multi-national financial institutions, and our deposits at certain of these institutions exceed insured limits. Market conditions and changes in financial regulations and policies can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position. In addition, changes in regulations governing financial institutions are beyond our control and difficult to predict; consequently, the impact of such changes on our business and results of operations is difficult to predict and may have an adverse effect on us.

Risks Related to the Discovery and Development of BHB-1893 and Our Future Product Candidates

We are substantially dependent on the success of our only product candidate, BHB-1893, which is a cardiac myosin inhibitor being developed for the treatment of HCM. If we are unable to advance BHB-1893 into later-stage clinical development or unable to obtain regulatory approval and commercialize BHB-1893 for the treatment of HCM, or experience significant delays in doing so, our business will be materially harmed.

To date, as an organization, we have not completed the development of any product candidates. Because we have limited financial and management resources, we are focused on a single indication, HCM, and we are substantially dependent on the success of our only product candidate, BHB-1893, which has undergone significant clinical development by Hengrui, including a dose-ranging Phase 2 study in symptomatic obstructive HCM ("oHCM"), a Phase 2 study in non-obstructive HCM ("nHCM"), multiple clinical pharmacology studies including a bridging study in Australia, and an ongoing Phase 3 study in oHCM in China. LIONHEART-HCM, our global Phase 3 trial in oHCM, is enrolling patients and we plan to initiate TRUEHEART-HCM, our Phase 2b trial evaluating a fixed-dose regimen of BHB-1893 in oHCM and NOBLEHEART-HCM, our global Phase 3 trial in nHCM in the first half of 2027. Participants from our global studies will be candidates to enroll in HEARTSONG-LTE, our planned long-term extension study.

If BHB-1893 fails to demonstrate sufficient efficacy or an acceptable safety profile in clinical trials, or if we are unable to obtain regulatory approval for BHB-1893, we would not have alternative product candidates to pursue, which would have a material adverse effect on our business and prospects. In addition, the current treatment landscape for HCM includes established therapies, and our ability to successfully develop and commercialize BHB-1893 will depend on our ability to demonstrate meaningful clinical benefit relative to existing treatment options.

The success of BHB-1893 will depend on several factors, including the following:

- successful and timely initiation and enrollment of clinical trials and completion of clinical trials with favorable results;
- the safety, tolerability and pharmacokinetic profile of BHB-1893 observed in clinical trials;
- acceptance of regulatory submissions by the U.S. Food and Drug Administration ("FDA") and/or comparable foreign regulatory authorities for the conduct of clinical trials of BHB-1893 or any future product candidates, including acceptance by the FDA of an investigational new drug application ("IND") and foreign clinical data for BHB-1893 prior to commencement of our planned Phase 3 trials and our proposed design of such planned clinical trials;
- the frequency and severity of adverse safety findings in nonclinical studies and adverse events ("AEs") in clinical trials;
- timely and successful completion of nonclinical studies, including toxicology studies, biodistribution studies and in vitro dose projection studies in animals, where applicable;
- acceptance of BHB-1893, if approved, by HCM patients, the medical community and third-party payors, and their perspective on the cost, safety, tolerability and efficacy and perceived advantages of alternative therapies for HCM, including the current standard of care;
- maintaining relationships with contract research organizations ("CROs") and clinical sites for the clinical development of BHB-1893 and such CROs and clinical sites complying with clinical trial protocols, Good Clinical Practices ("GCPs") and other applicable requirements;
- demonstrating the safety and efficacy of BHB-1893 to the satisfaction of applicable regulatory authorities;
- maintaining relationships with our third-party manufacturers and ongoing compliance with current good manufacturing practices ("cGMPs"), as well as making arrangements with our third-party manufacturers for commercial manufacturing capabilities at a cost and scale sufficient to support commercialization;
- establishing sales, marketing and distribution capabilities and launching commercial sales of BHB-1893, if and when approved, whether alone or in collaboration with others;

- obtaining, establishing, maintaining and enforcing patent and any potential trade secret protection or regulatory exclusivity for BHB-1893;
- the sufficiency of our financial resources to fund our operations; and
- maintaining and growing an organization of people who can develop and, if approved, commercialize, market and sell BHB-1893.

For example, BHB-1893 may be associated with adverse side effects or unexpected toxicities that are not identified until later stages of clinical development or after regulatory approval. In addition, BHB-1893 may fail to demonstrate the level of efficacy necessary to support regulatory approval or to differentiate it from existing HCM therapies. Because our entire pipeline is concentrated on a single product candidate, any adverse safety findings, lack of efficacy or other clinical setbacks with BHB-1893 would have a material adverse effect on our business, and we would not have other product candidates to mitigate such impact. The timing, outcome and cost of developing BHB-1893 and obtaining regulatory approval is difficult to predict and dependent on a number of factors that are outside our reasonable control. If we experience safety, tolerability or efficacy issues in our clinical trials of BHB-1893, or if such issues arise with HRS-1893, or if the data from these trials are not favorable, our clinical development plans could be materially negatively affected or delayed, or we may not receive regulatory approval for BHB-1893, which would materially harm our business and likely cause the market price of our common stock to decline.

In addition, even if BHB-1893 receives regulatory approval, changes in the standard of care for HCM, including the approval of new competing therapies, could reduce the commercial potential of BHB-1893. The FDA or comparable foreign regulatory authorities may also impose post-marketing requirements, including additional clinical trials or collateral risk mitigation measures such as a REMS, that could increase our costs and delay or limit the commercial success of BHB-1893.

These risks also apply to any additional product candidates that we may develop in the future. Furthermore, our future resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We rely on clinical data generated by Hengrui from clinical trials that were not designed or conducted by us, and such data may not be adequate to support our regulatory submissions or future clinical development plans. If we are unable to confirm or replicate the results from Hengrui's clinical trials, if those trials were not conducted in accordance with applicable law, including GCPs, or if the FDA or comparable foreign regulatory authorities do not accept such data, our development programs could be materially delayed or harmed.

Our sole product candidate, BHB-1893, was in-licensed from Hengrui pursuant to the Exclusive License Agreement. Prior to our in-licensing of BHB-1893, Hengrui designed and conducted certain nonclinical studies and clinical trials for BHB-1893, including a dose-ranging Phase 2 study in symptomatic oHCM, a Phase 2 study in nHCM, multiple clinical pharmacology studies including a bridging study in Australia, and an ongoing Phase 3 study in oHCM in China. Our assumptions about the development potential of BHB-1893 are based in significant part on the data generated from these Hengrui-sponsored studies. We were not involved with and did not control the design, conduct, monitoring or reporting of these studies, and we have limited ability to independently verify the accuracy, completeness or reliability of the data generated by Hengrui. We also did not control whether Hengrui's clinical trials were conducted in accordance with GCPs, cGMP requirements or other applicable regulatory standards enforced by the FDA or comparable foreign regulatory authorities. Therefore, we are dependent on Hengrui, and any third parties acting on its behalf, having conducted their research and development in accordance with the applicable protocols, legal and regulatory requirements, and scientific standards; having accurately reported the results of all nonclinical studies and clinical trials conducted with respect to such product candidates and having correctly collected and interpreted the data from these studies and trials. These risks also apply to any additional product candidates that we may acquire or license in the future.

To date, we have not completed a comprehensive audit of the data that was generated by Hengrui with respect to BHB-1893. If the clinical data generated by Hengrui prove to be inadequate, unreliable or insufficient to support our regulatory submissions, including any IND or new drug application ("NDA") filings with the FDA, we may be required to conduct additional nonclinical studies or clinical trials, which could significantly delay our development timelines and require substantial additional expenditures. The FDA or comparable foreign regulatory authorities may disagree with our interpretation of Hengrui's data, may not accept data from clinical trials conducted outside the U.S., or may require us to conduct additional studies to confirm or supplement the results from Hengrui's trials. For example, clinical trials conducted in China may involve patient populations, standards of care, clinical practices or regulatory requirements that differ from those in the U.S., and the FDA may determine that data from such trials are not representative of the U.S. population or U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, the design of Hengrui's clinical trials, including dosing regimens, titration protocols, patient eligibility criteria and endpoint definitions, may differ materially from our planned global Phase 3 trials. Such design differences may limit the ability to pool or cross-reference data, and the FDA may require us to conduct additional studies if it determines that Hengrui's trial designs are not sufficiently similar to our planned protocols to support our NDA submissions.

In addition, our ability to access and use clinical data for Hengrui's ongoing trials and any new trials conducted in China will be highly dependent on acceptance and approvals from Human Genetic Resources Administration of China ("HGRAC") and China's Cyberspace Administration. HGRAC approval timelines may be unpredictable and could cause material delays or potential restrictions on exporting Chinese clinical data. There is no guarantee that the HGRAC will not interfere with our ability to obtain and use clinical data for trials conducted in China in a timely manner or in a way that facilitates our use of such data.

Positive results observed in Hengrui's earlier-stage clinical trials and nonclinical studies may not be replicated in our planned global late-stage clinical trials, and BHB-1893 may fail to show the desired safety, tolerability, pharmacokinetic profile and efficacy in broader patient populations or at the doses we intend to evaluate. Clinical study results may be susceptible to varying interpretations, and medical professionals, investors and regulatory authorities may analyze or weigh study data differently than we do. Alternative methodologies for analyzing clinical data may lead to differing conclusions, including with respect to the safety or efficacy of BHB-1893. In addition, we may observe materially and adversely different safety results as we conduct our own clinical trials compared to the results observed in Hengrui's studies. We have not, as a company, completed any clinical trials of BHB-1893 in HCM patients to date, including in the U.S.

Furthermore, if Hengrui or its investigators, CROs or clinical trial sites failed to comply with applicable GCPs, cGMPs or other regulatory requirements in the conduct of the clinical trials for BHB-1893, the clinical data generated in such trials may be deemed unreliable by the FDA or comparable foreign regulatory authorities, and we may be required to perform additional clinical trials before obtaining marketing approval. Upon inspection, regulatory authorities may determine that Hengrui's clinical trials were not conducted in compliance with GCP regulations or other applicable requirements and conclude that the data from Hengrui's trials are not reliable. Any inability of the FDA to conduct a GCP inspection of the data, including due to geopolitical reasons or other access limitations, or a determination by a regulatory authority that the data from Hengrui's clinical trials are unreliable or insufficient could require us to repeat, extend the duration of, or increase the size of our clinical trials, which could significantly delay commercialization and require significantly greater expenditures, or could prevent commercialization altogether.

Because we are substantially dependent on the success of BHB-1893 as our sole product candidate, any inability to rely on or confirm the clinical data generated by Hengrui could have a material adverse effect on our business, financial condition, results of operations and prospects, including, but not limited to, significant delays in our planned global late-stage clinical development, increased development costs and an inability to obtain regulatory approval for BHB-1893.

We have not yet completed all testing of BHB-1893 in clinical trials. Interim, topline and preliminary results from our or Hengrui's nonclinical studies or clinical trials are not necessarily predictive of the results or analyses of such results of later clinical trials. If we cannot replicate the positive results from any nonclinical studies or clinical trials of BHB-1893 or any other potential future product candidates that have positive results, or if we suffer any other significant setbacks in our later clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize BHB-1893 or other potential future product candidates.

Success in nonclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Nonclinical studies, Phase 1 and Phase 2a clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics, and to understand the side effects of product candidates at various doses and dosing schedules. Success in nonclinical or animal studies and early clinical trials does not ensure that later large-scale efficacy trials will be successful, nor does it predict final results. BHB-1893 may fail to show the desired safety, tolerability, pharmacokinetic profile, and efficacy in clinical development despite positive results in nonclinical studies or having successfully advanced through initial clinical trials. The results of our and Hengrui's completed and ongoing clinical trials and nonclinical studies may not be predictive of results in our planned global late-stage clinical trials, and BHB-1893 may fail to show the desired safety and efficacy in broader HCM patient populations.

In addition, the clinical data generated to date for BHB-1893 were generated by Hengrui in relatively small Phase 2 trials, primarily in patients in China. Certain of these data, including the 52-week open-label extension results from Hengrui's Phase 2 trial in oHCM and the analyses of diastolic function from Hengrui's Phase 2 trial in nHCM presented at the AHA Scientific Sessions 2026, were derived from open-label clinical trial designs without a control arm or from ad hoc, pooled or otherwise exploratory analyses. The FDA and comparable foreign regulatory authorities may not consider such data to be supportive of the safety or efficacy of BHB-1893, including for any potential benefit on cardiac structure or the underlying course of HCM.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in nonclinical testing and earlier-stage clinical trials. Such setbacks have occurred and may occur for many reasons, including: clinical sites and investigators may deviate from clinical trial protocols or GCP requirements, 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 post-treatment follow-up; BHB-1893 may fail to demonstrate effectiveness or safety in certain patient populations or subpopulations or at all; 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. Data obtained from nonclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the development of BHB-1893.

Similarly, from time to time, we may publish interim, topline or preliminary results from our nonclinical studies and clinical trials, which are based on a preliminary analysis of then-available data. We also make assumptions, estimations, calculations and conclusions as part of our preliminary analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. Interim results from clinical trials that we may complete 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. Preliminary or topline results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, topline and preliminary data should be viewed with caution until the final data are available. Adverse differences between interim, topline or preliminary data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

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 our company in general. 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 investors 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, BHB-1893 or any future product candidates, may be harmed, which could harm our business, operating results, prospects or financial condition.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain the required regulatory approval for any product candidate, our business will be substantially harmed.

We are not permitted to market, commercialize, sell or promote any product candidate in the U.S. until we receive regulatory approval of an NDA for such product candidate in a specific indication from the FDA. Our business is dependent on our ability to successfully complete nonclinical and clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize BHB-1893 and any future product candidates in a timely manner. The time required to obtain approval or other marketing authorizations by the FDA and comparable foreign authorities is unpredictable, and it typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, practices, regulations and the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for BHB-1893, and it is possible that we may never obtain regulatory approval for BHB-1893 or any product candidates we may seek to develop in the future.

Prior to obtaining approval to commercialize any product candidate in the U.S. or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidate is safe and effective for its intended use. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for BHB-1893 or any future product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional nonclinical studies or clinical trials for BHB-1893 or any future product candidates either prior to or after approval, or it may object to elements of our clinical development programs.

BHB-1893 and any future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials and interpretation of data from clinical trials or nonclinical studies;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- non-acceptance of nonclinical or clinical data generated in China by Hengrui;
- the data collected from clinical trials may not be sufficient to support the submission and approval of an NDA by the FDA or other submission to obtain regulatory approval in the European Union or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies, practices, or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of products in development across the industry, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval and marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market BHB-1893 or any future product candidates, which would significantly harm our business, financial condition, results of operations and prospects. The FDA and comparable foreign authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be granted for any product candidate that we develop. Even if we believe the data collected from future clinical trials of BHB-1893 or any future product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority.

Even if we complete clinical testing and receive approval of an NDA or foreign marketing application for BHB-1893 or any future product candidates, the FDA or the applicable foreign regulatory agency may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-marketing clinical trials. The FDA or the applicable foreign regulatory agency also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request, and the FDA or applicable foreign regulatory authority may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization, or failure to obtain our desired product labeling, would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

In addition, the FDA and other regulatory authorities may change their policies, issue additional regulations or revise existing regulations or take other actions, which may prevent or delay approval of BHB-1893 or our future product candidates on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained. Further, macroeconomic and other global conditions could impact the ability of the FDA and comparable foreign regulatory authorities to provide any required approvals or marketing authorizations for BHB-1893 or any future product candidates or result in the delay of such approvals or authorizations.

Preclinical and clinical product development involves a lengthy and expensive process, with an uncertain outcome.

Our current assumptions about BHB-1893's development potential are based on the data generated by Hengrui from nonclinical studies and clinical trials; however, we may observe materially and adversely different safety or efficacy results as we conduct our clinical trials. In order to obtain FDA approval to market a new drug product, we must demonstrate the safety and efficacy of the drug in humans in a manner that satisfies the agency's standards. It is impossible to predict when or if BHB-1893 or any future product candidates will prove effective or safe in humans or will receive regulatory approval. The leadership changes at the FDA in the current presidential administration may compound this uncertainty. Before obtaining marketing approval from regulatory authorities, including the FDA, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of BHB-1893 or any future product candidates in humans. A failure of one or more clinical trials can occur at any stage of testing or at any time during the trial process. The outcome of nonclinical testing and early clinical trials may not be predictive of the results of later clinical trials as to safety or efficacy, particularly if later clinical trials have a materially different trial design. The historical failure rate for product candidates in our industry is high, particularly in the earlier stages of development. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We have not completed all of the clinical trials required for the approval of BHB-1893. We cannot assure you that any nonclinical study or clinical trial that we are conducting, or may conduct in the future, will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market BHB-1893 or any future product candidates. We believe data from a single pivotal trial may be sufficient to support regulatory approval of BHB-1893 in oHCM. However, the FDA may require more than one adequate and well-controlled clinical trial to support approval, which would significantly delay our development timeline and increase costs.

