Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended 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: 001-39421

ORCHESTRA BIOMED HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	92-2038755
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

150 Union Square Drive
New Hope, Pennsylvania 18938
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (215) 862-5797

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	OBIO	The Nasdaq Stock Market LLC

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 Exchange Act). Yes ☐ No ☒

As of November 9, 2026, the registrant had 78,704,957 shares of common stock, $0.0001 par value per share, outstanding.

Table of Contents

		Page
PART I. FINANCIAL INFORMATION		1
Item 1.	Financial Statements	1
	Unaudited Condensed Consolidated Financial Statements:	
	Condensed Consolidated Balance Sheets as of September 30, 2026 (Unaudited) and December 31, 2025	1
	Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Nine Months Ended September 30, 2026 and 2025	2
	Condensed Consolidated Statements of Stockholders' Equity for the Three and Nine Months Ended September 30, 2026 and 2025	3
	Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2026 and 2025	4
	Notes to Unaudited Condensed Consolidated Financial Statements	5
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	29
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	41
Item 4.	Controls and Procedures	41
PART II. OTHER INFORMATION		41
Item 1.	Legal Proceedings	41
Item 1A.	Risk Factors	42
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	42
Item 3.	Defaults Upon Senior Securities	42
Item 4.	Mine Safety Disclosures	42
Item 5.	Other Information	42
Item 6.	Exhibits	43
Signatures		43

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this "Quarterly Report") contains forward-looking statements. All statements other than statements of historical facts contained in this report, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of clinical trials, research and development costs, regulatory approvals, 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, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this report include, but are not limited to, statements about:

- our ability to raise financing in the future, including our ability to borrow additional funds under our current debt financing arrangements;
- our success in retaining or recruiting, or changes required in, our officers, key employees or directors;
- our ability and/or the ability of third-party vendors and partners to manufacture our product candidates;
- our ability to source critical components or materials for the manufacture of our product candidates;
- our ability to achieve and sustain profitability;
- our ability to achieve our projected development and commercialization goals;
- the rate of progress, costs and results of our clinical studies and research and development activities, including, among other things, the timing of completion of follow-up and reporting of primary endpoint data from the BACKBEAT Trial and the date by which we expect to complete enrollment of our Virtue Trial;
- market acceptance of our product candidates, if approved;
- our ability to compete successfully with larger companies in a highly competitive industry;
- changes in our operating results, which make future operations results difficult to predict;
- serious adverse events, undesirable side effects that could halt the clinical development, regulatory approval or certification, of our product candidates;
- our ability to manage growth or control costs related to growth;
- economic conditions that may adversely affect our business, financial condition and stock price;
- our reliance on third parties to drive successful marketing and sale of our initial product candidates, if approved;
- our reliance on third parties to manufacture and provide important materials and components for our products and product candidates;
- our and our partners' abilities to obtain necessary regulatory approvals and certifications for our product candidates in an uncomplicated and inexpensive manner;

- our ability to maintain compliance with regulatory and post-marketing requirements;
- adverse medical events, failure or malfunctions in connection with our product candidates and possible subjection to regulatory sanctions;
- healthcare costs containment pressures and legislative or administrative reforms which affect coverage and reimbursement practices of third-party payors;
- our ability to protect or enforce our intellectual property, unpatented trade secrets, know-how and other proprietary technology;
- our ability to obtain necessary intellectual property rights from third parties;
- our ability to protect our trademarks, trade names and build our name recognition;
- our ability to maintain the listing of our common stock on The Nasdaq Stock Market LLC ("Nasdaq");
- the success of our licensing agreements; and
- our public securities' liquidity and trading.

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 report and are subject to a number of risks, uncertainties, and assumptions described under the headings "Item 1A. Risk Factors" in Part I of our Annual Report on Form 10-K for the year ended December 31, 2025 (the "2025 10-K") filed with the SEC on March 12, 2026 as well as 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. We do not plan to publicly update or revise any forward-looking statements contained herein whether as a result of any new information, future events, or otherwise, except as required by law.

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 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.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

ORCHESTRA BIOMED HOLDINGS, INC.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)
(Unaudited)

	September 30, 2026	December 31, 2025
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 27,761	$ 34,690
Marketable securities	74,146	71,822
Accounts receivable, net	56	95
Inventory	221	310
Prepaid expenses and other current assets	987	994
Total current assets	103,171	107,911
Property and equipment, net	2,284	1,715
Right-of-use assets	1,001	1,496
Strategic investments	—	2,495
Deposits and other assets	1,280	1,240
TOTAL ASSETS	$ 107,736	$ 114,857
LIABILITIES, SERIES A PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 5,030	$ 6,095
Accrued expenses and other liabilities	8,367	9,890
Operating lease liability, current portion	831	751
Total current liabilities	14,228	16,736
Royalty purchase agreement	36,795	16,482
Note payable	21,152	—
Loan payable	14,462	14,268
Derivative liability	1,593	2,749
Operating lease liability, less current portion	304	936
Other long-term liabilities	456	308
TOTAL LIABILITIES	88,990	51,479
Series A Preferred Stock, $0.0001 par value per share; 200,000 issued and outstanding at September 30, 2026 and December 31, 2025; aggregate liquidation preference of $20,000	10,964	9,808
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized	—	—
Common stock, $0.0001 par value per share; 340,000,000 shares authorized; 61,453,041 and 57,032,963 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively.	6	6
Additional paid-in capital	433,704	416,083
Accumulated other comprehensive (loss) income	(153)	60
Accumulated deficit	(425,775)	(362,579)
TOTAL STOCKHOLDERS' EQUITY	7,782	53,570
TOTAL LIABILITIES, SERIES A PREFERRED STOCK AND STOCKHOLDERS' EQUITY	$ 107,736	$ 114,857

