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): November 10, 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 November 10, 2026, Braveheart Bio, Inc. (the "Company") announced its financial results and business highlights for the quarter ended September 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 November 10, 2026, furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: November 10, 2026

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

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

52-week data presented at AHA Scientific Sessions 2026 further strengthen BHB-1893's potential differentiation, with encouraging clinical activity and support for a highly simplified dosing regimen

LIONHEART-HCM oHCM Phase 3 enrolling with interim analysis expected in second half of 2027; TRUEHEART-HCM fixed-dose oHCM Phase 2b and NOBLEHEART-HCM Phase 3 in nHCM on track to initiate in first half of 2027

Cash, cash equivalents and investments of $503.5 million; cash runway expected into 2029

SAN FRANCISCO, Nov. 10, 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 third quarter ended September 30, 2026, and provided a business update.

"BHB-1893 continues to show a consistent, potentially differentiated profile across multiple clinical studies and our mechanistic work," said Travis Murdoch, M.D., President and Chief Executive Officer of Braveheart Bio. "The 52-week data presented at AHA showed rapid, deep responses that continued to improve over time, including meaningful improvements in pVO2 and KCCQ-CSS, and evidence supporting a highly simplified dosing regimen. These results inform our updated development strategy, including TRUEHEART-HCM, which will evaluate a fixed dose in oHCM on top of standard of care. With LIONHEART-HCM enrolling, NOBLEHEART-HCM on track to initiate in the first half of 2027 and a strong balance sheet, we are focused on delivering a potential best-in-disease profile with a simple dosing paradigm for patients with HCM."

Recent Business Highlights

AHA Scientific Sessions 2026 Clinical Data Presentations

- *52-Week Open-Label Extension in Obstructive HCM ("oHCM"):* Braveheart Bio and partner Hengrui Pharma presented 52-week open-label extension ("OLE") data from the Phase 2 study of BHB-1893 in 42 patients with oHCM in a late-breaking oral presentation. Mean peak oxygen uptake ("pVO2") and Kansas City Cardiomyopathy Questionnaire - Clinical Summary Score ("KCCQ-CSS") improved by 2.7 mL/kg/min and 17.3 points, respectively, from OLE baseline. By Week 1, before any titration, 67% of patients achieved a Valsalva left ventricular outflow tract gradient ("LVOT-G") below 30 mmHg; 90% reached this threshold at one or more visits during 52 weeks of treatment. At Week 52, 57% of patients remained on the 40 mg twice-daily starting dose. In an exploratory analysis, gradient and NT-proBNP levels after washout were lower following 52 weeks of treatment than following 12 weeks, consistent with potential reverse remodeling. BHB-1893 was generally well tolerated, with no on-treatment severe or serious adverse events.

- *New data supporting differentiated mechanism of action:* Braveheart Bio presented preclinical mechanistic data from engineered heart tissue models and an ad hoc pooled analysis of the Phase 2 study of BHB-1893 in non-obstructive HCM ("nHCM"). 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). 52-week data from the nHCM Phase 2 OLE are expected in the first half of 2027.

Development Strategy Update

- On November 6, 2026, Braveheart Bio hosted an investor event, "HCM Spotlight: Advancing a Next-Generation Cardiac Myosin Inhibitor," featuring leading HCM experts, and outlined its updated clinical development strategy for BHB-1893, which is designed to minimize titration while optimizing efficacy. A replay is available in the Investors section of Braveheart Bio's website.

- *LIONHEART-HCM, Global Phase 3 Trial in oHCM:* LIONHEART-HCM is enrolling patients. It is a global, randomized, double-blind, active-comparator-controlled Phase 3 trial evaluating the efficacy and safety of BHB-1893 compared to metoprolol in patients with symptomatic oHCM, using a 40 mg twice-daily starting dose with a single potential titration step to 60 mg at Week 4. The primary endpoint is change in pVO2 from baseline to Week 24; secondary endpoints include LVOT gradient, NT-proBNP and KCCQ-CSS. Results from an interim analysis of LVOT gradient at Week 12 are expected in the second half of 2027.