We may incur additional costs and experience delays in completing, or ultimately be unable to complete, the development and commercialization of BHB-1893 or any future product candidates.

We may incur additional costs and experience delays in clinical trials for BHB-1893 and any future product candidates, and we do not know whether our planned or future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. We may experience numerous unforeseen events during or as a result of nonclinical studies or clinical trials that could delay or prevent our ability to continue or complete clinical development, receive marketing approval or commercialize BHB-1893 or any future product candidates, including:

- regulators or institutional review boards not authorizing us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- experiencing delays in reaching, or failing to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of BHB-1893 or any future product candidates producing negative or inconclusive results, including failure to demonstrate statistical significance, leading to the need to conduct additional clinical trials or abandon product development programs;
- failing to demonstrate statistical significance in clinical trials of BHB-1893 or any future product candidates, which may impact the timing and design of late-stage clinical trials for such product candidates, or failing to demonstrate statistical significance in late-stage trials despite promising early stage results;
- the number of patients required for clinical trials of BHB-1893 or any future product candidates being larger than we anticipate; enrollment in these clinical trials being slower than we anticipate, for example, due to the availability of standard of care therapy or other treatment options, changes to standard of care therapy or other treatment options, and the reluctance of patients to discontinue standard of care therapy or other treatment options in order to participate in certain of our future clinical trials; or participants dropping out of these clinical trials or failing to return for post-treatment follow-up at a higher rate than we anticipate;
- BHB-1893 or any future product candidates having undesirable side effects (including drug-drug interactions), unexpected toxicology findings, or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials;
- our third-party contractors or partners failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards requiring that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- future collaborators, if any, conducting clinical trials in ways they view as advantageous to them but that are suboptimal to us;
- the cost of clinical trials of BHB-1893 or any future product candidates being greater than we anticipate; and
- the supply or quality of BHB-1893 or any future product candidates or other materials necessary, including comparator drug or placebo, to conduct clinical trials of BHB-1893 or any future product candidates being insufficient, inadequate or too costly.

If we are required to conduct additional clinical trials or other testing of BHB-1893 or any future product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of BHB-1893 or any future product candidates or other testing, if the results of these trials or tests are not favorable or if there are safety concerns, we may, among other things:

- be delayed in obtaining marketing approval for BHB-1893 or any future product candidates;

- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements;
- be subject to a REMS or comparable requirement; or
- have the product removed from the market after obtaining marketing approval.

Moreover, principal investigators for our future 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 a 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 interpretation of the study. The FDA or a 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, or rejection, of our marketing applications by the FDA or applicable foreign regulatory authority, and may ultimately lead to the denial of marketing approval.

Targeting the cardiac myosin protein is novel, and there are currently no FDA-approved therapies specifically indicated for nHCM, which subjects the design and execution of our clinical development program for our sole product candidate, BHB-1893, to complexities and known and unknown risks, including those related to novel and/or subjective clinical endpoints.

We intend to develop BHB-1893 as a cardiac myosin inhibitor to establish a new standard of care. While products targeting the cardiac myosin protein have been approved by the FDA and comparable foreign regulatory authorities, including Camzyos® (mavacamten) developed by Bristol-Myers Squibb Co. ("BMS") and the recently approved MYQORZO® (aficamten) developed by Cytokinetics Inc. ("Cytokinetics"), the cardiac myosin inhibitor class remains relatively novel, and the development of BHB-1893 as a cardiac myosin inhibitor to establish a new standard of care for HCM may present developmental challenges that are difficult to predict as BHB-1893 proceeds through clinical trials, including our planned global late-stage clinical development. It is also difficult for us to predict the time and cost of development of BHB-1893, whether any of our clinical trials will be successful, and whether our approach will result in the successful development and regulatory approval of BHB-1893. Any development problems we experience, or unexpected regulatory feedback, in the future related to BHB-1893 may cause significant delays or unanticipated costs, and such development problems may not be able to be solved. The novelty of our approach may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of BHB-1893 or lead to significant post-approval limitations or restrictions. For example, the FDA could require additional studies that may be difficult or impossible to perform, or prohibitively costly. Any of these factors may prevent us from completing clinical trials that we may initiate and obtaining regulatory approval of or commercializing BHB-1893 on a timely or profitable basis, if at all.

There are currently no FDA-approved therapies specifically indicated for nHCM. The clinical trial requirements of the FDA and other comparable regulatory agencies and the criteria these regulators use to determine the safety and efficacy of any product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential product. As a result, the regulatory pathway, including acceptable trial design, endpoints, and the level of clinical evidence required for approval, is less established than for oHCM. The FDA may not consider the endpoints of our clinical trials to provide clinically meaningful results, or the FDA may require evaluation of additional or different clinical endpoints in later-stage clinical trials or may not accept the clinical endpoints evaluated in later-stage clinical trials. The FDA may impose requirements for nHCM approval that differ materially from those we anticipate, including in the design or conduct of our clinical trials, which could delay or prevent approval or require us to conduct additional trials.

Our nonclinical studies and clinical trials may fail to demonstrate the safety and efficacy of BHB-1893 or any future product candidates, or serious or unacceptable adverse side effects or unexpected toxicology findings may be identified during the development of BHB-1893 or any future product candidates, which could prevent or delay further clinical development, regulatory approvals and commercialization, impact the product's labeling, if approved, increase our costs or necessitate the abandonment or limitation of the development of BHB-1893 or any future product candidates.

Clinical trials often fail to demonstrate safety or efficacy of a product candidate studied for the target indication. If BHB-1893 or any future product candidates are associated with serious or significant adverse side effects in clinical trials or have adverse safety findings in nonclinical studies, we may need to abandon their development or limit development to more narrow uses in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a benefit-risk perspective. The FDA or other comparable foreign regulatory authority or an institutional review board or ethics committee may also require that we suspend, discontinue or limit our clinical trials based on safety information, or that we conduct additional animal or human studies regarding the safety and efficacy of BHB-1893 or any future product candidates, which we have not planned or anticipated. Such findings could further result in regulatory authorities failing to provide marketing authorization for BHB-1893 or any future product candidates or limiting the scope of the indication, if approved. Many product candidates that initially showed promise in early-stage testing have later been found to cause adverse side effects that prevented further development of the product candidate.

Additionally, if BHB-1893 or any future product candidates receives marketing approval, and we or others subsequently identify undesirable side effects associated with use of such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend or limit approvals of such product or seek an injunction against its manufacture or distribution;
- we may be required to recall a product;
- regulatory authorities may require additional warnings on the labels, such as a boxed warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way a product is distributed or administered, conduct additional clinical trials or change the labeling of a product or be required to conduct additional post-marketing studies or surveillance;
- we could be sued and held liable for harm caused to patients;
- sales of the product may decrease significantly or the product could become less competitive;
- we may not be able to achieve or maintain third-party payor coverage and adequate reimbursement; and
- our reputation and physician or patient acceptance of our products may suffer.

There can be no assurance that we will resolve any issues related to any product-related AEs to the satisfaction of the FDA or comparable foreign regulatory authorities in a timely manner or at all. Moreover, any of these events could prevent us from achieving or maintaining market acceptance of a particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

We may not be able to obtain orphan drug designation or exclusivity for BHB-1893 or any future product candidates, and even if we do, we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

We may seek orphan drug designation or exclusivity in the indications targeted by BHB-1893 or any future product candidates. Regulatory authorities in some jurisdictions, including the U.S. and Europe, may designate drugs for relatively small patient populations as orphan drugs. For example, under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition. In order for the FDA to grant orphan drug exclusivity to BHB-1893 or any future product candidates, the agency must find that the product candidate is indicated for the treatment of a condition or disease that affects fewer than 200,000 individuals in the U.S. or that affects 200,000 or more individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making the product candidate available for the disease or condition will be recovered from sales of the product in the U.S. Orphan drug designation must be requested before submitting an NDA. The FDA may conclude that the condition or disease for which we seek orphan drug exclusivity does not meet the required standard.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular drug for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same approved use or indication for seven years, except in limited circumstances such as if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated.

In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product candidate for the same approved use or indication if the FDA concludes that the later product candidate is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care compared with the product that has orphan exclusivity. In the U.S., orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

A similar regulatory scheme governs approval of orphan product candidates by the European Medicines Agency (“EMA”) in the European Union. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA (as applicable) from approving another marketing application for the same or another similar product candidate for the same orphan therapeutic indication for that time period. The applicable period is seven years in the U.S. and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if at the end of the fifth year it is determined that a product no longer meets the criteria for orphan drug designation, including if the product is sufficiently profitable so that market exclusivity is no longer justified.

While we may in the future seek designations for BHB-1893 or any future product candidates with the FDA and comparable foreign regulatory authorities that are intended to confer benefits such as a faster development process, an accelerated regulatory pathway or priority review, there can be no assurance that we will successfully obtain such designations. In addition, even if one or more of BHB-1893 or any future product candidates are granted such designations, we may not be able to realize the intended benefits of such designations.

The FDA and comparable regulatory authorities offer certain designations for product candidates that are designed to encourage the research and development of product candidates that are intended to address conditions with significant unmet medical need. These designations may confer benefits such as additional interaction with regulatory authorities, a potentially accelerated regulatory pathway and priority review of the marketing application(s). However, there can be no assurance that we will successfully obtain such designations for BHB-1893 or any future product candidates. In addition, while such designations could expedite the development or approval process, they generally do not change the standards of product quality, safety or efficacy required to be demonstrated in support of approval. Even if we obtain such designations for BHB-1893 or any future product candidates, there can be no assurance that we will realize their intended benefits.

For example, we may seek a Fast Track Designation for BHB-1893 or our future product candidates. If a product is intended for the treatment of a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind the Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development activities.

We may seek Breakthrough Therapy Designation for any product candidate that we develop. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval and priority review.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe BHB-1893 or any future product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. Further, the receipt of Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to conventional FDA procedures and does not assure approval by the FDA. In addition, even if any product candidate we develop qualifies for Breakthrough Therapy Designation, the FDA may later decide that the drug no longer meets the conditions for qualification and rescind the designation.

Even in the absence of obtaining Fast Track and/or Breakthrough Therapy Designations, a sponsor can seek priority review at the time of submitting a marketing application. The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting adverse reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months from FDA's acceptance of the application for review. Priority review designation may be rescinded if a product no longer meets the qualifying criteria.

We may not be able to submit INDs or IND amendments to commence clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

We may not be able to submit INDs on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that no issues will arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their requirements or expectations in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs.

Any product candidate for which we obtain marketing approval could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

As part of its decision to approve or grant marketing authorization for BHB-1893 or any future product candidates, the FDA or other regulatory agencies may require us to perform certain post-marketing activities, such as completion of ongoing or planned studies, initiation of new studies or post-marketing clinical trials (including to assess safety risks), or additional analyses of existing data. Typically, we are required to provide annual updates on the progress of such required activities and to complete the activities by the assigned completion dates. Later discovery of previously unknown problems with BHB-1893 or any future product candidates, including AEs of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of such products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on or revisions to the labeling or marketing of a medicine;
- restrictions on the distribution or use of a medicine, including under a REMS program;
- fines, receipt of warning or untitled letters or suspension of clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or withdrawal of marketing approvals;
- product seizure or detention or refusal to permit the import or export of BHB-1893 or any future product candidates; and
- injunctions or the imposition of civil or criminal penalties.

Additionally, the FDA and other regulatory agencies closely regulate the post-approval marketing and promotion of medicines to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Although physicians may prescribe products for uses not described in the product's labeling, known as off-label uses, in their professional medical judgment, the FDA and comparable foreign regulatory agencies impose stringent restrictions on manufacturers' communications regarding off-label use, and if we market our products, if approved, in a manner inconsistent with their approved labeling, we may be subject to enforcement action for off-label marketing by the FDA and other federal and state enforcement agencies, including the Department of Justice and other comparable foreign regulatory agencies. Violation of the Federal Food, Drug, and Cosmetic Act ("FDCA") and other statutes, including the False Claims Act ("FCA"), relating to the promotion and advertising of prescription products may also lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws, state consumer protection laws and laws of other comparable foreign regulatory agencies.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any product candidates we develop and adversely affect our business, financial condition, results of operations and prospects. If we were found liable for violations of the FDCA or FCA, we could be subject to significant fines or monetary penalties or exclusion from federal healthcare programs, any of which could substantially harm our financial position and business.

If we experience delays or difficulties in the enrollment and/or retention of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected, and our receipt of necessary regulatory approvals could be delayed or prevented.

Successful and timely completion of clinical trials will require that we identify and enroll a sufficient number of patients. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population and competition for patients with other trials. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. We may not be able to initiate or continue clinical trials for BHB-1893 if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities, or if a large number of patients withdraw. We cannot predict how successful we will be at enrolling subjects in future clinical trials. In particular, the availability of FDA-approved cardiac myosin inhibitors ("CMIs") for oHCM, including mavacamten and aficamten, may make it difficult to enroll patients in our placebo-controlled Phase 3 oHCM trial, as patients and physicians may prefer to pursue or maintain approved therapies rather than participate in a clinical trial with a placebo arm. We may conduct clinical trials that would require patients to discontinue standard of care therapy, and we may experience challenges finding, enrolling and retaining HCM patients in our planned clinical trials who are willing to discontinue their current treatment regimens to participate in our trials. Subject enrollment is affected by other factors including:

- the patient eligibility criteria as defined in the applicable protocol;
- the size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- the actual and perceived risks and benefits of the product candidate in the trial;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- 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 the current standard of care and any new drugs that may be approved for HCM, which may vary across the jurisdictions where we plan to conduct our clinical trials;
- the willingness of patients to be enrolled in our clinical trials;
- the success of efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain informed consent;
- the risk that patients enrolled in our clinical trials will drop out of the trials prior to completion;
- the cost to, or lack of adequate compensation for, prospective patients; and
- the proximity and availability of clinical trial sites to prospective patients.

Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for BHB-1893, which would cause the value of our company to decline and limit our ability to obtain additional financing. Furthermore, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we will have limited influence over their performance.

Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients. We cannot assure you that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays or difficulties in enrollment, or be required by the FDA or comparable foreign regulatory authorities to increase our enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

The results of clinical trials conducted at clinical trial sites outside the U.S. might not be accepted by the FDA, and data developed outside of a foreign jurisdiction similarly might not be accepted by such foreign regulatory authority.

Clinical trials for BHB-1893 have been and are currently being conducted outside of the U.S. by Hengrui, including in Australia and China, and we may conduct additional clinical trials outside of the U.S. in the future. For example, clinical trials conducted in Australia using "unapproved therapeutic goods," or those that have not yet been evaluated by the Therapeutic Goods Administration ("TGA") for quality, safety and efficacy, must occur pursuant to either the Clinical Trial Notification Scheme or the Clinical Trial Approval Scheme. In each case, the trial is supervised by a Human Research Ethics Committee ("HREC"), an independent review committee set up under the guidelines of the Australian National Health and Medical Research Council that reviews, approves and provides continuing oversight of trial protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects. Although the FDA or comparable foreign regulatory authorities may accept data from clinical trials conducted outside the relevant jurisdiction, acceptance of these data is subject to certain conditions. For example, the FDA requires that the clinical trial must be well-designed and conducted and performed by qualified investigators in accordance with ethical principles such as institutional review board or ethics committee approval and informed consent, the trial population must adequately represent the U.S. population and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Further, the FDA may consider an on-site inspection to be necessary in which case they must be able to validate the data through such an inspection or other appropriate means. If access to clinical trial sites or documentation is delayed or restricted, including for geopolitical reasons, the FDA may not accept such data in support of a marketing application which would adversely affect our development and approval plans. In addition, while these clinical trials are subject to the applicable local laws, acceptance of the data by the FDA will be dependent upon its determination that the trials were conducted consistent with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from trials conducted outside of the U.S. as adequate support of a marketing application. Similarly, any data submitted to foreign regulatory authorities may not adhere to their standards and requirements for clinical trials and data from trials conducted outside of such jurisdiction may not be accepted.

If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in BHB-1893 or any future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction. Recent policy proposals in the U.S., if enacted in the future, may make acceptance by the FDA or inclusion in a marketing application of foreign data more difficult or costly. The FDA has also signaled increased scrutiny of foreign GCP inspections and greater transparency of GCP inspection outcomes. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted, which may increase costs or time required to complete the clinical trial.