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

ORCHESTRA BIOMED HOLDINGS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenue:				
Partnership revenue	$ —	$ 721	$ —	$ 2,120
Product revenue	91	140	289	445
Total revenue	91	861	289	2,565
Expenses:				
Cost of product revenues	28	49	85	139
Research and development	17,734	14,027	50,105	41,362
Selling, general and administrative	5,625	7,098	17,827	19,625
Total expenses	23,387	21,174	68,017	61,126
Loss from operations	(23,296)	(20,313)	(67,728)	(58,561)
Other income (expense):				
Interest expense, net	(2,463)	(515)	(5,052)	(385)
Change in the fair value of derivative liability	867	—	1,156	—
Gain on sale of strategic investments	6,142	—	8,428	—
Total other income (expense)	4,546	(515)	4,532	(385)
Net loss	$ (18,750)	$ (20,828)	$ (63,196)	$ (58,946)
Adjustment to carrying value of Series A Preferred Stock	(867)	—	(1,156)	—
Net loss attributable to common stockholders	$ (19,617)	$ (20,828)	$ (64,352)	$ (58,946)
Net loss attributable to common stockholders per share				
Basic and diluted	$ (0.30)	$ (0.40)	$ (1.01)	$ (1.37)
Weighted-average shares used in computing net loss attributable to common stockholders per share, basic and diluted	64,620,127	52,186,503	63,724,985	43,006,790
Comprehensive loss				
Net loss	$ (18,750)	$ (20,828)	$ (63,196)	$ (58,946)
Unrealized (loss) gain on marketable securities	(72)	29	(213)	(7)
Comprehensive loss	$ (18,822)	$ (20,799)	$ (63,409)	$ (58,953)

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

ORCHESTRA BIOMED HOLDINGS, INC.
Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share and per share data)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, January 1, 2026	57,032,963	$ 6	$ 416,083	$ 60	$ (362,579)	$ 53,570
At-the-Market offering, net of issuance costs of $150	1,451,439	—	5,855	—	—	5,855
Unrealized loss on marketable securities	—	—	—	(100)	—	(100)
Stock-based compensation	—	—	2,851	—	—	2,851
Restricted stock unit vesting	140,035	—	(354)	—	—	(354)
Exercise of stock options	6,278	—	26	—	—	26
Adjustment to carrying value of Series A Preferred Stock	—	—	35	—	—	35
Net loss	—	—	—	—	(20,691)	(20,691)
Balance, March 31, 2026	58,630,715	$ 6	$ 424,496	$ (40)	$ (383,270)	$ 41,192
Unrealized loss on marketable securities	—	—	—	(41)	—	(41)
Stock-based compensation	—	—	2,505	—	—	2,505
Restricted stock unit vesting	222,084	—	(262)	—	—	(262)
Exercise of stock options	2,250	—	8	—	—	8
Exercise of pre-funded warrants	1,250,000	—	—	—	—	—
Adjustment to carrying value of Series A Preferred Stock	—	—	(324)	—	—	(324)
Net loss	—	—	—	—	(23,755)	(23,755)
Balance, June 30, 2026	60,105,049	$ 6	$ 426,423	$ (81)	$ (407,025)	$ 19,323
At-the-Market offering, net of issuance costs of $155	1,219,499	—	6,013	—	—	6,013
Unrealized loss on marketable securities	—	—	—	(72)	—	(72)
Stock-based compensation	—	—	2,286	—	—	2,286
Restricted stock unit vesting	124,743	—	(162)	—	—	(162)
Exercise of stock options	3,750	—	11	—	—	11
Adjustment to carrying value of Series A Preferred Stock	—	—	(867)	—	—	(867)
Net loss	—	—	—	—	(18,750)	(18,750)
Balance, September 30, 2026	61,453,041	$ 6	$ 433,704	$ (153)	$ (425,775)	$ 7,782

