UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 8, 2026

Braveheart Bio, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-43432**	**99-2981994**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

One Letterman Drive, Building A, Suite A4-300 San Francisco, CA	**94129**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 415-707-6312

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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. ☐

Item 2.02 Results of Operations and Financial Condition.

On September 8, 2026, Braveheart Bio, Inc. (the "Company") announced its financial results and business highlights for the quarter ended June 30, 2026. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information included under Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release issued by Braveheart Bio, Inc. on September 8, 2026, furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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SIGNATURE

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

Braveheart Bio, Inc.

Date: September 8, 2026

By: /s/ J. Paul Rickey
Name: J. Paul Rickey
Title: Chief Financial Officer

Braveheart Bio Reports Second Quarter 2026 Financial Results and Provides Business Update

Phase 3 LIONHEART-HCM Trial of BHB-1893 in Obstructive Hypertrophic Cardiomyopathy (oHCM) Initiated

Cash and Cash Equivalents of $122.8 Million as of June 30, 2026, or $527.3 Million After Giving Effect to Braveheart Bio's Initial Public Offering, Expected to Support Advancement of BHB-1893 Through Late-Stage Clinical Development

SAN FRANCISCO, September 8, 2026: Braveheart Bio, Inc. (Nasdaq: BRVE), a clinical-stage biopharmaceutical company developing next-generation therapeutics for hypertrophic cardiomyopathy ("HCM") and other serious cardiovascular diseases, today reported unaudited financial results for the second quarter ended June 30, 2026, and provided a business update.

"Our clinical programs continue to advance, and our IPO this summer has provided a strong financial foundation to advance the development of our global Phase 3 programs and evaluate the potential of BHB-1893 as the preferred treatment option in two indications," said Travis Murdoch, M.D., Chief Executive Officer and President of Braveheart Bio. "Sites are being activated and patients are screening for our LIONHEART-HCM Phase 3 study in obstructive HCM ("oHCM"), and we are on track to dose the first patient this year. We continue to expect results from an interim analysis from LIONHEART-HCM in the second half of 2027. In addition, our program in non-obstructive HCM ("nHCM") is advancing; we now have an active U.S. investigational new drug application ("IND") and expect to initiate our NOBLEHEART-HCM Phase 3 study in the first half of 2027."

Second Quarter and Recent Business Highlights

BHB-1893 Clinical Development

- In May 2026, Braveheart Bio and Hengrui Pharmaceuticals Co., Ltd. announced results from a randomized, double-blind, placebo-controlled Phase 2 trial evaluating HRS/BHB-1893 in nHCM. The results were featured in a late-breaking presentation at the 2026 annual meeting of the Heart Failure Association of the European Society of Cardiology. In this trial, BHB-1893-treated patients were observed to have rapid, substantial, and statistically significant reductions in secondary endpoints that are cardiac biomarkers, which were observed to rapidly reverse during trial drug washout. Patients' functional status and exercise capacity were also higher at the end of the trial compared to baseline. On echo, BHB-1893 treated patients showed statistically significant, dose-dependent improvements in myocardial relaxation, hemodynamic benefit, and cardiac remodeling compared to placebo-treated patients, including observed improvements in diastolic function. Additionally, no patients in the intervention cohorts required trial drug interruption for LVEF reductions, which, together with BHB-1893's pharmacokinetic profile, supports a generally favorable profile. Braveheart Bio has an open IND, and expects to initiate NOBLEHEART-HCM, a global Phase 3 trial in nHCM in the first half of 2027.
- Following Phase 2 oHCM results announced in March 2026, Braveheart Bio has 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 oHCM.

Additional Highlights

- In April 2026, Braveheart Bio completed the third closing of its Series A preferred stock financing, issuing an aggregate of 60,000,000 shares at $1.00 per share for gross proceeds of $60.0 million.
- Braveheart Bio completed an initial public offering in August 2026, issuing an aggregate of 24,437,500 shares of common stock at $18.00 per share for gross proceeds of approximately $439.9 million. Braveheart Bio's common stock began trading on the Nasdaq Global Market under the ticker symbol "BRVE" on August 6, 2026.