Conducting clinical trials outside the U.S. also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements, and supply chain predictability concerns;
- inconsistent standards for recordkeeping, reporting and evaluating clinical data and AEs;
- the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs;

- varying standards or availability of HCM care, resulting in data that may differ from patients who have received the U.S. standard of care therapy;
- the failure to properly translate or interpret patient-reported outcome endpoints;
- additional administrative burdens associated with foreign regulatory scheme;
- any pandemic, epidemic or public health emergencies;
- diminished protection of intellectual property in some countries; and
- political instability, civil unrest, war or similar events that may jeopardize our ability to commence, conduct or complete a clinical trial and evaluate resulting data.

A significant portion of our equity is held by a Chinese company and for so long as a Chinese company continues to hold a significant equity interest in us, changes in U.S. and Chinese laws and geopolitical developments may adversely affect our business, results of operations, financial condition and prospects.

Hengrui, which is a Chinese corporation, holds a significant portion of our outstanding equity. Future developments in U.S. and Chinese laws, regulations and policies may adversely affect our ability to operate as a publicly traded company in the U.S. for so long as Hengrui, or other Chinese investors, continue to beneficially own a significant percentage of our outstanding shares of common stock. The relationship between the U.S. and China is subject to ongoing change and uncertainty. In recent years, the U.S. government has made statements and taken a number of actions, including legislative and regulatory actions, directed at Chinese companies and Chinese-affiliated interests, including the issuance of executive orders restricting the operations of certain Chinese companies in the U.S., restricting the amount of U.S. sensitive personal data that can be accessed by those companies, imposing sanctions on Chinese nationals, adding Chinese companies to the U.S. government's restricted party lists, enacting legislation such as the Comprehensive Outbound Investment National Security (COINS) Act and the Protecting Americans from Foreign Adversary Controlled Applications Act, and initiating national security reviews of software applications and other interests linked to foreign adversaries, including China. In addition, executive orders, regulations, and enacted law have been issued barring American investment into certain Chinese companies. The Chinese government has taken certain reciprocal measures, including the passage of the Anti-Foreign Sanctions Law, enactment of Industrial and Supply Chain Security Regulations, and the imposition of sanctions on American nationals and organizations.

Hengrui's significant equity interest in us could subject us to heightened regulatory scrutiny, regardless of its merit, which could have an adverse effect upon our business (including our results of operations, financial condition, and cash flows) ability to raise additional capital, ability to engage in certain transactions, strategic opportunities, and other prospects. Additionally, should we become the target of, or be indirectly impacted by, new legislation, executive orders or regulatory actions addressed at protecting American investments in companies with significant Chinese ownership or affiliations, our business, results of operations, financial condition and prospects could be materially and adversely affected. Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may increase the cost of manufacturing our product candidates and materials, affect the demand for our drug products (if and once approved), the competitive position of our product candidates, and import or export of raw materials and finished product candidate used in our, Hengrui's and any future collaborators' nonclinical studies and clinical trials, particularly with respect to any product candidates and materials that we import from China, including pursuant to the Exclusive License Agreement. Furthermore, any deterioration in U.S.-China relations could adversely impact our relationship with Hengrui, including our ability to maintain and benefit from the Exclusive License Agreement, which could have a material adverse effect on our business and the development and commercialization of BHB-1893 and any future product candidates.

Even if we, Hengrui or any future collaborator obtain approval for BHB-1893 or any future product candidate in one jurisdiction, we may never obtain approval for or commercialize such candidate in any other jurisdiction, which would limit our ability to realize its full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the U.S. does not ensure approval by regulatory authorities in other countries or jurisdictions.

However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. For example, if Hengrui fails to obtain approval for HRS-1893 in China, it could negatively impact our ability to obtain approval for BHB-1893 in the U.S. or any other jurisdiction. In addition, regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation, as well as additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional nonclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those 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 regulatory requirements in international markets or to obtain and maintain required 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 any product we develop will be unrealized.

Risks Related to Our Dependence on Third Parties

We depend on our Exclusive License Agreement with, and the comprehensiveness of the intellectual property licensed from, Hengrui to continue developing, and if approved, commercialize BHB-1893. Termination of the Exclusive License Agreement, and issues related to intellectual property we license from Hengrui, would have a material adverse effect on our business.

We are a party to the Exclusive License Agreement with Hengrui under which we are granted rights to intellectual property that are important to our business, and we expect that we may enter into additional license agreements in the future. Under the Exclusive License Agreement, we have secured an exclusive license for certain intellectual property and know-how relating to cardiac myosin inhibitors to commercialize certain compounds, patents and proprietary information and inventions. The Exclusive License Agreement imposes obligations on us to use commercially reasonable efforts to develop and commercialize licensed products in our territory, to achieve certain regulatory milestone obligations within specified timelines, and to pay Hengrui milestone payments, royalties and other fees. If we fail to comply with our obligations under the Exclusive License Agreement, or we are subject to a bankruptcy, Hengrui may have the right to terminate the license, in which event we would not be able to market or exploit products covered by the license, including BHB-1893, if approved. Future license agreements we enter into may include similar obligations and termination rights, and our business could suffer if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. In particular, we are substantially dependent on the success of BHB-1893, and to the extent we are unable to develop other product candidates at the time of such termination, the termination of the Exclusive License Agreement would have a material adverse effect on our business, financial condition, results of operations and prospects, including, but not limited to, cessation of our operations. See "*Business—Hengrui License Agreement*," included in our IPO final prospectus dated August 5, 2026 filed with the SEC, for a description of the Exclusive License Agreement.

Additionally, certain rights that are material to at least our BHB-1893 development program and licensed to us in the Exclusive License Agreement were licensed by Hengrui from third parties pursuant to upstream license agreements. Any termination of any of these licenses or disruption in the availability of these rights would have a materially adverse effect on our development programs, operations and our commercial viability. In case of such termination or disruption, we may be unable to obtain licenses to the relevant rights on commercially reasonable terms or at all.

We may need to obtain additional licenses from third parties to advance our research or allow commercialization of BHB-1893 or any future product candidates, and we cannot provide any assurances that third-party patents do not exist that might be enforced against BHB-1893 or any future products in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same intellectual property licensed to us. Thus, we may be required to expend significant time and resources to develop or license replacement intellectual property. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business. Additionally, third parties that own intellectual property rights could seek either an injunction prohibiting our sales, and/or,

compensation for our use of such intellectual property rights, such as running royalties and infringement damages.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors (including indirect, up-stream licensors) regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under, and obligations imposed by, the license agreement and other interpretation-related issues;
- whether and the extent to which BHB-1893 or any future product candidates and processes may infringe on intellectual property of third parties that are not subject to the licensing agreement;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the third parties' intellectual property without their authorization;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed intellectual property in relation to our development and commercialization of BHB-1893 or any future product candidates, and what activities satisfy those diligence obligations; and
- the inventorship and ownership of inventions and know-how, including such disputes resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

Our business is subject to the risks associated with having a collaboration partner and third-party manufacturer based in China.

Our business is subject to the risks associated with having Hengrui, an entity located in China, as our collaboration partner and our sole manufacturer for BHB-1893, including:

- adverse political and economic conditions, particularly those negatively affecting the trade relationship between the U.S. and China;
- trade protection measures, such as tariff increases, and import and export licensing and control requirements;
- potentially negative consequences from changes in tax laws;
- difficulties associated with the Chinese legal system, including increased costs and uncertainties associated with enforcing contractual obligations in China and frequent and unexpected shifts in laws and regulations;
- historically lower protection of intellectual property rights;
- requirements relating to China's data security rules and regulations;
- requirements relating to China personal information protection laws;
- U.S. legal restrictions and prohibitions on the transfer or grant of access of bulk U.S. sensitive personal data to individuals and entities in China;
- U.S. legal restrictions (current and proposed) on U.S. investment in companies with certain Chinese ownership and/or control;
- changes and volatility in currency exchange rates;
- workforce uncertainty;

- unexpected or unfavorable changes in regulatory requirements; and
- difficulties in managing foreign relationships and operations generally.

Sustained uncertainty about, or the further escalation of, trade and political tensions between the U.S. and China could result in a disadvantageous research and manufacturing environment in China, particularly for U.S. based companies, including retaliatory restrictions that hinder or potentially inhibit our ability to rely on manufacturing partners and other service providers that operate in China. Recent and potential future tariffs imposed by the U.S. on goods imported from China, including pharmaceutical ingredients and finished drug products, could increase the cost of clinical supply if we continue to source drug substance or drug product from Hengrui or other Chinese manufacturers. Such cost increases could materially impact our operating expenses and development timelines.

Geopolitical tensions and any escalation thereof could result in additional legislative or regulatory actions in the U.S. or China that may directly or indirectly affect our business or the value of our common stock. This includes legislative or regulatory actions that could restrict our ability to work with certain foreign suppliers, including Chinese entities, and limit access to federal contracts, grants, and loans, and materially disrupt our supply chain and development timelines. In December 2025, for example, the National Defense Authorization Act for Fiscal Year 2026 was enacted, which included Section 851, commonly referred to as the “BIOSECURE Act.” The BIOSECURE Act restricts U.S. government agencies from procuring biotechnology equipment or services from, or entering into contracts with, entities that use biotechnology equipment or services from, designated “biotechnology companies of concern” (the “BCCs”), and from expending federal loan or grant funds for such equipment or services.

The BIOSECURE Act directs the Office of Management and Budget (“OMB") to publish an initial list of BCCs by December 2026, and implementing regulations are expected to follow. The BIOSECURE Act itself requires that the BCC list include any companies designated by the U.S. Department of Defense (“DoD”) on the so-called Section 1260H List of Chinese military companies operating in the United States. In June 2026, DoD released the latest list of Section 1260H companies, which included WuXi AppTec Ltd. WuXi AppTec sued in federal court on June 11, and on August 7, 2026 the court issued a preliminary injunction barring DoD from enforcing or giving effect to the designation while the case proceeds.

We currently use WuXi AppTec Ltd. for process development support.

We also rely on Hengrui to manufacture BHB-1893 in China, and expect to continue to rely on third-party contract manufacturing organizations and other vendors that operate in China in the future. While none of our vendors are currently listed as a BCC, WuXi AppTec’s inclusion in the 1260H List means that it could be listed as a BCC when OMB publishes its list. There is also a risk that other vendors may be added as BCCs in the future. In addition, even absent a formal BCC designation, U.S. research institutions and other federal funding recipients may seek to limit or restrict relationships with vendors that have been flagged under or that work with entities that have been flagged under BIOSECURE-related designations, which could indirectly affect our development activities. If our current or future vendors with which we work are designated as BCCs in the future, or if our collaborators, customers, investors, or future commercial partners become subject to BIOSECURE-related restrictions as a result of their relationships with such vendors, we could be required to terminate or restructure existing arrangements, transition manufacturing or other services to alternative suppliers, or delay or suspend development activities. Any such transition could involve significant cost, operational complexity, regulatory risk, and delays, and alternative suppliers may not be available on acceptable terms or at all.

We are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the U.S. or Chinese governments, political unrest or other unstable conditions in China. The passage of the People’s Republic of China’s Biosecurity Law in April 2021, and subsequent legislation that China or the U.S. may adopt in the future, or other events in China could disrupt our ability to continue to rely upon manufacturers located in China, including Hengrui. In addition, if we are not able to obtain adequate supplies of BHB-1893 or the drug substances used to manufacture it, it will be more difficult for us to develop BHB-1893 and compete effectively. New legislation, regulations or court decisions may impede, delay, limit, or increase the cost of manufacturing our products. Such events could result in our clinical or commercial supply of product being interrupted or limited, which could harm our business.

If there is adoption of the draft regulations (or expansion in a final rule) pursuant to the COINS Act, Hengrui's equity in our company could subject us to increased regulatory scrutiny or adversely affect our ability to raise additional capital, engage in certain transactions or pursue strategic opportunities. These pressures may strain relations with Hengrui, our sole manufacturer of BHB-1893, and could require us to restructure existing manufacturer arrangements and capital structure.

We intend to rely on third parties to conduct a significant portion of our clinical trials for BHB-1893 and any potential future clinical trials for our future product candidates, and if those third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements, or meet expected deadlines, our ability to seek or obtain regulatory approval for or commercialize any of our current or future product candidates may be delayed.

We expect to rely on CROs and other third parties, including but not limited to clinical data management organizations, healthcare institutions operating as clinical sites and clinical investigators, to conduct future clinical trials for BHB-1893 and other future product candidates that we may progress to clinical development. These CROs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. In particular, we have licensed our sole product candidate from Hengrui, which has conducted and is conducting certain nonclinical studies and clinical trials of our product candidate in China. We intend to leverage the clinical capabilities and data generated by Hengrui to inform and support our global development programs. While we have and will have agreements governing the activities of our third-party contractors, including Hengrui, we have limited influence over their actual performance, and we have no control over the data generated by Hengrui on our product candidates. Any of these third parties may terminate their engagements with us, some in the event of an uncured material breach and some at any time for convenience. If any of our relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. Switching or adding CROs or other vendors involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO or vendor commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. We may encounter challenges or delays in our CRO/vendor relationships in the future which may cause a material adverse impact on our business, financial condition and prospects.

Further, CROs may not assign as high a priority to our programs or pursue them as diligently as we would if we were undertaking these programs ourselves. The activities conducted by our CROs therefore may not be completed on schedule or in a satisfactory manner. CROs may also give higher priority to relationships with our competitors and potential competitors than to their relationships with us. Outside of the U.S., we are particularly dependent on our CROs' expertise in communicating with clinical trial sites and regulatory authorities and ensuring that our clinical trials and related activities and regulatory filings comply with applicable laws.

In addition, any third parties conducting our clinical trials will not be our employees, and, except for including contractual obligations and remedies for breach of such obligations in our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical programs. If these 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 is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approvals for or successfully commercialize BHB-1893 or any future product candidates. Consequently, our results of operations and the commercial prospects for BHB-1893 or any future product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other development activities that could harm our competitive position.

We expect to rely on these parties for execution of our nonclinical studies and clinical trials, and generally do not directly control their businesses or related activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards and requirements, and our reliance on our CROs and other third parties does not relieve us of our regulatory responsibilities. In addition, we and our CROs are required to comply with Good Laboratory Practice ("GLP") requirements, as applicable, for certain nonclinical studies. The FDA also requires us to comply with GCPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register certain clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes for publication. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Regulatory authorities enforce these requirements through periodic inspections of laboratories conducting GCP studies, trial sponsors, principal investigators and trial sites. If we or any of our CROs or other third parties, including trial sites, fail to comply with applicable GCPs, 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. Further, upon inspection by a given regulatory authority, such regulatory authority may not agree with our determination that any of our clinical trials complies with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP conditions. Our failure to comply with these requirements may require us to repeat clinical trials, which would delay the regulatory approval process.

We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of BHB-1893 or any future product candidates or commercialization of our products, producing additional losses and depriving us of potential revenue.

We may seek to establish collaborations, license agreements and other similar arrangements with third parties for the development or commercialization of BHB-1893 or any future product candidates. If we are not able to establish them on commercially reasonable terms, or if those arrangements are not successful, we may have to alter our development and commercialization plans.

The development and potential commercialization of BHB-1893 or any future product candidates will require substantial additional funding. We may seek to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of BHB-1893 or any future product candidates, including for the commercialization of BHB-1893 or any future product candidates that are approved for marketing outside the U.S. If we enter into any such additional arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our future collaborators dedicate to the development or commercialization of BHB-1893 or any future product candidates. Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all.

We face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the potential differentiation of BHB-1893 or any future product candidates from competing product candidates, the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities outside the U.S., the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, and industry and market conditions generally. The collaborator may also consider alternative product candidates for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for BHB-1893 or any future product candidates. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop BHB-1893 or any future product candidates or bring them to market and generate product revenue.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Collaborations involving BHB-1893 or any future product candidates would pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected, or at all;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with BHB-1893 or any future product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to one or more of BHB-1893 or any future product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development or commercialization, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated, including for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

We may not be able to negotiate future collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of any product candidate that we planned to collaborate on, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop BHB-1893 or any future product candidates or bring them to market and generate revenue, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, any future collaborations that we enter into may not be successful. The success of our future collaboration arrangements will depend heavily on the efforts and activities of our future collaborators. Disagreements between parties to a collaboration arrangement can be difficult to resolve if neither of the parties has final decision-making authority. If conflicts arise between any future collaborators and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. For example, our future collaborators could conduct multiple product development efforts and could develop, either alone or with others, products in related fields that are competitive with the product candidates we may develop. In addition, collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party, and any such termination or expiration may adversely affect us financially or harm our business.

Risks Related to Our Intellectual Property

If we or our licensors are unable to obtain, maintain and enforce intellectual property rights relating to BHB-1893 or any future product candidates, or if the scope of the protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, our ability to successfully commercialize BHB-1893 or any future product candidates may be adversely affected and we may not be able to compete effectively in our markets.