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, January 1, 2025	38,194,442	$ 4	$ 342,780	$ 52	$ (309,878)	$ 32,958
Unrealized loss on marketable securities	—	—	—	(15)	—	(15)
Stock-based compensation	—	—	2,965	—	—	2,965
Restricted stock unit vesting	95,958	—	(387)	—	—	(387)
Exercise of stock options	22,112	—	91	—	—	91
Net loss	—	—	—	—	(18,755)	(18,755)
Balance, March 31, 2025	38,312,512	$ 4	$ 345,449	$ 37	$ (328,633)	$ 16,857
Unrealized loss on marketable securities	—	—	—	(21)	—	(21)
Stock-based compensation	—	—	3,250	—	—	3,250
Restricted stock unit vesting	331,041	—	(428)	—	—	(428)
Net loss	—	—	—	—	(19,363)	(19,363)
Balance, June 30, 2025	38,643,553	$ 4	$ 348,271	$ 16	$ (347,996)	$ 295
Issuance of common stock and pre-funded warrants in private placement, net of issuance costs of $4,635	17,624,027	2	57,778	—	—	57,780
Unrealized gain on marketable securities	—	—	—	29	—	29
Stock-based compensation	—	—	3,013	—	—	3,013
Restricted stock unit vesting	197,151	—	(269)	—	—	(269)
Issuance of warrants pursuant to debt financing	—	—	239	—	—	239
Issuance of warrants pursuant to the royalty purchase agreement	—	—	3,480	—	—	3,480
Net loss	—	—	—	—	(20,828)	(20,828)
Balance, September 30, 2025	56,464,731	$ 6	$ 412,512	$ 45	$ (368,824)	$ 43,739

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

ORCHESTRA BIOMED HOLDINGS, INC.
Condensed Consolidated Statements of Cash Flows
(in thousands, except share and per share data)
(Unaudited)

	Nine Months Ended September 30,	
	2026	2025
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (63,196)	$ (58,946)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	287	245
Stock-based compensation	7,642	9,228
Non-cash interest expense on liability related to the royalty purchase agreement	5,313	761
Accrued interest expense on liability related to the note payable	1,152	—
Gain on sale of strategic investments	(8,428)	—
Accretion and interest related to marketable securities	(424)	(491)
Non-cash lease expense	495	450
Change in the fair value of derivative liability	(1,156)	—
Amortization of deferred financing fees	194	151
Changes in operating assets and liabilities:		
Accounts receivable	39	40
Inventory	89	(192)
Prepaid expenses and other assets	(33)	287
Accounts payable, accrued expenses and other liabilities	(2,460)	4,300
Operating lease liabilities – current and non-current	(552)	(406)
Deferred revenue	—	(2,120)
Net cash used in operating activities	(61,038)	(46,693)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(836)	(456)
Sales of marketable securities	60,506	41,910
Purchases of marketable securities	(62,619)	(50,683)
Sale of strategic investments	10,923	—
Net cash provided by (used in) investing activities	7,974	(9,229)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common stock and pre-funded warrants, net of issuance costs	—	57,780
Proceeds from the royalty purchase agreement	15,000	20,000
Proceeds from Medtronic loan	20,000	—
Proceeds from At-The-Market offering, net of issuance costs	11,868	—
Proceeds from exercise of stock options	45	91
Restricted stock units withheld for tax	(778)	(1,084)
Deferred financing costs - royalty purchase agreement	—	(1,114)
Net cash provided by financing activities	46,135	75,673
Net (decrease) increase in cash and cash equivalents	(6,929)	19,751
Cash and cash equivalents, beginning of the period	34,690	22,261
Cash and cash equivalents, end of the period	$ 27,761	$ 42,012
Supplemental Disclosures of Cash Flow Information		
Cash paid during the nine months ended September 30:		
Interest	$ 1,085	$ 1,086
Supplemental disclosure of noncash activities		
Non-cash investing activities:		
Purchases of property & equipment within accounts payable, accrued expenses and other liabilities	$ 20	$ 82
Warrants issued pursuant to debt financing	$ —	$ 239
Warrants issued pursuant to the royalty purchase agreement	$ —	$ 3,480
Deferred issuance costs included in accrued expenses and other current liabilities	$ —	$ 969

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

ORCHESTRA BIOMED HOLDINGS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Organization and Basis of Presentation

Orchestra BioMed Holdings, Inc. (collectively, with its subsidiaries, "Orchestra" or the "Company") is a biomedical innovation company accelerating high-impact technologies to patients through risk-reward sharing collaborations with market-leading global medical device companies. The Company's partnership-enabled business model focuses on forging strategic collaborations with leading medical device companies to drive successful global commercialization of products it develops. The Company's two flagship product candidates are Atrioventricular Interval Modulation Therapy ("AVIM Therapy") for the treatment of hypertension ("HTN"), the leading risk factor for death worldwide, and Virtue® Sirolimus AngioInfusion™ Balloon ("Virtue SAB") for the treatment of atherosclerotic artery disease, the leading cause of mortality worldwide.

The Company was incorporated in the Cayman Islands in 2020, as a special purpose acquisition company under the name Health Sciences Acquisitions Corporation 2 ("HSAC2"). On January 26, 2023, Orchestra BioMed, Inc., the Company's wholly owned subsidiary, and HSAC2 consummated a business combination pursuant to which, among other things, Orchestra BioMed, Inc. became a wholly owned subsidiary of HSAC2 and HSAC2 changed its name to Orchestra BioMed Holdings, Inc. (the "Business Combination"). HSAC2 Holdings, LLC (the "Sponsor") was the sponsor of HSAC2 prior to the Business Combination.