Second Quarter 2026 Financial Results

Cash and cash equivalents were $122.8 million as of June 30, 2026, compared to $89.2 million as of December 31, 2025. The June 30, 2026 balance does not reflect the net proceeds from Braveheart Bio's initial public offering ("IPO"), which closed in August 2026. The IPO resulted in aggregate net proceeds of approximately $404.5 million, after deducting underwriting discounts and commissions and offering expenses payable by Braveheart Bio. Including those net proceeds, cash and cash equivalents would have been approximately $527.3 million on an as-adjusted basis. Based on the current operating plan, Braveheart Bio estimates that its existing cash and cash equivalents, together with the net proceeds from its IPO, will be sufficient to fund its projected operating expenses and capital expenditure requirements into 2029.

Research and development (R&D) expenses were $11.1 million for the three months ended June 30, 2026, compared to $0.0 million for the same period in 2025. The increase was primarily due to the advancement of BHB-1893, preparation for the planned global Phase 3 program, and higher personnel-related costs.

General and administrative (G&A) expenses were $4.8 million for the three months ended June 30, 2026, compared to less than $0.1 million for the same period in 2025. The increase was primarily due to increased headcount and costs incurred to support Braveheart Bio's increased operations, business development, and preparation for operating as a public company.

Net loss was $15.0 million, and net loss attributable to common stockholders, after a deemed dividend upon the issuance of Series A preferred stock, was $18.6 million or $2.51 net loss per share, basic and diluted, for the three months ended June 30, 2026, compared to a net loss of $0.4 million, or $0.14 net loss per share, basic and diluted, for the same period in 2025.

The deemed dividend of $3.6 million is a non-cash charge representing the excess of the estimated fair value of the Series A preferred stock issued in April 2026 over the $1.00 per share purchase price. It increased net loss attributable to common stockholders for purposes of computing net loss per share and did not affect net loss or cash flows.

All share and per share amounts for all periods presented have been retroactively adjusted to give effect to the 1-for-4.38 reverse stock split of the Braveheart Bio's common stock effected on July 29, 2026.

As of September 3, 2026, Braveheart Bio had 90,038,969 shares of common stock outstanding, reflecting the conversion of all outstanding preferred stock into common stock and the issuance of 24,437,500 shares in Braveheart Bio's IPO, each of which occurred after June 30, 2026.

About Braveheart Bio

Braveheart Bio is a clinical-stage biopharmaceutical company focused on developing therapies for patients with hypertrophic cardiomyopathy (HCM) and other serious cardiovascular diseases. Braveheart Bio's lead product candidate, BHB-1893, is a next-generation oral small-molecule cardiac myosin inhibitor (CMI) being developed for the treatment of obstructive HCM (oHCM) and non-obstructive HCM (nHCM). Braveheart Bio is aiming to address the limitations of currently available CMIs by designing BHB-1893 for rapid onset, consistent depth of response, preservation of systolic function, prompt reversibility, and a straightforward approach to titration and monitoring. For more information, please visit www.braveheart.bio.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of, and made pursuant to the safe harbor provisions of, the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, each as amended. The words such as "anticipate," "believe," "expect," "intend," "may," "plan," "potential," "should," "will" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, express or implied statements regarding: the clinical development of BHB-1893 and other product candidates, including the initiation, timing, progress, results and future data releases of ongoing and planned clinical trials; the timing of initiation as well as expected results from the NOBLEHEART-HCM global Phase 3 trial; Braveheart Bio's interactions and communications with regulatory authorities and timing as well as anticipated results of submissions; the beneficial characteristics, and the potential safety, efficacy and therapeutic effects of Braveheart Bio's product candidates; its ability to develop and advance its potential future product candidates and programs; and expectations for the Braveheart Bio's uses of capital, expenses and financial results, including its cash runway into 2029.