We rely upon a combination of patents, licenses to intellectual property, and access to certain third-party trade secrets and confidentiality agreements to protect the intellectual property related to BHB-1893 or any of our future product candidates. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and rights, and proprietary information. Our success depends in large part on our ability to obtain and maintain, and access, patent and other intellectual property protection in the U.S. and in other countries with respect to BHB-1893 and any future product candidates. If we are unable to obtain or maintain patent protection with respect to BHB-1893 and its uses, or any of our future product candidates, our business, financial condition, resultant operations and prospects could be materially harmed.

We cannot predict whether the patent applications we currently or may in the future pursue will issue as patents in any particular jurisdiction or will provide sufficient protection against competitors or other third parties. Currently, much of our patent portfolio, including applications related to BHB-1893, are in various, relatively early stages of the patent prosecution process. We also cannot predict the outcome of any challenge by our competitors or third parties to the validity or enforceability of patents on which we rely. We cannot offer any assurances that the breadth of our granted patents will be sufficient to stop a competitor from developing and commercializing a product, including a generic product that would be competitive with BHB-1893 or any future product candidates. Furthermore, any successful challenge to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of the competitive advantage necessary for the successful commercialization of BHB-1893 or any future product candidates. Further, if we encounter delays in regulatory approval, the period of time during which we could market a product candidate under patent protection would be reduced, even if we obtained patent term extension for such delays, which might not fully compensate for such delays.

Our ability to obtain and maintain valid and enforceable patents depends on our inventions being patentable in light of the prior art and satisfaction of other substantive and formal requirements of patentability. Regarding prior art, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to invent the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to make the inventions claimed in those owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. If a third party can establish that we or our licensors were not the first to make or the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and, even if issued, they and other issued patents on which rely, may be challenged and invalidated or rendered unenforceable. Furthermore, even if a patent is granted, our competitors or other third parties may be able to circumvent the patent by developing similar or alternative products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The patent prosecution process is expensive and time-consuming. We may not be able to prepare, file and prosecute all necessary or desirable patent applications at a commercially reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, depending on the terms of any existing and future in-licenses to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering material intellectual property in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted, enforced and maintained in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued which protect BHB-1893 or any future product candidates or which effectively prevent others from commercializing competitive products.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the U.S. and abroad. There may be prior art of which we are not aware that may affect the validity or enforceability of our patents. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of our patents, which may, nonetheless, ultimately be found to affect the validity or enforceability of our patents. We or our licensors may in the future, become subject to a third-party pre-issuance submission of prior art, opposition, derivation, revocation, re-examination, post-grant and *inter partes* review, or interference proceeding and other similar proceedings challenging our patent rights or the patent rights of others in the U.S. Patent and Trademark Office (the "USPTO") or other foreign patent office. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection of BHB-1893 and any future product candidates.

Furthermore, given the amount of time required for the development, testing and regulatory review of new product candidates (including BHB-1893), patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to BHB-1893 or any future product candidates.

In addition to the protection provided by our patent portfolio, we rely on our own trade secrets and access to certain third-party trade secret protection as well as confidentiality agreements to protect proprietary know-how that is not amenable to patent protection. Although we generally require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or intellectual property to enter into confidentiality agreements that are intended to protect trade secrets and know-how that we own or license, certain employees, consultants, advisors and relevant third parties may not have signed such agreements and we cannot provide any assurances that all such agreements have been duly executed or are sufficient to protect our rights, or that such trade secrets and other confidential proprietary information will not be disclosed or used in an unauthorized manner that harms us. Moreover, our competitors may independently develop knowledge, methods and know-how equivalent to the above-mentioned trade secrets. Additionally, competitors could purchase our products, if approved, and replicate some or all of the competitive advantages for which we do not have patent protection to our competitive disadvantage. If any trade secrets were to be lawfully obtained or independently developed by a competitor, we might not have any means to prevent them, or those to whom they communicate them, from using such trade secrets or information to compete with us. If any trade secrets were to be disclosed to, or independently developed by a competitor, our competitive position would be harmed.

We also seek to preserve the integrity and confidentiality of our proprietary data and third-party trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. However, our agreements and security measures may be breached, and we may not have adequate remedies for any breach. Also, if the steps taken to maintain trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret or may lose any purported trade secret protection. In addition, others may independently discover the trade secrets and our proprietary information. For example, the FDA and analogous regulatory bodies outside the US consider whether to make additional information in connection with applications for marketing authorization (such as applications for marketing authorization that we envision for our product candidates including BHB-1893) publicly available on a routine basis, and it is not clear at the present time how the FDA's and analogous non-US bodies' disclosure policies may change in the future. If we are unable to prevent material disclosure of the non-patented intellectual property related to BHB-1893 or any future product candidates to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and if we do not obtain protection under the Hatch-Waxman Amendments and similar non-U.S. legislation for extending the term of patents covering each of BHB-1893 or any future product candidates, our business may be materially harmed.

Patents have a limited lifespan. In the U.S., if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if additional patents covering our BHB-1893 or any future product candidates are obtained, once the patent life has expired for a product, we may be open to competition from competitive medications, including generic medications. 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. Because of these term limits, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. If we do not have sufficient patent life to protect BHB-1893 or any future product candidates, our business, financial condition, results of operations, and prospects may be adversely affected.

Depending upon the timing, duration and conditions of FDA marketing approval of BHB-1893 or any future product candidates, one or more of our U.S. patents, including any patents that may issue covering BHB-1893, may be eligible for limited patent term extension ("PTE") under the Drug Price Competition and Patent Term Restoration Act of 1984 (referred to as the "Hatch-Waxman Amendments"), and similar legislation in the European Union. The Hatch-Waxman Amendments permit a PTE of up to five years for a patent covering an approved product that is a new chemical entity as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent 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. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Additionally, administrative changes at the USPTO or other applicable patent authorities, such as layoffs, reduced hiring, and/or funding, may result in delays in issuance of a patent or in accrual of PTE, thereby reducing the amount of patent term extension that could otherwise be received. Administrative changes (e.g., at the FDA or USPTO) may also lead to delays in review and analysis of regulatory submissions or requests for PTE, which could result in a PTE not being timely granted (e.g., before the expiration of the patent) and there may be no patent eligible for extension. Moreover, the length of the extension could be less than we request, and we cannot be certain what the length of the extension would be or if we will receive an extension at all. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner.

In addition, upon approval of a drug, each of the U.S. patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. U.S. patents that cover the drug and issue after approval by the FDA can be listed in the Orange Book within 30 days. Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. We cannot guarantee that a patent that may cover BHB-1893 or any of our future product candidates can or will be appropriately listed in the Orange Book.

Laws governing analogous PTE in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain PTE or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and nonclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially and could have a material adverse effect on our business.

If we fail to comply with our obligations in any current intellectual property licenses with third parties, or fail to obtain such licenses in the future, we could lose rights that are material to our business.

We have licensed third-party intellectual property that is material to our business through the Exclusive License Agreement, and may enter into additional license agreements in the future. We do not and will not own the patents or patent applications that underlie these licenses, and we may not control either the prosecution or the enforcement of the patents. Under such circumstances, we may be forced to rely upon our licensors to properly prosecute and file those patent applications and prevent infringement of those patents. Therefore, we cannot be certain that the prosecution, maintenance and enforcement of these patent rights will be in a manner consistent with the best interests of our business.

If we or our licensors fail to maintain such patents, or if we or our licensors lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize BHB-1893 or any future product candidates that are the subject of such licensed rights could be adversely affected.

Our rights to use the intellectual property and practice the inventions claimed in the licensed patents and patent applications are subject to our licensors abiding by the terms of those licenses and not terminating them. In addition, existing license agreements do, and future agreements may, impose diligence, development and commercialization timelines and milestone payment, royalty, insurance and other obligations for development of certain programs. If we fail to comply with our obligations, our licensors may have the right to terminate the licenses, in which event we might not be able to develop, manufacture or market any product that is covered by the intellectual property we in-license from such licensor and may face other penalties. If our Exclusive License Agreement or any of our future licenses are terminated, we may lose our patent rights on a territory-by-territory basis, and such rights may be lost worldwide. Termination of any license agreement could reduce or eliminate our rights under these agreements and may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property. Any of the foregoing outcomes could prevent us from commercializing relevant product candidates, which could have a material adverse effect on our operating results and overall financial condition.

In addition, disputes regarding obligations in licenses may require us to take expensive and time-consuming legal action to resolve, and, even if we are successful, may delay our ability to commercialize products and generate revenue. Further, if we are unable to resolve license issues that arise, we may lose rights to practice intellectual property that is required to make, use or sell products. We may require additional licenses in the future. Licenses to additional third-party intellectual property and materials that may be required for our development programs may not be available on commercially reasonable terms, or at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more-established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us.

In addition, disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including disputes concerning scope of rights granted under the license agreement and other interpretation-related issues; whether and the extent to which BHB-1893 or any future product candidates and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; 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. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. If we are unable to successfully obtain rights to required third-party intellectual property rights, we may have to abandon development of the relevant program or product candidate or expend time and resources re-designing the program or product candidate, which could have a material adverse effect on our business.

Intellectual property rights that we in-license in the future may also be granted through sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize BHB-1893 or any future product candidates may be materially harmed.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any future patents we obtain.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the U.S. Furthermore, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific, and factual issues. Changes in either patent laws or interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Patent reform legislation in the U.S. and other countries, including the Leahy-Smith America Invents Act (the “Leahy-Smith Act”) enacted in September 2011, could increase the uncertainties around patent protection, costs, and the enforcement or defense of our patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. The Leahy-Smith Act included a number of significant changes to U.S. patent law. Such provisions affect the way patent applications are prosecuted, redefine prior art, and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. After March 2013, the Leahy-Smith Act transformed the U.S. into a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. This requires us to be cognizant of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing, we cannot be certain that we 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 patents or patent applications.

Further, recent 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. For example, the Supreme Court of the United States held in *Amgen v. Sanofi* (2023) that a functionally claimed genus was invalid for failing to comply with the enablement requirement of the Patent Act. In addition, the Federal circuit recently issued a decision, *In re Cellect, LLC* (2023) involving the interaction of patent term adjustment (PTA), terminal disclaimers, and obvious-type double patenting which may affect the patent term of any issued patents that rely on any PTA. In addition to increasing uncertainty with regard to our or our licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our or our licensors' existing patents and patents that we or our licensors might obtain in the future. We cannot predict how future decisions by the courts, Congress or the USPTO may impact the value of our or our licensors' patents. In the 2013 case Assoc. for Molecular Pathology v. Myriad Genetics, Inc., for instance, the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. For example, the Inflation Reduction Act (IRA) passed by Congress authorizes the Secretary of the Department of HHS to negotiate prices directly with participating manufacturers for selected medicines covered by Medicare even if these medicines are protected by an existing patent. For small molecule medicines, the process begins seven years after initial approval by the FDA. While we do not believe that the IRA or its effects will impact our ability to obtain patents in the near future, we cannot be certain whether it will affect our patent strategy in the long run. Similarly, any adverse changes in the patent laws of other jurisdictions could have a material adverse effect on our business and financial condition. Changes in the laws and regulations governing patents in other jurisdictions could similarly have an adverse effect on our ability to obtain and effectively enforce our patent rights.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

While we are not currently involved in any disputes relating to our intellectual property, competitors may infringe the patents we have applied for. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. If we initiate legal proceedings against a third party to enforce a patent covering BHB-1893 or any future product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and/or unenforceable. In patent litigation in the U.S., counterclaims alleging invalidity and/or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent.

In an infringement proceeding, a court may decide that the patent claims we are asserting are invalid and/or unenforceable, or may refuse to stop the other party from using the intellectual property at issue on the grounds that our patent claims do not cover the intellectual property in question. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, *inter partes* review and equivalent proceedings in foreign jurisdictions (for example, opposition proceedings). Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover BHB-1893 or any future product candidates. The outcome following legal assertions of infringement, invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on BHB-1893 or any future product candidates. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could have a material adverse impact on our business.

Our defense of litigation or interference proceedings may fail and require us to cease using certain intellectual property or force us to take a license under the intellectual property rights of the prevailing party, if available. Even if successful, litigation or interference proceedings may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the U.S.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain.

While no third parties to our knowledge have initiated legal proceedings against us to date, as BHB-1893 and any future product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. We cannot provide any assurance that BHB-1893 or our future product candidates do not infringe other parties' patents or other proprietary rights, and competitors or other parties may assert that we infringe their proprietary rights in any event. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to BHB-1893 or our future product candidates, including infringement, interference or derivation proceedings, post-grant review and *inter partes* review before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize BHB-1893 or any future product candidates. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is high and requires us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would agree with us and invalidate the claims of any such U.S. patent. Similarly, the burdens on us to invalidate patent claims in foreign jurisdiction may vary substantially and courts in those jurisdictions may not agree with us that the claims are invalid. The outcome of proceedings involving assertions of infringement, invalidity and unenforceability during patent litigation is unpredictable. Furthermore, if a patent holder believes that BHB-1893 or any future product candidates infringes its patent, the patent holder may sue us even if we have received patent protection for our intellectual property. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay manufacturing or sales of the drug or product candidate that is the subject of the actual or threatened suit. Moreover, given the vast number of patents in our field of intellectual property, we cannot be certain that BHB-1893 or our future product candidates do not or will not infringe existing patents or that we will not infringe patents that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue commercializing BHB-1893 or any future product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same intellectual property rights licensed to us. If we fail to obtain a required license, we may be unable to effectively market product candidates based on our intellectual property, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Alternatively, we may need to redesign our products, which may be impossible or require substantial time and monetary expenditure. Under certain circumstances, we could be forced, including by court orders, to cease commercializing BHB-1893 or any future product candidates. In addition, in any such proceeding or litigation, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed the patent at issue. A finding of infringement that prevents us from commercializing BHB-1893 or any future product candidates, requires us to redesign our products, or forces us to cease some of our business operations could materially harm our business and could adversely affect our ability to compete in the marketplace.

The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock. Ultimately, any such litigation could substantially increase our operating losses and reduce our resources available for development activities, and we may not have sufficient financial or other resources to adequately engage in such litigation.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties or claims asserting ownership of what we regard as our own intellectual property.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies, or at research institutions, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals have or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Further, although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators, and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. An inability to incorporate such technologies or features would harm our business and may prevent us from successfully commercializing our technologies or product candidates. In addition, we may lose personnel as a result of such claims and any such litigation, or the threat thereof, may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our technologies or product candidates, which could adversely affect our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

We may be subject to claims challenging the inventorship or ownership of our intellectual property, including any patents we obtain.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patent applications, any patents we obtain, or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing BHB-1893 or any future product candidates. Although it is our policy to require our employees 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 executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. If we no longer own intellectual property rights that are required to commercialize and protect our products, we may need to obtain license to those rights, which may not be available on commercially reasonable terms, or at all. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Reliance on third parties requires us to share trade secrets, which increases the possibility that trade secrets will be misappropriated or disclosed, and confidentiality agreements with employees and third parties may not adequately prevent disclosure of trade secrets and protect other proprietary information.

We rely on certain third-party trade secrets, technical know-how, proprietary information and other confidential information to protect BHB-1893 and as otherwise useful to our business, and expect to do so for our future product candidates. Monitoring unauthorized uses and disclosures of trade secrets and other confidential information is difficult, and we do not know whether the steps we have taken to protect our confidential intellectual property will be effective. We seek to protect our confidential information, in part, through confidentiality and non-disclosure agreements with our employees, consultants, collaborators, suppliers and other parties. These agreements typically restrict the ability of our employees, consultants, advisors and third-party contractors to use or disclose our proprietary information or publish data potentially relating to our proprietary information. Despite our efforts to protect trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other proprietary information by the parties to these agreements. There can be no assurance that these agreements will not be breached, including by disclosure of our confidential information. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and trade secret status could be lost as a result. We also cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary product candidates and processes. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators or others is inadvertently disclosed or subject to a breach or violation, we may be liable to the owner of that confidential information. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary product candidates and processes and third-party trade secrets will be effective.

If we rely on third parties to manufacture or commercialize BHB-1893 or any future product candidates, or if we collaborate with additional third parties for the development of BHB-1893 or any future product candidates, we must, at times, share proprietary information with them. We may also conduct joint research and development programs that may require us to share potential trade secrets under the terms of our research and development partnerships or similar agreements. Despite the contractual provisions employed when working with third parties, the need to share confidential information increases the risk that such potential trade secrets become known by our competitors, are inadvertently incorporated into the product candidates 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 other confidential information, a competitor's discovery of such information or other unauthorized use or disclosure thereof could have an adverse effect on our business and results of operations.

Enforcing a claim that a third party illegally obtained and is using trade secrets or proprietary information is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets and the enforceability of confidentiality or similar types of agreements may vary from jurisdiction to jurisdiction.