Orchestra BioMed, Inc. was incorporated in Delaware in January 2017 and was formed to acquire operating and other assets as well as to raise capital conducted through private placements. In May 2018, Orchestra BioMed, Inc. concurrently completed its formation mergers with Caliber Therapeutics, Inc., a Delaware corporation, BackBeat Medical, Inc., a Delaware corporation, and FreeHold Surgical, Inc., a Delaware corporation. Orchestra BioMed, Inc. completed the conversions of BackBeat Medical, Inc. to BackBeat Medical, LLC, a Delaware limited liability company ("BackBeat"), of FreeHold Surgical, Inc. to FreeHold Surgical, LLC, a Delaware limited liability company ("FreeHold"), and of Caliber Therapeutics, Inc. to Caliber Therapeutics, LLC, a Delaware limited liability company ("Caliber") in 2019.

Caliber

Caliber Therapeutics, Inc. was incorporated in Delaware in October 2005 and began development of its lead product candidate Virtue SAB in 2008. Virtue SAB is a patented first-of-its-kind, non-coated drug/device combination product candidate for the treatment of atherosclerotic artery disease that is designed to infuse a large liquid dose of a proprietary extended release formulation of sirolimus called SirolimusEFR™ into the vessel wall during balloon angioplasty without any coating on the balloon surface or the need to leave a permanent implant such as a stent in the artery.

BackBeat

BackBeat Medical, Inc. was incorporated in Delaware in January 2010 and began development of its lead product candidate AVIM Therapy that same year. AVIM Therapy is a patented, cardiac pacing therapy for HTN that can be delivered as firmware on a standard dual-chamber pacemaker and is designed to immediately, substantially and sustainably lower blood pressure while simultaneously modulating the autonomic nervous system. Refer to Note 3 – *"Medtronic Agreement"* for details regarding the Exclusive License and Collaboration Agreement, dated as of June 30, 2022, by and among, Orchestra BioMed, Inc., BackBeat and Medtronic, Inc. (an affiliate of Medtronic plc) (the "Medtronic Agreement" and as amended pursuant to the Medtronic Agreement Amendment (as defined below), the "Amended Medtronic Agreement").

FreeHold

FreeHold Surgical, Inc. was incorporated in Delaware in May 2010 and began development of its hands-free, intracorporeal retractor device for minimally-invasive surgery in 2012. FreeHold is engaged in the development, sales and marketing of its retractor products that provide optimized visualization and total surgeon control during laparoscopic and robotic procedures.

Basis of Presentation and Liquidity

The accompanying unaudited interim condensed consolidated financial statements have been prepared pursuant to the rules and regulations of the U.S. Securities and Exchange Commission ("SEC") for interim financial reporting. These condensed statements are unaudited and, in the opinion of management, include all adjustments (consisting of normal recurring adjustments and accruals) necessary to fairly present the results of the interim periods. The condensed consolidated balance sheet at December 31, 2025 has been derived from the audited financial statements at that date. Operating results and cash flows for the nine months ended September 30, 2026 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2026 or any other future period. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") have been omitted in accordance with the rules and regulations for interim reporting of the SEC. These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2025 filed with the SEC on March 12, 2026 together with the related notes thereto.

The Company has a limited operating history and the sales and income potential of its businesses and markets are unproven. As of September 30, 2026, the Company had an accumulated deficit of $425.8 million and has experienced net losses each year since its inception. The Company expects to incur substantial operating losses in future periods and will require additional capital as it seeks to advance its products to commercialization. The Company is subject to a number of risks and uncertainties similar to those of other companies of the same size within the biomedical device industry, such as uncertainty of clinical trial outcomes, uncertainty of additional funding, and history of operating losses.

The Company follows the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 205-40, *Presentation of Financial Statements — Going Concern*, which requires management to assess the Company's ability to continue as a going concern within one year after the date the financial statements are issued.

Based on the available balance of cash and cash equivalents and marketable securities as of September 30, 2026, management has concluded that sufficient capital is available to fund its operations and meet cash requirements through the one-year period subsequent to the issuance date of these financial statements. Management may consider plans to raise capital through the one-year period subsequent to the issuance date of these financial statements through issuance of equity securities, debt securities, and/or additional development and commercialization partnerships for other products within the Company's development pipeline. The source, timing and availability of any future financing will depend principally upon market conditions and on the progress of the Company's research and development programs.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures in the condensed consolidated financial statements and accompanying notes. Management bases its estimates on historical experience and on assumptions believed to be reasonable under the circumstances. Actual results could differ materially from those estimates. Areas where significant estimates exist include, but are not limited to, research and development costs incurred, effective interest expense related to the Royalty Purchase Agreement (as defined below) (see Note 13 – *"Royalty Purchase Agreement"* for additional information), effective interest expense related to the Medtronic Loan Agreement (as defined below) (see Note 14 – *"Debt Financing"* for additional information), and the fair value of the derivative liability related to the Company's Series A Preferred Stock, $0.0001 par value per share (the "Series A Preferred Stock") (see Note 8 – *"Derivative Liability"* for additional information).

Cash and Cash Equivalents

Cash and cash equivalents are held in banks or in custodial accounts with banks. Cash equivalents are defined as all liquid investments and money market funds with maturity from date of purchase of 90 days or less that are readily convertible into cash.