- *Hengrui Pharma's Study 301, a Phase 3 Trial in oHCM in China:* Hengrui Pharma, Braveheart Bio's collaboration partner in Greater China, has completed enrollment in its Phase 3 trial of HRS-1893 on top of standard of care, with topline results expected in the first half of 2027.

- *NOBLEHEART-HCM, Global Phase 3 Trial in nHCM:* Braveheart Bio has completed its end-of-Phase 2 meeting with the FDA and plans to initiate NOBLEHEART-HCM in the first half of 2027. NOBLEHEART-HCM is a planned global, randomized, double-blind, placebo-controlled Phase 3 trial evaluating BHB-1893 in adults with symptomatic nHCM. The trial design includes a potential single titration step at Week 4. The dual primary endpoints are change in pVO2 and KCCQ-CSS from baseline to Week 36.

- *TRUEHEART-HCM, Phase 2b Fixed-Dose Trial in oHCM:* TRUEHEART-HCM is a planned Phase 2b trial evaluating 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. Braveheart Bio has received supportive FDA feedback on the fixed-dose approach and is finalizing the protocol to enable trial initiation in the U.S. in the first half of 2027.

- Braveheart Bio completed its upsized initial public offering in August 2026, selling 24,437,500 shares of common stock, including the full exercise of the underwriters' option to purchase additional shares, 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.

Third Quarter 2026 Financial Results

Cash, cash equivalents and investments were $503.5 million as of September 30, 2026, compared to $89.2 million as of December 31, 2025. Based on the current operating plan, Braveheart Bio estimates that its existing cash, cash equivalents and investments will be sufficient to fund its projected operating expenses and capital expenditure requirements into 2029.

Research and development (R&D) expenses were $17.5 million for the three months ended September 30, 2026, compared to less than $0.1 million for the same period in 2025. The increase was primarily due to clinical and manufacturing costs to support the initiation and enrollment of LIONHEART-HCM, higher personnel-related costs and a $1.0 million milestone under the Hengrui license agreement.

There was no in-process research and development ("IPR&D") expense for the three months ended September 30, 2026, compared to $58.8 million for the same period in 2025, which related to the in-license of BHB-1893 from Hengrui.

General and administrative (G&A) expenses were $12.6 million for the three months ended September 30, 2026, compared to $0.5 million for the same period in 2025. The increase was primarily due to personnel-related costs, including stock-based compensation, and consultant and legal costs to support Braveheart Bio's growth and operations as a public company. G&A expenses for the three months ended September 30, 2026 included $7.8 million of non-cash stock-based compensation expense, of which $6.1 million related to liability-classified modified executive restricted stock awards that are remeasured to fair value each reporting period.

Net loss was $26.5 million, or $0.51 net loss per share, basic and diluted, for the three months ended September 30, 2026, compared to a net loss of $59.1 million, or $10.05 net loss per share, basic and diluted, for the same period in 2025.

Braveheart Bio, Inc.
Selected Condensed Statement of Operations Data (unaudited)
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 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)
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

Selected Condensed Balance Sheet Data (unaudited)
(in thousands)

	September 30, 2026	December 31, 2025
Cash, cash equivalents and investments	$ 503,520	$ 89,161
Total assets	514,450	89,350
Total liabilities	16,848	5,333
Redeemable convertible preferred stock	—	149,889
Total stockholders' equity (deficit)	497,602	(65,872)

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 enrollment, progress and expected results from the LIONHEART-HCM global Phase 3 trial; the potential for data from Hengrui’s Phase 3 trial of BHB-1893 in oHCM, together with the LIONHEART-HCM interim analysis, to support a New Drug Application submission; the timing of topline results from Hengrui’s Phase 3 trial and of 52-week data from the Phase 2 nHCM open-label extension; the timing of initiation as well as expected results from the NOBLEHEART-HCM global Phase 3 trial in nHCM; the timing of initiation, progress and expected results from the TRUEHEART-HCM Phase 2b fixed- dose study; 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 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 reliance on clinical data generated by Hengrui and on Hengrui for the manufacture of BHB-1893; 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; risks related to geopolitical developments and U.S. and Chinese laws and regulations, including the BIOSECURE Act; 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 Quarterly Report on Form 10-Q for the quarter ended September 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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