We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and defending patents covering BHB-1893 or any future product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our intellectual property in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as that in the U.S. or Europe. These products may compete with BHB-1893 or any future product candidates, and our and our licensors' future patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the U.S., but may issue as patents with claims of different scope or may even be refused in other jurisdictions. Furthermore, the requirements for patentability differ in certain jurisdictions and countries. Some countries do not grant claims directed to methods of treatment or have additional restrictions on the scope of method of treatment claims compared to the U.S. Accordingly, depending on the country, the scope of patent protection may vary for the same product candidate.

While we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain protection efforts in all such markets. Additionally, the prosecution of patent applications in other jurisdictions is often a longer process and patents may be granted at a later date than in the U.S., potentially delaying our ability to assert such patents against competitors. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize BHB-1893 or any future product candidates in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition in those jurisdictions.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the U.S. and Europe, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property rights, which could make it difficult for us to stop the infringement of any patents we obtain or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any patents we obtain at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, 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. 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 license.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

In Europe, a new unitary patent system took effect on June 1, 2023, which may significantly impact European patents, including those granted before the introduction of the new system. Under the new system, applicants can, upon grant of a European patent, opt for that patent to become a unitary patent which will be subject to the jurisdiction of a new unitary patent court ("UPC"). During the first seven years of the UPC's existence, patents granted before the implementation of the new system can be opted out of UPC jurisdiction, and validated as national patents in any one or more of the UPC countries. We may decide to opt out future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, 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. 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 countries who are signatories to the UPC. The UPC will 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. Further, because the UPC is a new court system and there is no precedent for the court's laws, 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. In addition to changes in patents laws, geo-political actions in the U.S. and in foreign countries (such as the Russia and Ukraine conflict, conflict in the Middle East, including the Iran conflict, retaliatory measures by foreign countries in response to actions by the U.S., in particular, tariffs) could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. Many foreign countries could threaten to impose retaliatory measures that may adversely impact our intellectual property rights in those countries. For example, Brazil enacted Law No. 15.122/2025 (known as the "Economic Reciprocity Law"), which provides a framework that allows for the suspension of obligations related to foreign entity's intellectual property rights. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government 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 patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the U.S. over the lifetime of our patents and/or applications and any patent rights we may obtain or license in the future. Furthermore, the USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse of a patent or patent application can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patents or patent applications, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering BHB-1893 or any future product candidates or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize BHB-1893 or any future product candidates in any indication for which they are approved.

Any trademarks we have obtained or may obtain may be infringed or otherwise violated, or successfully challenged. If our trademarks and trade names are not adequately protected, or if we are unable to obtain desired trademarks or trade names, then we may not be able to build brand name recognition in our markets of interest and our business may be adversely affected.

We expect to rely on trademarks as one means to distinguish BHB-1893 or any future product candidates, if approved for marketing, from the product candidates of our competitors. Once we select new trademarks and apply to register them, our trademark applications may not be approved. During trademark registration proceedings in the U.S. and foreign jurisdictions, we may receive rejections. We are given an opportunity to respond to those rejections, but we may not be able to overcome such rejections.

We have also not yet registered trademarks for BHB-1893 or any future product candidates in any jurisdiction. Any trademark applications we file may be rejected and registered trademarks may not be obtained, maintained or enforced. If we do not successfully register our trademarks, we may encounter difficulty in enforcing, or be unable to enforce, our trademark rights against third parties, which could adversely affect our business and our ability to effectively compete in the marketplace.

In addition, any proprietary name we propose to use with BHB-1893 in the U.S. will need to be approved by the FDA, regardless of whether we have registered, or applied to register, the proposed proprietary name as a trademark. The FDA conducts a review of proposed proprietary names, including an evaluation of potential for confusion with other products' proprietary names, as part of the NDA review process. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

In addition, our unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on, misappropriating or violating other marks. In the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademark registrations may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand BHB-1893 or any future product candidates, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion.

Our competitors may also infringe or otherwise violate our trademarks and we may not have adequate resources to enforce our trademarks. We may not be able to protect our rights to our trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. Any of the foregoing events may have a material adverse effect on our business.

Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. 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, then 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, trade names, domain names or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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. The following examples are illustrative:

- BHB-1893 and any future product candidates, if approved, may eventually become commercially available in generic or biosimilar product forms;
- others may be able to make products that are similar to or otherwise competitive with BHB-1893 or any future product candidates but that are not covered by the claims of our current or future patents;
- an in-license necessary for the manufacture, use, sale, offer for sale or importation of BHB-1893 or any future product candidates may be terminated by the licensor;
- we or future collaborators might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license;
- we or future collaborators might not have been the first to file patent applications covering certain of our inventions;

- we or future collaborators may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently commercialize the technology and/or file a patent covering such intellectual property;
- others may independently develop similar or alternative product candidates or duplicate BHB-1893 or any future product candidates without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our patents;
- it is possible that there are unpublished patent applications that may later issue with claims covering BHB-1893 and any future product candidates similar to ours;
- it is possible that our patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable or result in a change in ownership;
- issued patents that we own or in-license may be held invalid or unenforceable as a result of legal challenges by our competitors;
- issued patents that we own or in-license may not provide coverage for all aspects of BHB-1893 or any future product candidates in all countries;
- our competitors might conduct research and development activities in countries where we 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;
- ownership of our patents or patent applications may be challenged by third parties;
- we may not develop additional proprietary intellectual property that is patentable; and
- the patents of third parties may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.

We currently have rights to intellectual property, through the Exclusive License Agreement, to identify and develop BHB-1893, and we may add additional licenses in the future as we expand our pipeline. Although we have succeeded in licensing intellectual property from Hengrui, we cannot assure our stockholders that we will be able to in-license or acquire the rights to any other product candidates from third parties on acceptable terms or at all.

In addition, the Exclusive License Agreement provides, and any future license agreements may provide, that our fields of use exclude particular fields or exclude certain territories amongst other exclusivity restrictions. If we determine that rights to such fields are necessary to commercialize BHB-1893 or any future product candidates or maintain our competitive advantage, we may need to obtain additional license rights in order to continue developing, manufacturing or marketing BHB-1893 or any future product candidates. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses.

Various third parties practice in competitive areas and may have issued patents or patent applications that will issue as patents in the future, which could impede or preclude our ability to commercialize BHB-1893 or any future product candidates. For any third-party patents that could be relevant to BHB-1893 or any future product candidates, we rely in part on the "safe harbor" or research exemption under 35 U.S.C. § 271(e)(1), which exempts activities related to pursuing FDA approval for a drug product from patent infringement. However, while U.S. patent law provides such a "safe harbor" to our clinical product candidates under this provision, that exemption may expire when an NDA is submitted. Given the uncertainty of clinical trials, we cannot be certain of the timing of their completion and it is possible that we may submit an NDA for one of our future product candidates at a time when one or more relevant third-party patents is in force. It may therefore be necessary for us to use the patented or proprietary intellectual property of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. If we are unable to license such intellectual property, or if we are forced to license such intellectual property on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales or an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same intellectual property licensed to us.

Additionally, we may collaborate with academic institutions to accelerate our nonclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in intellectual property resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program.

Furthermore, if we enter into future arrangements involving government funding, and we, or any academic institutions or third parties we collaborate with in future, make inventions as a result of such funding, our intellectual property rights to such discoveries may be subject to the applicable provisions of the Bayh-Dole Act of 1980. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. Any exercise by the government of certain of our rights could harm our competitive position, business, financial condition, results of operations and growth prospects.

In addition, the licensing or acquisition of third-party intellectual property rights is a highly competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the applicable product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign BHB-1893 or any future product candidates, or the methods for manufacturing them or to develop or license replacement intellectual property, 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 product candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

Additionally, if we fail to comply with our obligations under license agreements, 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 that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or current and future 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 impede, or delay or prohibit the further development or commercialization of one or more potential product candidates that rely on such agreements.

Risks Related to Manufacturing

If any third-party manufacturer of BHB-1893 or any future product candidates is unable to increase the scale of its production of BHB-1893 or any future product candidates or increase the product yield of its manufacturing, then our manufacturing costs may increase and commercialization may be delayed.

In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of BHB-1893 or any future product candidates, our third-party manufacturers will be required to increase their production and optimize their manufacturing processes while maintaining the quality of BHB-1893 or any future product candidates. The transition to larger scale production could prove difficult. In addition, if our third-party manufacturers are not able to optimize their manufacturing processes to increase the product yield for BHB-1893 or any future product candidates, or if they are unable to produce increased amounts of BHB-1893 or any future product candidates while maintaining the same quality, then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate profits and have a material adverse impact on our business and results of operations.

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

As product candidates proceed through nonclinical studies to late-stage clinical trials towards potential approval and commercialization, various aspects of the manufacturing process such as manufacturing methods and formulation, may be altered in an effort to optimize processes and product characteristics, and such optimization may not be achieved. Any such changes could cause BHB-1893 or any future product candidates to perform differently and affect the results of our clinical trials, and limit our ability to rely on data from clinical trials conducted with an earlier version of our product candidate. Such changes may also require additional testing, or notification to or approval by the FDA or another comparable regulatory authority. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of BHB-1893 or any future product candidates and jeopardize our ability to commence sales and generate revenue.

If our third-party manufacturers or suppliers do not comply with laws regulating the protection of the environment and health and human safety, our business could be affected adversely.

We and any third-party contract development and manufacturing organizations (“CDMOs”) and suppliers we engage are subject to numerous federal, state and local environmental, health, and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from the use of hazardous materials by us or by one of our third party-manufacturers, we could be held liable for any resulting damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. We and our third-party manufacturers and suppliers cannot eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain general liability insurance as well as workers’ compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities.

In addition, we and our third-party manufacturers and suppliers may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which may increase the cost of their services to us. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities for us or our third-party manufacturers and suppliers, or adversely impact our supply chain or reputation, which could in turn materially adversely affect our business, financial condition, results of operations and prospects.

We rely on Hengrui to manufacture our sole product candidate, BHB-1893, which may increase the risk that we will not have sufficient quantities of our product candidate or products or such quantities at an acceptable time and cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities for the production of clinical or commercial supplies of our sole product candidate, BHB-1893, and we plan to continue outsourcing all manufacturing of BHB-1893 to third parties. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture BHB-1893 on a clinical or commercial scale. Hengrui currently supplies all drug substance and drug product for our clinical development of BHB-1893. We are working to develop ex-China manufacturing pathways with CDMOs, but such alternatives are not yet available and may not be available in a timely manner, if at all. Until alternative supply sources are qualified, we are entirely dependent on Hengrui for clinical supply, and any disruption to Hengrui's manufacturing operations could halt or delay our clinical development. If the Exclusive License Agreement is terminated, then our supply from Hengrui would also be terminated. This reliance increases the risk that we will not have sufficient quantities of BHB-1893, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We are in the process of further establishing agreements with third party manufacturers for the long-term clinical and commercial supply of BHB-1893. We may be unable to conclude agreements for commercial supply with third-party manufacturers, or may be unable to do so on acceptable terms. The third-party manufacturers may not successfully carry out their contractual duties or obligations, the occurrence of which could substantially increase our costs and limit our supply of such product candidates. The demand for third-party manufacturers' services is very high, and such manufacturers could be subject to market transactions including mergers, acquisitions and other market consolidation transactions that limit their ability to provide products and services to us thereby increasing the time and cost it could take us to manufacture our sole product candidate, BHB-1893.

Our reliance on Hengrui and any future reliance on CDMOs for manufacturing activities will reduce our direct control over these activities, but will not relieve us of our responsibility to ensure compliance with all required regulations. In particular, we do not have control over a supplier's or manufacturer's compliance with laws, regulations and applicable cGMP standards or similar regulatory requirements and other laws and regulations, such as those related to environmental health and safety matters. If Hengrui or any future CDMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we may be unable to obtain regulatory approval of our potential future marketing applications. In addition, we have no direct operational control over Hengrui's ability to maintain adequate quality control, quality assurance and qualified personnel. Hengrui or any future CDMOs may face manufacturing or quality control problems causing production and shipment delays, or they may fail to maintain compliance with the applicable cGMP requirements.

Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers, including Hengrui, entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- possible breach of cGMP;
- halt of manufacturing operations due to audit or inspection failures;
- the possible diversion of manufacturing capacity to other customers by the third party;

- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers, including Hengrui, may not be able to comply with cGMP, regulations or similar regulatory requirements outside the U.S. Our failure, or the failure of our third-party manufacturers, including Hengrui, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of BHB-1893 or any future product candidates. The FDA has signaled that foreign GCP inspections will be increasing alongside greater transparency of GCP inspection outcomes. It is possible that Hengrui or other third-party manufacturers may in the future receive allegations of noncompliance or regulatory enforcement that may implicate the production and supplies of BHB-1893 or any future product candidates.

BHB-1893 may compete with other product candidates and products for access to manufacturing facilities. In addition, in order to conduct late-stage clinical trials of BHB-1893, we will need to have it manufactured in large quantities. Hengrui or any future third-party manufacturers may be unable to successfully increase the manufacturing capacity for BHB-1893 in a timely or cost-effective manner, or at all. Moreover, if Hengrui or any future third-party manufacturers are unable to successfully scale up the manufacture of BHB-1893 in sufficient quality and quantity, the development, testing and clinical trials of BHB-1893 may be delayed or infeasible, and regulatory approval of BHB-1893 may be delayed or not obtained, which could significantly harm our business. Similar risks would apply to third-party manufacturing of any future product candidates.

In addition, we rely on Hengrui to transfer manufacturing know how, analytical methods, reference standards and any process improvements relating to BHB-1893, and may in the future similarly rely on licensors and other third-party manufacturers for transfers relating to BHB-1893 or our future product candidates. If we do not receive, retain or are otherwise unable to use such know how, we may incur additional transition costs, need to repeat development or validation activities and experience delays in manufacturing and delivery. Drug substance or drug product supplied by third parties may not comply with regulatory quality requirements or have sufficient stability for commercialization, which could require additional investment, revalidation or process changes and delay our development, approval and commercialization plans. Manufacturing may also depend on raw materials, single source reagents or specialized equipment that may be difficult to secure. Because some supply originates outside the U.S., any delay in obtaining or maintaining required import or export licenses or clearances could delay our timelines. Termination, expiration or breach of our supply, manufacturing or technology transfer arrangements could have a material adverse effect on our business.

If the third parties, including Hengrui, that we engage to manufacture product for our nonclinical studies and clinical trials should cease to continue to do so for any reason, including due to geopolitical disruptions, natural disasters, pandemics, epidemics, trade wars, political unrest, economic conditions, changes in legislation or other events beyond their control, we likely would experience delays in advancing these clinical trials while we identify and qualify replacement suppliers, and we may be unable to obtain replacement supplies on terms that are favorable to us.

Our use of foreign CROs and CDMOs in some other jurisdictions may be or may become subject to U.S. laws, including sanctions, trade restrictions and other regulatory requirements, which may increase the cost of and cause delays in the procurement or supply of materials for, or manufacture of, BHB-1893 or any future product candidates or have an adverse effect on our ability to secure significant commitments from governments to purchase its potential therapies. We are also subject to risks relating to Hengrui's presence in China. See "*Our business is subject to the risks associated with having a collaboration partner and third-party manufacturer based in China.*"

Large pharmaceutical companies with greater resources, either through acquisitions, market consolidation or otherwise, may be able to obtain privileged access to manufacturing capacity and supply of material needed for the manufacture of BHB-1893 or other similar competing drugs. If our competitors are able to use their resources to secure preferential access to the supply capacity of third party manufacturers, or if third party manufacturers elect to terminate any contracts with us in favor of exclusive contracts with other larger pharmaceutical companies, our ability to obtain supply of BHB-1893 or any other future product candidates may be impacted resulting in significant delays and higher costs for development and commercialization of BHB-1893 or any other future product candidates. We may not be able to complete our clinical trials or market BHB-1893 or any other future product candidates at scale without stable partnerships with third party manufacturers. Shifting our manufacturing relationship to another third-party manufacturer takes significant time and resources, and could delay development and commercialization of BHB-1893 or any other future product candidates.

Risks Related to Legal and Regulatory Compliance

Our business operations and our relationships with healthcare providers, third-party payors, patients and other parties in the healthcare industry are subject, directly or indirectly, to significant regulation under a broad range of healthcare laws, including fraud and abuse laws. Any action against us for violation of such laws could harm our reputation and require significant resources for defense. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Pharmaceutical manufacturers, and the parties with which such manufacturers interact, are subject to extensive and complex regulation under a broad range of healthcare laws. Such laws, some of which will apply only if and when we have a marketed product, constrain our business operations, including the research and development, manufacturing, distribution, sales and promotion of BHB-1893 or any future product candidates and products, if any are approved in the future, as well as educational and charitable activities. Arrangements with healthcare providers, third-party payors, patients and other parties in the healthcare industry professionals, which may have a significant impact on our business, are regulated by fraud and abuse and other healthcare laws. For more information, see "*Business—Government Regulation—Other U.S. Healthcare Laws and Compliance Requirements*" in our IPO final prospectus dated August 5, 2026 filed with the SEC.