Marketable Securities

The Company accounts for its marketable securities with remaining maturities of less than one year, or where its intent is to use the investments to fund current operations or to make them available for current operations, as short-term investments. These investments represent debt investments in corporate or government securities that are designated as available-for-sale and are carried at fair value, with unrealized gains and losses reported in stockholders' equity as accumulated other comprehensive (loss) income. The disclosed fair value related to the Company's investments is based on market prices from a variety of industry standard data providers and generally represent quoted prices for similar assets in active markets or have been derived from observable market data.

Strategic Investments

Management had made investments in certain companies and assessed whether the Company exerted significant influence over its strategic investments. The Company considered the nature and magnitude of its investment, any voting and protective rights it held, any participation in the governance of the other company, and other relevant factors such as the presence of a collaboration or other business relationships. To date, the Company has concluded that it did not have the ability to exercise significant influence over its strategic investments.

As of December 31, 2025, the Company's strategic investments consisted of preferred shares of Vivasure Medical Limited ("Vivasure"), a privately-held company and related party. The investments in Vivasure did not have readily determinable fair values and were recorded at cost, less any impairment, plus or minus changes resulting from observable price changes in orderly transactions for identical or similar investments of the same issuer. Additionally, as the investments in Vivasure were not readily marketable, the Company categorized the investments as non-current assets. As of December 31, 2025, the carrying value of the investments in Vivasure was $2.5 million. On January 9, 2026, Haemonetics Corporation, a global medical technology company focused on delivering innovative solutions designed to improve patient outcomes, announced its acquisition of Vivasure. As a result, the Company recognized a gain of $8.4 million on the sale of strategic investments during the nine months ended September 30, 2026 (see Note 5 – *"Marketable Securities and Strategic Investments"* for additional information).

Fair Value of Financial Instruments

The Company applies ASC 820, *Fair Value Measurement* ("ASC 820"), which establishes a framework for measuring fair value and clarifies the definition of fair value within that framework. ASC 820 defines fair value as an exit price, which is the price that would be received for an asset or paid to transfer a liability in the Company's principal or most advantageous market in an orderly transaction between market participants on the measurement date. The fair value hierarchy established in ASC 820 generally requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Observable inputs reflect the assumptions that market participants would use in pricing the asset or liability and are developed based on market data obtained from sources independent of the reporting entity. Unobservable inputs reflect the entity's own assumptions based on market data and the entity's judgments about the assumptions that market participants would use in pricing the asset or liability and are to be developed based on the best information available in the circumstances.

The carrying value of the Company's cash and cash equivalents, accounts receivable, prepaid expense, accounts payable, and accrued expenses approximate fair value because of the short-term maturity of these financial instruments. In addition, the Company records its investment in marketable securities at fair value. See Note 4 – *"Financial Instruments and Fair Value Measurements"* for additional information regarding fair value measurements. For additional information on the fair value measurements performed related to the derivative liability, see Note 8 – *"Derivative Liability."*

The valuation hierarchy is composed of three levels. The classification within the valuation hierarchy is based on the lowest level of input that is significant to the fair value measurement. The levels within the valuation hierarchy are described below:

Level 1 — Assets and liabilities with unadjusted, quoted prices listed on active market exchanges. Inputs to the fair value measurement are observable inputs, such as quoted prices in active markets for identical assets or liabilities.

Level 2 — Inputs to the fair value measurement are determined using prices for recently traded assets and liabilities with similar underlying terms, as well as direct or indirect observable inputs, such as interest rates and yield curves that are observable at commonly quoted intervals.

Level 3 — Inputs to the fair value measurement are unobservable inputs, such as estimates, assumptions, and valuation techniques when little or no market data exists for the assets or liabilities.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable represent amounts due from customers. The allowance for doubtful accounts is recorded for estimated losses by evaluating various factors, including relative creditworthiness of each customer, historical collections experience and aging of the receivable. As of September 30, 2026 and December 31, 2025, an allowance for doubtful accounts was not deemed necessary.

Inventory

Inventory is stated at the lower of standard cost (which approximates actual cost on a first-in, first-out basis) and net realizable value. Net realizable value represents the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The Company analyzes its inventory levels and writes down inventory that has become obsolete or has a cost basis in excess of its expected net realizable value or inventory quantities in excess of expected requirements. Excess requirements are determined based on comparison of existing inventories to forecasted sales, with consideration given to inventory shelf life. Expired inventory is disposed of, and the related costs are recognized in cost of goods sold. As of September 30, 2026 and December 31, 2025, an impairment charge as a result of obsolete inventory was not deemed necessary.

Research and Development Prepayments, Accruals and Related Expenses

The Company incurs costs of research and development activities conducted by its third-party service providers, which include the conduct of preclinical and clinical studies. The Company is required to estimate its prepaid and accrued research and development costs at each reporting date. These estimates are made as of the reporting date of the work completed over the life of the individual study in accordance with agreements established with the Company's service providers. The Company determines the estimates of research and development activities incurred at the end of each reporting period through discussion with internal personnel and outside service providers, as to the progress or stage of completion of trials or services, as of the end of the reporting period, pursuant to contracts with the third parties and the agreed upon fee to be paid for such services. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are accepted by the Company or the services are performed. Accruals are recorded for the amounts of services provided that have not yet been invoiced.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation and amortization is computed using the straight-line method over the estimated useful lives of the respective assets. Leasehold improvements are amortized over the lesser of their useful life or the remaining life of the lease. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation and amortization are removed from the balance sheet and any resulting gain or loss is reflected in operations in the period realized. Maintenance and repairs are charged to operations as incurred.