Any forward-looking statements in this press release are based on Braveheart Bio's current expectations and assumptions. These statements are neither promises nor guarantees and involve risks, uncertainties and other important factors that could cause actual results to differ materially from those expressed or implied by the forward-looking statements, including, without limitation, risks relating to: Braveheart Bio's research and development activities; Braveheart Bio's ability to obtain the requisite regulatory approvals on the expected timeline, if at all; uncertainties relating to clinical development activities; Braveheart Bio's dependence on third parties to conduct clinical trials, manufacture its product candidates and develop and commercialize its product candidates, if approved; Braveheart Bio's ability to attract, integrate and retain key personnel; risks related to Braveheart Bio's financial condition and need for substantial additional funds in order to complete development activities and commercialize a product candidate, if approved; risks related to regulatory developments and approval processes of the U.S. Food and Drug Administration and comparable foreign regulatory authorities; risks related to establishing and maintaining Braveheart Bio's intellectual property protections; and risks related to the competitive landscape for Braveheart Bio's product candidates; as well as the other risks and uncertainties described under the heading "Risk Factors" section in Braveheart Bio's upcoming Quarterly Report on Form 10-Q for the quarter ended June 30, 2026 and any subsequent filings Braveheart Bio makes with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date of this press release. Except as required by applicable law, Braveheart Bio undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Braveheart Bio intends to use its Investor Relations website as a means of disclosing material nonpublic information and for complying with its disclosure obligations under Regulation FD. Accordingly, investors should monitor Braveheart Bio's Investor Relations website, in addition to following Braveheart Bio's press releases, SEC filings, public conference calls, presentations, and webcasts.

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

	Three Months Ended		Six Months Ended	
	June 30, 2026	June 30, 2025	June 30, 2026	June 30, 2025
Operating expenses				
Research and development (includes related party amounts of $389 and $6,389 for the three and six months ended June 30, 2026, respectively)	$ 11,125	$ —	$ 22,039	$ —
In-process research and development	—	354	—	448
General and administrative (includes nominal related party amounts for the three and six months ended June 30, 2026, respectively)	4,757	27	8,892	32
Total operating expenses	15,882	381	30,931	480
Loss from operations	(15,882)	(381)	(30,931)	(480)
Other income				
Interest income	889	—	1,660	—
Other income	5	—	3	—
Total other income	$ 894	$ —	$ 1,663	$ —
Net loss	$ (14,988)	$ (381)	$ (29,268)	$ (480)
Deemed dividends upon issuance of redeemable convertible preferred stock	(3,615)	—	(3,615)	—
Net loss attributed to common stockholders	$ (18,603)	$ (381)	$ (32,883)	$ (480)
Net loss per share, basic and diluted	$ (2.51)	$ (0.14)	$ (4.61)	$ (0.34)
Weighted-average shares of common stock outstanding, basic and diluted	7,401,783	2,792,409	7,133,871	1,403,918

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

	As of June 30, 2026	As of December 31, 2025
Assets		
Current assets		
Cash and cash equivalents	$ 122,831	$ 89,161
Prepaid expenses and other current assets	614	119
Total current assets	123,445	89,280
Property and equipment, net	23	—
Operating lease right-of-use assets	607	—
Deferred offering costs	2,811	—
Other long-term assets	70	70
Total assets	$ 126,956	$ 89,350
Liabilities, redeemable convertible preferred stock, and stockholders' deficit		
Current liabilities		
Accounts payable (includes related party amounts of $0 and $73, respectively)	$ 2,669	$ 1,058
Accrued expenses and other current liabilities (includes related party amounts of $389 and $3,272, respectively)	6,012	4,184
Current portion of lease liabilities	377	—
Total current liabilities	9,058	5,242
Lease liabilities, net of current portion	198	—
Other long-term liabilities	86	91
Total liabilities	9,342	5,333
Commitments and contingencies		
Series A redeemable convertible preferred stock, $0.0001 par value; 185,000,000 shares authorized at June 30, 2026 and December 31, 2025; 185,000,000 and 125,000,000 shares issued and outstanding at June 30, 2026 and December 31, 2025, respectively; $185,000 and $125,000 liquidation preference at June 30, 2026 and December 31, 2025, respectively	187,845	124,214
Nonvoting Series A redeemable convertible preferred stock, $0.0001 par value; 32,500,000 shares authorized, issued and outstanding at June 30, 2026 and December 31, 2025; $32,500 liquidation preference at June 30, 2026 and December 31, 2025	25,675	25,675
Stockholders' deficit		
Common stock, $0.0001 par value; 335,500,000 shares authorized at June 30, 2026 and December 31, 2025 (303,000,000 voting and 32,500,000 nonvoting); 15,943,937 shares issued at June 30, 2026 and December 31, 2025; and 7,535,986 and 6,685,088 shares outstanding at June 30, 2026 and December 31, 2025, respectively	1	1
Additional paid-in capital	—	179
Accumulated deficit	(95,907)	(66,052)
Total stockholders' deficit	(95,906)	(65,872)
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	$ 126,956	$ 89,350