Healthcare laws regulating our business activities are broad and any exceptions may be narrow. Requirements may differ across jurisdictions. There may be limited guidance on the interpretation of the laws and their application to our specific activities. Interpretations of these laws by government enforcement agencies and courts are evolving. Efforts to ensure that our business operations will comply with applicable healthcare laws and regulations will involve substantial costs. We will need to develop and implement robust compliance policies and processes to seek to prevent and detect non-compliance and update such policies and processes as our operations and government expectations evolve, which will involve substantial and ongoing costs, and even with such policies and processes we cannot be certain to prevent non-compliance.

Given the broad scope, limited guidance and evolving government interpretations, our business activities may nonetheless potentially be subject to challenge under these healthcare laws despite efforts to ensure compliance. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Such an action could also harm our reputation and adversely affect our business as a result. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in federal and state funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations, any of which could harm our business.

Even if we obtain regulatory approvals for BHB-1893 or any future product candidates, they will remain subject to ongoing regulatory oversight.

Even if we obtain any regulatory approvals for BHB-1893 or any future product candidates, such product candidates, once approved, will be subject to ongoing regulatory requirements applicable to manufacturing, labeling, packaging, storage, advertising, promoting, sampling, record-keeping and post-marketing activities, among other things. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and GCP requirements for any clinical trials that we conduct post-approval. Manufacturers of approved products and their facilities are subject to continual review and periodic and unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. Any regulatory approvals that we receive for BHB-1893 or any future product candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or requirements that we conduct potentially costly post-marketing testing, including additional trials and heightened surveillance to monitor the quality, safety and efficacy of the drug. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval. We will further be required to promptly report any serious and unexpected adverse drug experiences and certain quality or production problems with our products to regulatory authorities along with other periodic reports.

Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to ensure compliance. We will also have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drug products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we will not be allowed to promote our products for indications or uses for which they do not have approval, commonly known as off-label promotion. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies, including their sales force, with respect to off-label uses of products for which marketing approval has not been issued. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The holder of an approved NDA must submit new or supplemental applications and obtain prior approval for certain changes to the approved product, product labeling, or manufacturing process. Further, FDA's Office of Prescription Drug Promotion ("OPDP") actively scrutinizes promotional communications, including digital and social media; any materials that are false, misleading or promote unapproved uses can lead to enforcement actions and could necessitate corrective communications. In the current administration, the FDA has increased its enforcement scrutiny over prescription drug advertising, particularly direct-to-consumer product promotion and advertising. If the FDA finds any of our promotional communications or advertising to be violative, we may receive an untitled or warning letter, requests for corrective advertising, or fines, amongst other enforcement tools available to the FDA. Moreover, a company that is found to have improperly promoted off-label uses of their products may be subject to significant civil, criminal and administrative penalties.

In addition, drug manufacturers are subject to payment of annual fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the NDA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with any product, if approved, such as adverse experiences of unanticipated severity or frequency, or problems with the facility where the product is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requesting revisions to the approved labeling to add new safety information, imposing of post-market studies or clinical trials to assess new safety risks or imposing distribution restrictions or other restrictions under a REMS program, requesting a recall or requiring withdrawal of the product from the market or suspension of manufacturing. If we fail to comply with applicable regulatory requirements following approval of BHB-1893 or any future product candidates, a regulatory authority may:

- issue an untitled letter or warning letter asserting that we are in violation of the law or issue unfavorable statements about the safety or effectiveness of our products;
- seek an injunction or product seizure or impose administrative, civil or criminal penalties or monetary fines, disgorgement or profits or revenue;

- suspend or withdraw regulatory approvals;
- restrict product distribution or use, including full or partial holds on any planned clinical trials;
- refuse to approve a pending NDA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the drug;
- seize or detain the drug or otherwise require the withdrawal of the drug from the market;
- refuse to permit the import or export of product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize BHB-1893 or any future product candidates and harm our business, financial condition, results of operations and prospects.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

The U.S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of BHB-1893 or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. For more information, see "*Business—Government Regulation—Healthcare Reform*" in our IPO final prospectus dated August 5, 2026 filed with the SEC.

Our revenue prospects could be affected by changes in healthcare spending and policy in the U.S. and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

Among policy makers and third-party payors in the U.S. and elsewhere, there is significant and ongoing interest in implementing changes in the delivery and payment for healthcare services in order to contain healthcare costs, improve quality and/or expand access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives and changing policies and practices of the third-party payors. There has also been heightened governmental scrutiny in the U.S. of pharmaceutical pricing practices considering the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient support programs, or reform government program reimbursement methodologies for products. As an example, the Inflation Reduction Act of 2022 ("IRA") contains several provisions that will impact our business to varying degrees, including provisions that allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, among others. Further, the IRA also imposed rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our revenue generated from the sale of any approved products. In addition, the recently-enacted One Big Beautiful Bill Act imposes new restrictions on funding for government health care programs and on individual eligibility for coverage under those programs, which may lead to lower reimbursements for drugs covered by those programs.

Other legislative efforts have added government program eligibility work requirements, more frequent eligibility redeterminations, and increased cost-sharing for beneficiaries. Although the effect on our business is currently unknown, any decrease in the number of insured patients or reimbursement levels for our products could adversely affect our revenue and commercial prospects.

Individual states in the U.S. have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Adoption of new legislation at the federal or state level could affect demand for, or pricing of, any future products if approved for sale. We cannot predict the ultimate content, timing or effect of any federal and state reform efforts. There is no assurance that federal or state healthcare reform will not adversely affect our future business and financial results. Additionally, implementation by third party payors of policies and practices to limit coverage, manage utilization, reduce payment of drug products could adversely affect our ability to sell our products profitably. All these efforts may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

In addition, FDA regulations, guidance, or practices may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. If executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for BHB-1893 or any future product candidates. We cannot determine how changes in regulations, statutes, policies or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- significant changes to the design of planned clinical trials that impact their duration or cost;
- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recalls, replacements, or discontinuance of one or more of our products, if approved; and
- additional recordkeeping.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of BHB-1893 or any future product candidates, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory approvals for BHB-1893 or any future product candidates would harm our business, financial condition, and results of operations. Further, we cannot predict the likelihood, nature, or extent of healthcare reform initiatives that may arise from future legislation or administrative action.

General legislative cost control measures may also affect reimbursement for BHB-1893 or any future product candidates. The Budget Control Act, as amended, resulted in the imposition of reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect into 2032 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

The costs of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. To date, there have been several recent U.S. congressional inquiries, as well as proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. The Trump Administration has issued executive orders and supported proposed regulatory initiatives in 2025 that could have a significant impact on the prices that we, or any collaborators, may receive for any approved products.

On May 12, 2025, President Trump signed an executive order directing the Secretary of HHS to set and communicate most-favored-nation ("MFN") price targets to manufacturers and propose a rulemaking plan to

impose MFN pricing if “significant progress” is not made, and also directing the federal government to support regulatory paths to allow direct-to-patient sales for companies that meet these targets. The executive order further states that the Administration will take additional action (for example, examining whether marketing approvals should be modified or rescinded or considering individual drug importation waiver authorities) should manufacturers fail to offer American consumers the MFN lowest price.

In July 2025, President Trump sent letters to certain pharmaceutical companies demanding that these companies extend MFN pricing to Medicaid and newly launched drugs as well as move to direct-to-consumer models priced at MFN pricing, and soliciting binding commitments by September 29, 2025. Since this time, multiple drug manufacturers have announced plans to, for certain of their drugs, lower prices to reflect similar pricing around the world, and to sell these reduced-price drugs on a direct-to-consumer purchasing platform developed by the federal government; however, it is not known what results will occur to the extent the recipients of these letters do not reduce their U.S. prices.

On December 19, 2025, CMS released two proposed rules that would incorporate MFN pricing principles into federal reimbursement for prescription drugs, and on October 2, 2026, CMS published the final rule for the first model, the Global Benchmark for Efficient Drug Pricing Model (“GLOBE”) for Medicare Part B. Under GLOBE, manufacturers of specified single source drugs and sole source biologics are required to pay incremental rebates based on international benchmark prices, with participation triggered for products meeting CMS’s spending and eligibility criteria for such products furnished in randomly selected geographic areas covering approximately 25% of Original Medicare Part B beneficiaries. CMS narrowed GLOBE’s scope relative to the proposed rule, including by excluding orphan-only drugs, plasma-derived products and certain cell and gene therapies. The second proposal, the Guarding U.S. Medicare Against Rising Drug Costs (“GUARD”) model for Medicare Part D, would similarly mandate manufacturer rebates for qualifying sole source drugs where the Medicare net price exceeds an MFN benchmark derived from international reference pricing methodologies. As proposed, GUARD would begin its performance period in 2027. CMS has not finalized GUARD, and we cannot predict whether or when it will be finalized or whether it will include exclusions or waivers similar to those in GLOBE. On October 7, 2026, the Pharmaceutical Research and Manufacturers of America filed suit in the U.S. District Court for the District of Columbia challenging GLOBE and seeking injunctive relief, and we cannot predict the outcome of that litigation or whether GLOBE will take effect on its current timeline. Additionally, in November 2025, CMS introduced the GENErating cost Reductions for U.S. Medicaid (“GENEROUS”) Model, a voluntary MFN framework for manufacturers participating in the Medicaid Drug Rebate Program. Although it is voluntary, the GENEROUS Model could also impact the drug pricing landscape for manufacturers, including because CMS has stated that it intends to waive mandatory GLOBE participation for any calendar quarter in which a manufacturer participates in GENEROUS. GLOBE, GUARD or similar MFN-based models, as finalized, expanded or modified, could adversely affect the prices we or any collaborator may obtain for any approved product.

We expect that healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for BHB-1893 or any future product candidates, if approved, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain and maintain profitability of our product and product candidates, if approved.

Inadequate funding for the FDA, the Securities and Exchange Commission and other government agencies, including from government shut downs, or other disruptions to these agencies’ operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

Over the last several years, the U.S. government has shut down multiple times, and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. Without appropriation of necessary funding to federal agencies or as a result of other presidential actions to reduce government spending or workforce, our business operations related to our product development activities for the U.S. market could be impacted. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key

personnel and accept the payment of user fees, diversion of resources through actions such as the Commissioner's National Priority Voucher Program, and statutory, regulatory, leadership and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the Securities and Exchange Commission (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.

Disruptions and personnel turnover, as a result of leadership changes, staff reductions or otherwise, at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. Changes and cuts in FDA staffing have been reported as creating instances of delays in the FDA's responsiveness or in its ability to review IND submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. There is also substantial uncertainty as to how regulatory reform measures being implemented by the current U.S. administration, and other political developments, such as government shutdowns or work stoppages, would impact other U.S. regulatory agencies, such as the FDA, SEC and USPTO, on which our operations rely. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, the USPTO and the SEC, furloughed critical employees and ceased critical activities. If a prolonged government shutdown occurs or a widespread freeze on federal funding occurs in the future, or if staffing changes prevent the FDA, USPTO or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, including formal and informal interactions with product developers, it could significantly impact the ability of the FDA, USPTO or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. In addition, state governments may seek to address or react to changes at the federal level with changes to their regulatory frameworks in a manner that could impact our operations. Further, in our operations as a public company, future government shutdowns or substantial leadership, personnel, and policy changes could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

If our current or any future product candidates obtain regulatory approval, additional competitors could enter the market with generic versions of such drugs, which may result in a material decline in sales of affected products.

Under the Hatch-Waxman Amendments, a pharmaceutical manufacturer may file an abbreviated new drug application ("ANDA"), seeking approval of a generic copy of an approved, small molecule innovator product. Under the Hatch-Waxman Amendments, a manufacturer may also submit an NDA under section 505(b)(2) that references the FDA's prior approval of the small molecule innovator product. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. The Hatch-Waxman Act also provides for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and reviewing) of an ANDA or 505(b)(2) NDA. These include, subject to certain exceptions, the period during which an FDA-approved drug is subject to orphan drug exclusivity. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." If there are patents listed in the Orange Book, a generic or 505(b)(2) applicant that seeks to market its product before expiration of the patents must include in the ANDA a "Paragraph IV certification," challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the innovator, too, and if within 45 days of receiving notice the innovator sues to protect its patents, approval of the ANDA is stayed for 30 months, or as lengthened or shortened by the court.

Accordingly, if BHB-1893 or any future product candidates are approved, competitors could file ANDAs for generic versions of our drug products or 505(b)(2) NDAs that reference our drug products, respectively. If there are patents listed for our drug products in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict which, if any, patents in our current portfolio or patents we may obtain in the future will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents, or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or license. Moreover, if any of our owned or in-licensed patents that are listed in the

Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could immediately face generic competition and its sales would likely decline rapidly and materially. Should sales decline, we may have to write off a portion or all of the intangible assets associated with the affected product and our results of operations and cash flows could be materially and adversely affected.

Risks Related to the Commercialization of BHB-1893 and Any Future Product Candidates

We face substantial competition. Our main competitors in the HCM market hold substantial market share and have substantially greater resources than we do. We may not be able to compete successfully in this environment and, in particular, against much larger competitors.

The biotechnology and pharmaceutical industries are characterized by rapid advances, intense competition and a strong emphasis on proprietary and novel products and product candidates. We face substantial competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from many different sources, including major pharmaceutical and biotechnology companies, academic institutions, governmental agencies, consortiums and public and private research institutions.

In particular, we expect to compete with BMS' approved product for oHCM, Camzyos® (mavacamten), and Cytokinetics' approved product for oHCM, MYQORZO® (aficamten), as well as additional product candidates in development for the treatment of HCM that would compete with BHB-1893, if approved. Edgewise Therapeutics, Inc. ("Edgewise Therapeutics") is developing EDG-7500, an investigational cardiac sarcomere modulator in clinical development for oHCM and nHCM, for which Edgewise Therapeutics has stated it plans to initiate Phase 3 development in the fourth quarter of 2026. In addition, in August 2026, Cytokinetics announced positive results from ACACIA-HCM, its Phase 3 trial of aficamten in nHCM, an indication we are also targeting, and Cytokinetics has stated that it plans to submit a supplemental new drug application ("sNDA") to the FDA for aficamten in nHCM in the fourth quarter of 2026. If approved, aficamten would be the first approved therapy for nHCM in the United States, which could make it more difficult for BHB-1893 to compete in nHCM. Cytokinetics has also submitted an sNDA to add the results of MAPLE-HCM, a Phase 3 trial comparing aficamten to metoprolol in oHCM, to its label, with a target action date of November 14, 2026. If any of these programs succeed, our commercial opportunity could be materially reduced. BMS holds substantial market share in BHB-1893's proposed markets, and has substantially greater name recognition, financial resources and expertise in research and development, manufacturing, nonclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Our commercial opportunity could be reduced or eliminated if BMS, Cytokinetics, Edgewise Therapeutics, or another competitor develops and commercializes products that are safer or more effective, have fewer or less severe side effects, or are more convenient or are less expensive than any product candidate that we may develop. BMS, Cytokinetics, Edgewise Therapeutics or another competitor may also obtain approval by FDA or comparable foreign regulatory authorities for its product candidates currently in development more rapidly than we may obtain approval for BHB-1893. Competing products could present superior treatment alternatives and could render BHB-1893 or any future product candidates obsolete or noncompetitive before we recover the expense of developing and commercializing BHB-1893 or any future product candidates. Even if BHB-1893 or any future product candidates achieves marketing approval, it may be priced at a significant premium over competitive products, resulting in reduced competitiveness. If we do not compete successfully, we may not generate or derive sufficient revenue from any product candidate for which we obtain marketing approval and may not become or remain profitable.

Smaller or early-stage companies could also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. This may include other small-molecule drug discovery companies using similar approaches or other types of therapies, such as gene therapy, gene editing and/or mRNA therapies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring intellectual property complementary to, or that may be necessary for, our programs. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

Even if BHB-1893 or any future product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If BHB-1893 or any future product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. There is currently a well-established standard of care for HCM, Camzyos® (mavacamten), with which physicians, HCM patients and payors are very familiar and for which an established benefit-risk profile exists. In addition, in December 2025 and February 2026, respectively, the FDA and the European Commission approved MYQORZO® (aficamten) (which has been approved in China and the United Kingdom), which targets the same mechanisms as Camzyos® (mavacamten). Even if BHB-1893 or any future product candidates are successful in registrational clinical trials, they may not be successful in displacing the current standard of care if we are unable to demonstrate competitive efficacy, safety, ease of administration and/or cost-effectiveness. For example, physicians may be reluctant or unwilling to take their patients off their current medication and switch their treatment regimen to BHB-1893 or any future product candidates, if approved, if the current medication is effective. Further, patients often acclimate to the treatment regimen that they are currently taking and may not want to switch unless recommended to do so by their physician for clinical reasons or required to do so due to lack of coverage and adequate reimbursement. Even if we are able to demonstrate BHB-1893 or any future product candidates' safety and efficacy to the FDA and other regulators and receive approval, concerns in the medical community related to the comparative efficacy or side effect profile of our products may hinder market acceptance and uptake.