Asset category	Depreciable life
Manufacturing equipment	10 years
Office equipment	3 – 7 years
Research and development equipment	7 years

Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the terms of the arrangement. The Company accounts for a contract as a lease when it has the right to control the asset for a period of time while obtaining substantially all of the asset's economic benefits. The Company determines the initial classification and measurement of its operating right-of-use ("ROU") assets and operating lease liabilities at the lease commencement date, and thereafter if modified. The lease term includes any renewal options that the Company is reasonably assured to exercise. The Company's policy is to not record leases with a lease term of 12 months or less on its balance sheets.

The ROU asset represents the right to use the leased asset for the lease term. The lease liability represents the present value of the lease payments under the lease. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its estimated secured incremental borrowing rate for that lease term. Lease expense for operating leases is recognized on a straight-line basis over the reasonably assured lease term based on the total lease payments and is included in operating expense in the condensed consolidated statements of operations and comprehensive loss.

Payments due under each lease agreement include fixed and variable payments. Variable payments relate to the Company's share of the lessor's operating costs associated with the underlying asset and are recognized when the event on which those payments are assessed occurs. Variable payments have been excluded from the lease liability and associated right-of-use asset.

The interest rate implicit in lease agreements is typically not readily determinable, and as such, the Company utilizes the incremental borrowing rate to calculate lease liabilities, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

Debt Discount and Debt Issuance Costs

Debt discounts and debt issuance costs incurred in connection with the issuance of debt are capitalized and reflected as a reduction to the related debt liability. The costs are amortized to interest expense over the term of the debt using the effective-interest method.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparing the carrying amount to the future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset. The Company has not identified any such impairment losses to date.

Revenue Recognition

The Company recognizes revenue under the core principle according to ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), to depict the transfer of control to the Company's customers in an amount reflecting the consideration to which the Company expects to be entitled. In order to achieve that core principle, the Company applies the following five step approach: (1) identify the contract with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract and (5) recognize revenue when a performance obligation is satisfied.

The Company's revenues were previously comprised of partnership revenues from the Terumo Agreement relating to the development and commercialization of Virtue SAB, and continue to include product revenue from the sale of FreeHold's intracorporeal organ retractors.

Partnership Revenues

Previously, the Company's partnership revenues have related to the Terumo Agreement (as defined below), which was terminated pursuant to a termination and right of first refusal agreement on October 24, 2025 (the "Termination and ROFR Agreement"). In future periods, partnership revenues may also include revenues related to the Amended Medtronic Agreement as discussed in Note 3 – *"Medtronic Agreement"*.

Product Revenues

Product revenues related primarily to sales of FreeHold's intracorporeal organ retractors are recognized at a point-in-time upon the shipment of the product to the customer, and there are no significant estimates or judgments related to estimating the transaction price. The product revenues consist of a single performance obligation, and the payment terms are typically 30 days. Product revenues are recognized solely in the United States.

Stock-Based Compensation

The Company applies ASC 718-10, *Compensation — Stock Compensation*, which requires the measurement and recognition of compensation expenses for all stock-based payment awards made to employees and directors including employee stock options under the Company's stock plans based on estimated fair values (see Note 10 – "*Stock-Based Compensation*"). Each award vests over the subsequent period during which the recipient is required to provide service in exchange for the award (the "vesting period"). The cost of each award is recognized as an expense in the financial statements over the respective vesting period on a straight-line basis.

Under the requirements of ASU 2018-07, the Company accounts for stock-based compensation to nonemployees under the fair value method, which requires all such compensation to be calculated based on the fair value at the measurement date (generally the grant date) and recognized in the Company's condensed consolidated statements of operations and comprehensive loss over the requisite service period. The Company accounts for forfeitures of stock-based awards as they occur.

Series A Preferred Stock

The Company applies ASC 480-10, *Distinguishing Liabilities from Equity* ("ASC 480"), which requires an evaluation to determine if liability classification is required for redeemable convertible stock. Liability classification is required for freestanding financial instruments that are (1) subject to an unconditional obligation requiring the issuer to redeem the instrument by transferring assets, such as those that are mandatorily redeemable, (2) instruments other than equity shares that embody an obligation of the issuer to repurchase its equity shares, or (3) certain types of instruments that obligate the issuer to issue a variable number of equity shares.

Securities that do not meet the scoping criteria to be classified as a liability under ASC 480 are subject to redeemable equity guidance, which prescribes that securities that may be subject to redemption upon an event not solely within the Company's control should be classified as mezzanine equity. Securities classified in mezzanine equity are initially measured at the fair value, net of issuance costs and excluding the fair value of bifurcated embedded derivatives, if any. Subsequent measurement is required when the combined initial amount recorded in mezzanine equity and its related derivative liability is greater than the period end carrying amount. Adjustments to the carrying amount are charged to retained earnings (or additional paid in capital if there are no retained earnings) and do not affect net loss or comprehensive loss in the condensed consolidated financial statements. Subsequent measurement of the carrying value of the redeemable convertible preferred stock is also required when the instrument is probable of becoming redeemable. The Company will accrete the redeemable convertible preferred stock to its redemption value once the instrument is probable of becoming redeemable. In certain circumstances, the redemption price may vary based on changes in stock price, in which case the Company recognizes changes in the redemption value immediately as they occur and adjusts the carrying value of the security to equal the then current maximum redemption value at the end of each reporting period.

Derivative Liability

The Company evaluates all its financial instruments, including convertible debt and redeemable convertible preferred stock, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. The Company applies significant judgment to identify and evaluate complex terms and conditions in these contracts and agreements to determine whether embedded derivatives exist. Embedded derivatives must be separately measured from the host contracts if all the requirements for bifurcation are met. The assessment of the conditions surrounding the bifurcation of embedded derivatives depends on the nature of the host contract. Bifurcated embedded derivatives are recognized at fair value, with changes in fair value recognized in the condensed consolidated statements of operations and comprehensive loss at each reporting period end. Bifurcated embedded derivatives are classified as a separate liability in the condensed consolidated balance sheets.

The Company's derivative liability is related to the conversion features embedded in the Series A Preferred Stock. See Note 7 – *"Common and Preferred Stock"* for additional information.

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss less the adjustment to carrying value of Series A Preferred Stock by the weighted-average number of shares of common stock of the Company ("Common Stock") outstanding for the period, without consideration of potential dilutive shares of Common Stock. Since the Company was in a loss position for the periods presented, basic net loss is the same as diluted net loss since the effects of potentially dilutive securities are antidilutive. Potentially dilutive securities include all outstanding warrants, stock options, Earnout Consideration (see Note 16 – *"Net Loss Per Share"*), unvested restricted stock awards,

convertible preferred shares (see Note 7 – *"Common and Preferred Stock"*) and restricted stock units. Shares of Common Stock outstanding but subject to forfeiture and cancellation by the Company (e.g., the Forfeitable Shares (as defined in Note 16)) are excluded from the weighted-average number of shares until the period in which such shares are no longer subject to forfeiture. Pre-funded warrants (see Note 9 – *"Warrants"*) are considered outstanding for the purposes of computing basic and diluted net loss per share because shares may be issued for little or no additional consideration and are fully vested and exercisable after the original issuance date of the pre-funded warrant. In periods in which there is net income, the Company would apply the two-class method to compute net income per share. Under this method, earnings are allocated to common stock and participating securities based on their respective rights to receive dividends, as if all undistributed earnings for the period were distributed. The two-class method does not apply in periods in which a net loss is reported.

Income Taxes

The Company accounts for income taxes using the asset-and-liability method in accordance with ASC 740, *Income Taxes* ("ASC 740"). Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on the deferred tax assets and liabilities of a change in tax rate is recognized in the period that includes the enactment date. A valuation allowance is recorded if it is more-likely-than-not that some portion or all the deferred tax assets will not be realized in future periods. At September 30, 2026 and December 31, 2025, the Company recorded a full valuation allowance on its deferred tax assets.

The Company follows the guidance in ASC Topic 740 – 10 in assessing uncertain tax positions. The standard applies to all tax positions and clarifies the recognition of tax benefits in the financial statements by providing for a two-step approach of recognition and measurement. The first step involves assessing whether the tax position is more-likely-than-not to be sustained upon examination based upon its technical merits. The second step involves measurement of the amount to be recognized. Tax positions that meet the more-likely than-not threshold are measured at the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate finalization with the taxing authority. The Company recognizes the impact of an uncertain income tax position in the financial statements if it believes that the position is more likely than not to be sustained by the relevant taxing authority. The Company will recognize interest and penalties related to tax positions in income tax expense as applicable.

Defined Contribution Plan

The Company has a defined retirement savings plan under Section 401(k) of the Internal Revenue Code. This plan allows eligible employees to defer a portion of their annual compensation on a pre-tax basis. Effective January 1, 2023, the Company participates in a matching safe harbor 401(k) Plan with a Company contribution of up to 3.5% of each eligible participating employee's compensation. Safe harbor contributions vest immediately for each participant. During the three and nine months ended September 30, 2026, the Company made $131,000 and $422,000, respectively, in contributions under this safe harbor 401(k) Plan. During three and nine months ended September 30, 2025, the Company made $104,000 and $343,000, respectively, in contributions under this safe harbor 401(k) Plan.

Comprehensive Loss

Comprehensive loss is comprised of net loss and changes in unrealized gains and losses on the Company's available-for-sale investments.

Segment Reporting

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its Chief Executive Officer. The Company has determined it operates in one segment. For further discussion on Segment Reporting, see Note 15 - *"Segment Disclosures."*

New Accounting Standards

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses* ("ASU 2024-03") to improve the disclosures about a public business entity's expenses and address requests from investors for more detailed information about the types

of expenses in commonly presented expense captions. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026. Early adoption is permitted. The Company is currently evaluating the impact of adopting ASU 2024-03 on its condensed consolidated financial statements.