Efforts to educate the medical community and third-party payors regarding the benefits of BHB-1893 or any future product candidates, if approved, may require significant resources, including management time and financial resources, and may not be successful. We have not yet established a sales force, marketing infrastructure, or distribution capabilities. We will need to build or contract for these capabilities well in advance of any potential approval, which will require substantial capital and management attention. If we are unable to do so, or if we choose to rely on a third party for commercialization and that relationship is unsuccessful, our ability to generate revenue from BHB-1893 could be materially harmed. If BHB-1893 or any future product candidates do not achieve an adequate level of market acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of BHB-1893 or any future product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments;
- whether a product candidate is approved, if ever, as an add-on to standard of care or as part of a proprietary combination therapy;
- the prevalence and severity of any side effects;
- our ability to offer our products at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- product labeling or product insert requirements of the FDA or comparable foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling, including any boxed warning;
- the product's acceptance into current standard of care treatment algorithms by medical societies that could affect payor and physician uptake;
- the effectiveness of sales and marketing efforts, and the strength of sales, marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for any product candidates, once approved;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- any restrictions on the use of our products together with other medications; and
- potential product liability claims and unfavorable publicity related to our products.

Any failure by BHB-1893 or any future product candidates that obtains regulatory approvals to achieve market acceptance or commercial success would adversely affect our business prospects.

The success of BHB-1893 or any future product candidate will depend significantly on coverage and adequate reimbursement by third party payors or the willingness of patients to pay for these products if not covered.

We believe that for BHB-1893 or any future product candidates which may be approved, our success depends on obtaining and maintaining coverage and adequate reimbursement for such products for their respective approved indications, and the extent to which patients will be willing to pay out-of-pocket for such products in the absence of reimbursement for all or part of the cost. Accordingly, we will need to establish a coverage and reimbursement strategy for any approved product candidate. In the U.S. and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Government and private third-party payors decide which products they will cover and establish reimbursement levels. Coverage and reimbursement varies among third party payors and new products face significant challenges in obtaining and maintaining coverage and adequate reimbursement, particularly if approved for indications with established treatments already on the market. For more information, see "*Business—Government Regulation—Coverage and Reimbursement*" in our IPO final prospectus dated August 5, 2026 filed with the SEC.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage for certain products, managing utilization of covered products and restricting the amount of reimbursement for covered products. Within the U.S., net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or requested by private payors in exchange for favorable coverage. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

There can be no assurance that BHB-1893 or any future product candidates, even if they are approved for sale in the U.S. or in other countries, will be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors, or that coverage and an adequate level of reimbursement will be available or that third-party payors' reimbursement policies will not adversely affect our ability to sell BHB-1893 or any future product candidates profitably.

The market for BHB-1893 or any future product candidates may be smaller than we estimate.

Our estimates of the potential market opportunity for BHB-1893 or any future product candidates include, or are expected to include, several key assumptions, based on our industry knowledge, industry publications and third-party research reports. These assumptions include the number of patients who have oHCM and nHCM, as well as the estimated reimbursement levels for each product candidate, if approved. While we believe our assumptions and the data underlying our estimates are reasonable, we have not independently verified the accuracy of the third-party data on which we have based our assumptions and estimates, and these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, including as a result of factors outside our control, thereby reducing the predictive accuracy of these underlying factors. Further, new studies may change the estimated incidence or prevalence of these diseases, and the potentially addressable patient population for BHB-1893 or any future product candidates may not ultimately be amenable to treatment with BHB-1893 or any future product candidates. If the actual market for any product candidates we may develop is smaller than we estimate, our revenues, if any, may be limited and it may be more difficult for us to achieve or maintain profitability.

Clinical trial and product liability lawsuits against us could divert our resources, cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

We face an inherent risk of clinical trial and product liability exposure related to the testing of BHB-1893 or any future product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop, especially if our products are prescribed for off-label uses (even if we do not promote such uses). For example, we may be sued if BHB-1893 or any future product candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing or sale.

Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability and a breach of warranties. Claims may be brought against us by clinical trial participants, patients or others using, administering or selling products that may be approved in the future. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against claims that BHB-1893 or any future product candidates caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for BHB-1893 or any future product candidates that we may develop;
- termination of clinical trials;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards paid to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- reduced resources of our management to pursue our business strategy;
- the inability to commercialize BHB-1893 or any future products that we may develop; and
- a decline in our stock price.

Although we maintain clinical trial liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval on any current or potential product candidates, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Business Operations, Employee Matters and Managing Our Growth

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. Each of our executive officers may currently terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

The loss of the services of our executive officers or other key employees could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approvals of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If

we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Further, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, it may harm our ability to recruit and retain highly skilled employees. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock, particularly after the expiration of the lock-up agreements described herein.

We expect to expand our clinical development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of September 30, 2026, we had 50 full-time employees, including 34 who were engaged in research and development activities. As we continue to build our organization and execute on our strategy, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, regulatory affairs and, if BHB-1893 or any future product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management, business, and development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to manage our growth effectively.

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

We currently operate and plan to operate in a highly regulated industry and we could now or in the future be subject to litigation, government investigation and enforcement actions on a variety of matters in the U.S. or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment and other claims and legal proceedings which 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 such 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 and results of operations. 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 and cause reputational harm.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates FDA or other comparable regulatory authority regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or other comparable regulatory authority, manufacturing standards, foreign, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud and abuse, such as the payment of kickbacks in return for business. 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. Misconduct by these parties could also involve the improper use or misrepresentation of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter 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 be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. Any of these could adversely affect our ability to operate our business and our results of operations.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

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, directors' and officers' and employment practices insurance, however, we may not be able to maintain adequate levels of insurance coverage in the future. Further, an insurance carrier may seek to cancel or deny coverage after a claim has occurred.

We may engage in strategic transactions that could increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, subject us to other risks, adversely affect our liquidity, increase our expenses, present significant distractions to our management and harm our financial condition and results of operations.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and strategic partnerships or out-licensing or in-licensing of intellectual property, product candidates or products. For example, we have entered into a license agreement with Hengrui that gives us exclusive rights to develop and commercialize BHB-1893 worldwide (except Mainland China, Hong Kong, Macau and Taiwan). Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. 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 licensed assets that we may acquire rights to in the future may disrupt our existing business, may cause delays related to the integration of any licensed or acquired assets, and may be a complex, risky and costly endeavor for which we may never realize the full benefits. Furthermore, we may experience losses related to our entry into any licensing or partnerships, including as a result of failure to realize expected benefits or the materialization of unexpected liabilities or risks, which could have a material negative effect on our results of operations and financial condition. 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 have a material adverse effect on our business, results of operations, financial condition and prospects.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations and the operations of our suppliers, CROs, CDMOs and clinical sites could be subject to earthquakes, power shortages, telecommunications or infrastructure failures, cybersecurity incidents, physical security breaches, water shortages, floods, hurricanes, typhoons, blizzards and other extreme weather conditions, fires, pandemics or epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely or expect to rely on third-party manufacturers or suppliers to produce BHB-1893 or any future product candidates and their components and on CROs and clinical sites to conduct our clinical trials, and do not currently have a redundant source of supply for all components of BHB-1893 or any future product candidates. Our ability to obtain clinical or, if approved, commercial, supplies of BHB-1893 or any future product candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption, and our ability to commence, conduct or complete our clinical trials in a timely manner could be similarly adversely affected by any of the foregoing. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Risks Related to Ownership of Our Common Stock and Our Status as a Public Company

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including:

- the timing and success or failure of clinical trials for BHB-1893 or any future product candidates or competing product candidates or any other change in the competitive landscape of our industry;
- our ability to successfully recruit and retain subjects for clinical trials and any delays caused by difficulties in such efforts;
- the timing and cost of, and level of investment in, research, development, regulatory approvals and commercialization activities relating to BHB-1893 or any future product candidates, which may change from time to time;
- the cost of manufacturing BHB-1893 or any future product candidates, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates;
- the level of demand and the indication for any approved products, which may vary significantly;
- the risk/benefit profile, cost, coverage, and reimbursement policies with respect to BHB-1893 or any future product candidates, if approved, and existing and potential future drugs that compete with BHB-1893 or any future product candidates;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- the timing and amount of any milestone, royalty or other payments payable by us or due to us under any collaboration, licensing or other similar agreement; and
- general market and economic conditions, including market conditions in the pharmaceutical and biotechnology sectors.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even if we have met any previously publicly stated revenue or earnings guidance.

The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could lose all or part of their investment.

The market price for our stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. These factors include:

- the commencement, enrollment or results of our clinical trials of BHB-1893 or any future product candidates;
- the success of competitive products gaining approvals or announcements by current and future competitors of their product development efforts;
- ability to obtain and maintain regulatory approval for BHB-1893 or any other product candidate we may develop, or additional indications thereof, or limitations to specific label indications or patient populations for their use, or changes or delays in the regulatory review process;
- our success or failure to identify, develop, acquire or license additional product candidates;
- the degree and rate of physician and market adoption of any of our current and future product candidates, if successfully developed and approved;
- manufacturing, supply or distribution delays or shortages, including our inability to obtain adequate supply of drug product, drug substance, raw materials or any commercially available product to be used in our clinical trials, at acceptable prices, or at all;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- unanticipated serious safety concerns related to the use of BHB-1893 or any future product candidates;
- conditions or trends in our industry;
- changes in the market valuations and stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- sales of our stock by us, our insiders or our stockholders, as well as the anticipation of lock-up releases or expiration of market stand-off or lock-up agreements;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, capital commitments or divestitures;
- recruitment or departure of senior management, directors or key personnel;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for BHB-1893 or any future product candidates;
- significant lawsuits, including patent or stockholder litigation;
- changes in the structure of healthcare payment systems;
- changes in accounting standards, policies, guidelines, interpretations or principles;
- regulatory or legal developments in the U.S. and foreign countries;

- general economic, industry, geopolitical and market conditions, such as military conflict or war, inflation and financial institution instability, or pandemics or epidemics, many of which are beyond our control; and
- other events or factors, many of which are beyond our control.

The stock market in general, and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the risks described in this section, or any of a broad range of other risks, could have a material adverse impact on the market price of our common stock. In the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted, could result in substantial costs and divert management's attention and resources.

We may not be able to satisfy listing requirements of Nasdaq or maintain a listing of our common stock on Nasdaq.

We must meet certain financial and liquidity criteria to maintain our common stock's listing on Nasdaq. If we violate Nasdaq's listing requirements, our common stock may be delisted. If we fail to meet any of Nasdaq's listing standards, our common stock may be delisted. In addition, our board of directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. A delisting of our common stock from Nasdaq may materially impair our stockholders' ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. The delisting of our common stock could significantly impair our ability to raise capital and the value of your investment.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This 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 could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly and impair our ability to raise adequate capital through the sale of additional equity or equity-linked securities.

As of September 30, 2026 we had 89,867,737 shares of common stock outstanding, including 7,798,660 shares of unvested restricted common stock. Of these, 24,437,500 shares sold in the IPO have been freely tradable immediately after the IPO and substantially all of the additional shares of common stock will be available for sale in the public market beginning 180 days after the date of our IPO final prospectus dated August 5, 2026 filed with the SEC following the expiration of lock-up agreements between our directors, officers, substantially all of our stockholders and the underwriters.

In addition, following the closing of the IPO, we filed a registration statement on Form S-8 under the Securities Act of 1933, as amended (the "Securities Act"), registering the issuance of 24,410,461 shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements on Form S-8 are available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and the restrictions of Rule 144 in the case of our affiliates.

Additionally, the holders of an aggregate of 49,657,532 shares of our common stock, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws may significantly reduce the value of our shares to a potential acquiror or make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock and may fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents also contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors will be elected each year;
- stockholders are not entitled to remove directors other than by a two-thirds vote and only for cause;
- stockholders are not permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

As of the date of this Quarterly Report, our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates beneficially own approximately 55.9% of our outstanding common stock. As a result, these persons, acting together, would be able to control certain matters requiring stockholder approval, including the election of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the current market price of our common stock and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

We have broad discretion in the use of our cash, cash equivalents, and investments, and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

Our management has broad discretion in the application of our cash, cash equivalents, and investments, including the net proceeds from the IPO, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply our funds effectively could result in financial losses that could have a material adverse impact on our business, cause the price of our common stock to decline, and delay the development of our product candidates. Pending their use, we may invest our cash, cash equivalents, and investments, in a manner that does not produce income or that loses value.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation of our common stock, if any, will be your sole source of gains and you may never receive a return on your investment.

You should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth 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 will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

Our amended and restated bylaws designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, 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 bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of, or a claim based on, fiduciary duty owed by any of our current or former directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws (including the interpretation, validity or enforceability thereof), or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery of the State of Delaware having personal jurisdiction over the indispensable parties named as defendants therein (the "Delaware Forum Provision"). The Delaware Forum Provision does not apply to any causes of action arising under the Securities Act or the Securities Exchange Act of 1934, as amended (the "Exchange Act"). 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. 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 bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the U.S. shall be the sole and exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act (the "Federal Forum Provision"). In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the U.S. may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies, in part, on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

General Risk Factors

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

In the ordinary course of our business, we and the third parties upon which we rely, process, collect, receive, store, use, transfer, protect, secure, dispose of, transmit, and share collectively referred to as processing proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property and trade secrets, collectively referred to as sensitive information. The secure processing, maintenance and transmission of sensitive information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions.

Cyber-attacks, malicious internet-based activity, online and offline fraud, security breaches and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which 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. These risks, as well as the number and frequency of cybersecurity events globally, may also be heightened during times of war or other major conflicts. In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm and diversion of funds.

We currently rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, employee email, and other functions. We also currently rely on commercially available tools from third-party service providers to process and safeguard our sensitive information and business data. 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 our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers 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.

Although, to our knowledge, we have not experienced any material security breach to date, we have experienced and may continue to experience threats or system failures which 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 information or our information technology systems, or those of the third parties upon whom we rely. For example, the loss of clinical trial data from our or Hengrui’s completed or ongoing or planned clinical trials could result in delays in our regulatory approvals efforts and significantly increase our costs to recover or reproduce the data. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents.

We may not be able to detect and remediate vulnerabilities in our information technology systems because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. It is not possible to prevent all threats to our information technology systems and those of our third-party service providers, over which we exert less control, and any controls we implement to do so may prove to be ineffective.

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 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 information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause delays or disruptions in our clinical trials and development of product candidates, deter customers from using our products, and negatively impact our ability to grow and operate our business.

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or enforcement actions, litigation, fines and penalties, criminal sanctions, disruptions of our business operations, reputational harm, loss of revenue or profits, and other adverse consequences.

In the ordinary course of business, we and third parties we rely on process personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about clinical trial participants and sensitive third-party data. Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, and contractual requirements.

The global legislative and regulatory framework governing personal data processing is rapidly evolving, increasingly complex, and subject to differing interpretations by courts and regulatory authorities, creating significant uncertainty. We must devote substantial resources to monitoring and complying with these developments, and there can be no assurance that our compliance efforts will be successful. Failure to comply, actual or perceived, may expose us to enforcement actions, private rights of action in certain jurisdictions, significant monetary penalties, and, in some cases, criminal sanctions.

In the United States, we are subject to numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure, transfer, security and processing of personal information, including federal and state health information privacy laws, security breach notification laws, and consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act). In addition, we may obtain health information from third parties (including research institutions) that are subject to HIPAA, which imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. We could be subject to criminal penalties if we knowingly obtain, use or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Regulators and legislators in the U.S. are increasingly scrutinizing and restricting certain cross-border data transfers and transactions involving certain foreign countries. In particular, the U.S. Department of Justice issued a rule referred to as the "Data Security Program" (the "DSP") to implement Executive Order 14117 effective as of April 8, 2025. The DSP prohibits or restricts certain transactions that involve access by "countries of concern" (including China) or "covered persons" (as defined in the DSP) to "government-related" or "bulk U.S. sensitive personal data," including but not limited to personal health data, genomic and other 'omic data and certain biospecimens of U.S. persons, or government-related data. Unless an exemption applies, the DSP does not exempt key-coded or otherwise anonymized, pseudonymized, de-identified or encrypted data. The DSP prohibits, among other things, a U.S. person from knowingly providing countries of concern or covered persons with access to bulk U.S. sensitive personal data through "data brokerage" transactions, or, if pursuant to a vendor, employment, or investment agreement, providing countries of concern or covered persons with access to bulk U.S. human 'omic data and related biospecimens. In addition, unless exempt, the DSP also restricts the provision of bulk U.S sensitive personal data (excluding human 'omic data and related biospecimens) to countries of concern or covered persons in the context of vendor agreements, employment agreements, and investment agreements, meaning such transactions can only occur if certain compliance obligations prescribed by the DSP are implemented. To date, we have not collected any human 'omic data or related biospecimens of U.S. persons. However, we may collect these data in connection with our Phase 3 clinical trials. If we collect human epigenomic, proteomic, or transcriptomic data on more than 1,000 U.S. persons or human genomic data on more than 100 U.S. persons (or biospecimens from which such data could be derived) and access to those data by covered persons is not exempt under the DSP, our relationship with Hengrui may have to change to ensure we are not in violation of the DSP. In addition, if we collect, store or maintain any other categories of bulk U.S. sensitive person data – for example, personal health data on greater than 10,000 U.S. persons – we may be required to implement security requirements issued by the Cybersecurity and Infrastructure Security Agency and additional compliance obligations under the DSP.

Compliance with the DSP may require us to invest heavily in data security and compliance measures, including recordkeeping, reporting, and auditing requirements. It may also require us to implement new processes, stop or restrict the provision of certain data access, including data access by Hengrui, or cease relationships with certain third parties or using certain tools or vendors, any of which could materially impact our business operations or hinder our ability to conduct clinical trials. Any actual or alleged violations of the DSP may be punishable by criminal and/or civil sanctions, injunctions, or other enforcement actions, which could materially adversely affect our business, results of operations, and financial condition.

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 individuals certain rights concerning their personal data. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these states exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. Furthermore, other states have proposed or enacted legislation that is focused on more narrow aspects of privacy. For example, a number of states have passed laws that protect biometric information and a smaller number of states have passed or are considering laws that are specifically focused upon health privacy, such as Washington's My Health My Data Act. The My Health My Data Act imposes new state restrictions and requirements on the processing and sale of consumer health data and creates a private right of action. The effects of state privacy laws are potentially significant and may require us to modify our data processing practices and policies and to incur substantial costs and potential liability in an effort to comply with such legislation.

Outside the U.S., an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, if we commence clinical trials in Europe, our processing of personal data in that context would become subject to the European Union's General Data Protection Regulation ("EU GDPR"), and/or the United Kingdom's so-called "UK GDPR" (together, the "GDPR"). The GDPR is wide-ranging in scope and imposes numerous requirements on companies that are subject to it, including having a legal basis for processing personal data, restrictions on the processing of sensitive data (such as health data), obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, notification of data breaches, requiring data protection impact assessments for high risk processing and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union and the UK, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million (£17.5 million) or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the U.S. or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the United Kingdom ("UK") have significantly restricted the transfer of personal data to the U.S. and other countries whose privacy laws it considers inadequate. Other jurisdictions may adopt similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the U.S. in compliance with law, these mechanisms are subject to legal challenges and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the U.S. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the U.S., or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the U.S., are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Additionally in the EEA, the NIS ("Network and Information Security") 2 Directive ("NIS 2") is replacing the cybersecurity legal framework under the current NIS framework, aiming to ensure a high level of cybersecurity in the region. The majority of obligations will come into force when national legislation implementing NIS 2 becomes effective in the relevant Member State. Member States had until October 17, 2024 to transpose NIS 2 into national legislation, although many countries have still not completed the transposition. As such, the cybersecurity regulatory landscape in the EEA is currently fragmented and uncertain. To the extent we are subject to NIS 2, we will require additional investment of our resources in compliance programs. Under NIS 2 companies may be subject to administrative fines of up to the higher amount of €10 million or 2% of worldwide turnover.

In addition to privacy and data 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 contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. If any privacy policies, marketing materials and other statements regarding data privacy and security that we publish are found to be deficient, lacking in transparency, deceptive, unfair or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, including the Federal Trade Commission, or other adverse consequences.

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 on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties we rely on fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we may 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); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials and development of product candidates); 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; adverse publicity; or substantial changes to our business model or operations.

We are subject to governmental export and import controls, economic sanctions, anti-corruption laws and regulations of the U.S. and other jurisdictions. We can face criminal liability and other serious consequences for violations of these laws and regulations, which could harm our business.

We are subject to and required to comply with various export control, import and trade and economic sanctions laws and regulations, including the U.S. Export Administration Regulations, U.S. customs and import regulations, and sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control (collectively referred to as "Trade Laws"). The Trade Laws may prohibit or restrict our ability to transfer, sell or supply, our products to certain governments, persons, entities, countries, and territories, including those that are the target of comprehensive sanctions or an embargo, such as Cuba, Iran, North Korea, the Crimea, the so-called Luhansk People's Republic, and the so-called Donetsk People's Republic regions of Ukraine.

Tariffs levied by the U.S. and other countries also may adversely affect financial markets and the global economy. For example, in early 2025, the U.S. imposed tariffs on imports on its trading partners, including Canada, Mexico, the EU and China. Historically, tariffs have led to increased trade and political tensions in the international community. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Tariffs could have a material adverse effect on our supply chain and business prospects as well as the larger biopharmaceutical industry. While certain tariffs have subsequently been suspended, modified or temporarily reduced, we cannot predict the results of trade negotiations between the U.S. government and other governments or the outcome of ongoing legal challenges to specific tariff policies.

Our reliance on third-party manufacturers, CROs, CDMOs, and international collaborators increases the risk that violations of Trade Laws could occur, including through the actions of third parties while acting on our behalf, even if such violations are inadvertent or unauthorized. These Trade Laws are complex, frequently changing and subject to evolving interpretations and enforcement priorities. Changes in the Trade Laws could result in a decreased ability to export or sell our products to existing or potential customers with international operations. Future changes in Trade Laws and enforcement could also result in increased compliance requirements and related costs which could materially adversely affect our business, results of operations, financial condition or cash flows.

We are also subject to anti-corruption and anti-bribery laws, including the U.S. Foreign Corrupt Practices Act of 1977, as amended (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 and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws, including the FCPA, generally prohibit companies and their employees, agents, CROs, contractors and other partners from offering, promising, giving, soliciting or authorizing others to give or receive anything of value, either directly or indirectly, to or from a non-U.S. government official in order to influence official action, or otherwise 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. Though we may implement policies and procedures reasonably designed to promote compliance with the FCPA and other anti-corruption laws, there is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA or other legal requirements. We can be held liable for the corrupt or other illegal activities of our employees, agents, CROs, contractors, and other partners, even if we do not explicitly authorize or have actual 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, damages, and legal expenses, reputational harm, and other consequences, which could have an adverse impact on our business, results of operations, financial condition or cash flows.

Artificial intelligence presents risks and challenges that can impact our business, including by posing cybersecurity risks to our confidential information, proprietary information, and personal data.

We may use, and our vendors may incorporate, artificial intelligence ("AI"), both in our own development and implementation of AI and through the adoption of commercially available tools. The use of AI presents risks and challenges that could adversely affect our business and reputation, including cybersecurity, data privacy, IT, confidentiality, regulatory, legal, operational, competitive, reputational, intellectual property and other risks. For example, use of certain AI tools may increase the risk of unauthorized disclosure of confidential information, compromise of proprietary intellectual property, or inadvertent inclusion of third-party intellectual property or other protected material, which could result in disputes, claims of infringement, legal liabilities or financial losses. The rapidly evolving regulatory landscape surrounding AI also poses a risk, as new laws and regulations could impose additional compliance burdens, resulting in increased operational costs to comply with U.S. and non-U.S. laws concerning the use of AI, the nature of which cannot be determined at this time.

Additionally, our vendors may incorporate AI tools into their offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. The use of generative AI models in our internal or third-party systems may create new attack surfaces or methods for adversaries, which could impact us and our vendors. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

If we fail to maintain an effective system of internal controls over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”), and the rules and regulations of the stock market on which our common stock is listed. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting.

Commencing with our second annual report on Form 10-K for the fiscal year ending December 31, 2027, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. Prior to the IPO, we have never been required to test our internal control within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner. In addition, when we lose our status as an “emerging growth company” and if we do not otherwise qualify as a “non-accelerated filer,” our independent registered public

accounting firm will be required to attest to the effectiveness of our internal control over financial reporting, which will require additional expense, resources and management commitment.

We may identify material weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities.

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

We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, 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 errors or mistakes. 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 or insufficient disclosures due to error or fraud may occur and not be detected.

We might not be able to utilize a significant portion of our net operating loss carryforwards.

We have generated, and expect to continue to generate, significant net operating loss ("NOL") carryforwards. As of December 31, 2025, we had federal net operating loss carryforwards of $ 4.3 million. Under current tax laws and regulations, these NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. The Company's federal NOLs generally may be carried forward indefinitely, but the deductibility of such federal NOLs is limited.

In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes as a result of the IPO and/or subsequent shifts in our stock ownership which may be out of our control. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs by federal or state taxing authorities or other unforeseen reasons, portions of our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities.

New tax laws or regulations, changes to existing tax laws or regulations or changes in their application to us may have a material adverse effect on our business, cash flows, financial condition or results of operations.

U.S. federal, state, local and foreign tax laws, regulations and administrative guidance are subject to change as a result of the legislative process and review and interpretation by the U.S. Internal Revenue Service, the U.S. Treasury Department and other taxing authorities. Changes to tax laws (which changes may have retroactive application), including with respect to net operating losses and research and development tax credits, could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge

investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

We are an "emerging growth company" and a "smaller reporting company" and, as a result of the reduced disclosure and governance requirements applicable to emerging growth companies and smaller reporting companies, our common stock may be less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). For as long as we continue to be an emerging growth company, we may take advantage of certain exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting; providing only two years of audited financial statements in addition to any required unaudited interim financial statements and a correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this Quarterly Report;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we will 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. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a large accelerated filer, which means, among other conditions, that the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Under Section 107(b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies, and we expect to rely on this exemption. Even after we no longer qualify as an emerging growth company, we may, under certain circumstances, still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We incur increased costs and demands upon management as a result of being a public company.

As a public company, we incur significant additional legal, accounting and other costs that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, Sarbanes-Oxley, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and certain corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say on pay" voting requirements that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have an adverse effect on our business. The increased costs will increase our net loss, and may require us to reduce costs in other areas of our business.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Adverse market or macroeconomic conditions or market volatility resulting from geopolitical events, economic developments, political unrest, high inflation, rising interest rates, new or increased tariffs and retaliatory tariffs, changes in international trade relationships, military conflicts, or other factors could materially and adversely affect our business operations.

Our business could be adversely affected by unstable economic and political conditions within the U.S. and foreign jurisdictions, such as economic downturn, changes in or disruptions of U.S. governmental agencies, whether from U.S. federal government shutdowns or reduced resources, changes to policy implemented by legislative and executive bodies that affect the geopolitical landscape, and other geopolitical events. The global economy and financial markets have experienced volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, actual or perceived changes in interest rates, inflation, declines in economic growth, global supply chain disruptions, increases in unemployment rates, and uncertainty about economic stability. Current inflationary trends in the global economy may impact salaries and wages, costs of goods and transportation expenses, among other things, and recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures may create market and economic instability. There can be no assurance that further deterioration in global economy and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including a decrease in the demand for our product candidates and in our ability to enter into agreements on acceptable terms.

The global economy and financial markets may also be adversely affected by the current or anticipated impact of political uncertainty, including military conflict, terrorism or other geopolitical events, including the ongoing war in Ukraine, the ongoing war in Iran, the Israel-Gaza conflict and the increasingly strained relationship between the U.S. and China. Although the length and impact of the ongoing military conflicts are highly unpredictable, these conflicts could lead to market disruptions, including significant volatility in commodity prices, availability of the credit markets and capital markets. Sanctions imposed by the U.S. and other countries in response to such conflicts may also continue to adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability.

Any disruptions to our supply chain as a result of unfavorable global economic conditions, including due to geopolitical conflicts or public health crises, could negatively impact the timely execution of our ongoing and future clinical development plans. In addition, there is a risk that our current or future service providers, manufacturers or other collaborators may not survive such difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business.

We may become involved in litigation that could divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.

From time to time, we may be subject to litigation claims through the ordinary course of our business operations regarding, but not limited to, securities litigation, employment matters, security of patient and employee personal data, contractual relations with collaborators and licensors and intellectual property rights. We may be exposed to such litigation even if no wrongdoing on our part has occurred. Litigation to defend ourselves against claims by third parties, or to enforce any rights that we may have against third parties, could result in substantial costs and diversion of our resources, causing a material adverse effect on our business, financial condition, results of operations or cash flows.

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

(a) Recent Sales of Unregistered Equity Securities

None.

(b) Use of Proceeds from Initial Public Offering

On August 5, 2026, our Registration Statement on Form S-1 (No. 333-298034) for our IPO was declared effective by the SEC, pursuant to which we issued and sold an aggregate of 24,437,500 shares of common stock (inclusive of 3,187,500 shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares) at a public offering price of $18.00 per share for aggregate gross proceeds of approximately $439.9 million and aggregate net cash proceeds of approximately $404.4 million, after deducting underwriter discounts and commissions of $30.8 million and other offering costs of $4.7 million.

Our IPO closed on August 7, 2026. Goldman Sachs & Co. LLC, Jefferies LLC, TD Securities (USA) LLC, Stifel, Nicolaus & Company, Incorporated, and Cantor Fitzgerald & Co., acted as joint bookrunning managers for the IPO.

None of the expenses associated with our IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to our affiliates.

There has been no material change in the planned use of proceeds from our IPO as described in our IPO final prospectus dated August 5, 2026 filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended.

(c) Issuer Repurchases of Securities

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

(a) None.

(b) None.

(c) During the three months ended September 30, 2026, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated any “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as those terms are defined in Item 408 of Regulation S-K.

Item 6. Exhibits

Exhibit Number	Description
3.1	Second Amended and Restated Certificate of Incorporation of Braveheart Bio, Inc. (incorporated by reference to Exhibit 3.1 to the Company’s Current Report on Form 8-K filed on August 7, 2026).
3.2	Second Amended and Restated Bylaws of Braveheart Bio, Inc. (incorporated by reference to Exhibit 3.2 to the Company’s Current Report on Form 8-K filed on August 7, 2026).

4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 (File No. 333-297456) filed on July 30, 2026).
10.1#	Braveheart Bio, Inc. 2026 Stock Option and Incentive Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1 (File No. 333-297456) filed on July 30, 2026).
10.2#	Braveheart Bio, Inc. 2026 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1 (File No. 333-297456) filed on July 30, 2026).
10.3#	Form of Indemnification Agreement, by and between the Registrant and its directors and executive officers (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1 (File No. 333-297456) filed on July 30, 2026).
10.4#	Senior Executive Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 333-297456) filed on July 14, 2026).
10.5#	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-297456) filed on July 30, 2026).
10.6#	Compensation Recovery Policy (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1 (File No. 333-297456) filed on July 14, 2026).
10.7#	Form of Amended and Restated Executive Employment Agreement (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1 (File No. 333-297456) filed on July 30, 2026).
10.8#	Executive Severance and Change in Control Plan and Summary Plan Description (incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1 (File No. 333-297456) filed on July 30, 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 and 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)

* Filed herewith.

** The certifications furnished in Exhibit 32.1 are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be “filed” for purposes of Section 18 of the Exchange Act, except to the extent that the Registrant specifically incorporates it by reference.

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Quarterly Report on Form 10-Q to be signed on its behalf by the undersigned, thereunto duly authorized.

BRAVEHEART BIO, INC.

Date: November 10, 2026

By: /s/ Travis Murdoch, M.D.
Name: Travis Murdoch, M.D.
Title: Chief Executive Officer and President
(principal executive officer)

BRAVEHEART BIO, INC.

Date: November 10, 2026

By: /s/ J. Paul Rickey
Name: J. Paul Rickey
Title: Chief Financial Officer
(principal financial and 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, Travis Murdoch, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Braveheart Bio, 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (c) 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

   (d) 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: November 10, 2026

By: /s/ Travis Murdoch, M.D.

Travis Murdoch, M.D.
Chief Executive Officer and President
(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, J. Paul Rickey, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Braveheart Bio, 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   (c) 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

   (d) 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: November 10, 2026

By: /s/ J. Paul Rickey

J. Paul Rickey
Chief Financial Officer
(principal financial and 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 on Form 10-Q of Braveheart Bio, Inc. (the "Company") for the period ending September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 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, as amended; 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: November 10, 2026 By: /s/ Travis Murdoch, M.D.

Travis Murdoch, M.D.
Chief Executive Officer and President
(principal executive officer)

Date: November 10, 2026 By: /s/ J. Paul Rickey

J. Paul Rickey
Chief Financial Officer
(principal financial and accounting officer)