3. Medtronic Agreement

In June 2022, Orchestra BioMed, Inc., BackBeat and Medtronic entered into the Medtronic Agreement for the development and commercialization of AVIM Therapy for the treatment of pacemaker-indicated patients with uncontrolled HTN despite the use of anti-hypertensive medications (the "Primary Field"). Under the terms of the Medtronic Agreement, the Company is sponsoring an ongoing multinational pivotal study, to support regulatory approval of AVIM Therapy in the Primary Field and is financially responsible for development, clinical and regulatory costs associated with this pivotal study. AVIM Therapy has been integrated into the Medtronic top-of-the-line, commercially available dual-chamber pacemaker system specifically for use in the pivotal trial, and Medtronic is providing development, clinical and regulatory resources in support of the pivotal trial, for which the Company is reimbursing Medtronic at cost.

Under the terms of the Medtronic Agreement, as amended pursuant to the Medtronic Agreement Amendment, Medtronic will have exclusive rights to commercialize AVIM-enabled pacing systems globally following receipt of regulatory approval. Medtronic would be entirely responsible for global commercialization following receipt of regulatory approvals, including manufacturing, sales, marketing and distribution costs.

The Company is expected to receive between $500 and $1,600 per AVIM-enabled device sold based on a formula of the higher of (1) a fixed dollar amount per AVIM-enabled device (amount varies materially on a country-by-country basis) or (2) a percentage of the AVIM Therapy-generated sales. Procedures using the AVIM-enabled pacemakers are expected to be billed under existing reimbursement codes.

Medtronic has a right of first negotiation through U.S. Food and Drug Administration ("FDA") approval of AVIM Therapy in the Primary Field, to expand its global rights to AVIM Therapy for the treatment of HTN patients not indicated for a pacemaker.

The Company assessed whether the Amended Medtronic Agreement fell within the scope of ASC 808 and concluded that the Amended Medtronic Agreement is a collaboration within the scope of ASC 808. In addition, the Company determined that Medtronic is a customer for a good or service that is a distinct unit of account, and therefore, the transactions in the Amended Medtronic Agreement should be accounted for under ASC 606.

The Company has concluded that the license granted to Medtronic is not distinct from the development and implementation services that will be provided to Medtronic through the completion of the development of HTN indication, as Medtronic cannot obtain the benefit of the license without the related development and implementation services. ASC 606-10-55-65 includes an exception for the recognition of revenue relating to licenses of intellectual property with sales-based or usage-based royalties. Under this exception, royalty revenue is not recorded until the subsequent sale or usage occurs, or the performance obligation has been satisfied, whichever is later.

The Company concluded that the exemption applies and therefore, the royalty revenue associated with these performance obligations will be recognized as the underlying sales occur. Additionally, pursuant to the Amended Medtronic Agreement, expenses incurred by Medtronic in connection with clinical device development and regulatory activities performed will be reimbursed by the Company. The Company will record such expenses as research and development expenses as incurred. During the three and nine months ended September 30, 2026, the Company incurred approximately $2.9 million and $8.3 million, respectively, of research and development costs related to these reimbursements pursuant to the Amended Medtronic Agreement, of which $4.7 million is included within accounts payable and accrued expenses in the Company's September 30, 2026 condensed consolidated balance sheet. During the three and nine months ended September 30, 2025, the Company incurred approximately $3.2 million and $10.6 million, respectively, of research and development costs related to these reimbursements pursuant to the Amended Medtronic Agreement.

Concurrently with the close of the Medtronic Agreement, Orchestra BioMed, Inc. also received a $40.0 million investment from Medtronic in connection with Orchestra BioMed, Inc.'s Series D-2 Preferred Stock financing. The equity was purchased at a fair value consistent with the price paid by other investors at that time, and accordingly, the proceeds received were recorded as an equity investment.

On July 31, 2025, Orchestra BioMed, Inc., BackBeat and Medtronic entered into an amendment to the Medtronic Agreement, which became effective on August 4, 2025 (the "Medtronic Agreement Amendment"), to provide, among other things, a development and commercialization framework for future AVIM-therapy integration into a dual-chamber leadless pacemaker. Pursuant to the Medtronic

Agreement Amendment, the Company will, among other things, be required to reimburse Medtronic for certain expenses incurred in connection with the integration of AVIM-therapy into Medtronic's dual-chamber leadless pacemaker, up to a specified cap.

On July 31, 2025, the Company and its wholly-owned subsidiaries, Orchestra BioMed, Inc. and BackBeat, entered into a loan agreement with Medtronic, pursuant to which Medtronic agreed to extend a convertible loan to the Company in the aggregate original principal amount of $20.0 million. For additional details, see Note 14 – *"Debt Financing."*

Concurrently with the close of the Medtronic Agreement Amendment on August 4, 2025, Medtronic, through an affiliate, Covidien Group S.à.r.l. ("Covidien"), purchased 4,077,427 shares of Common Stock at a purchase price of $2.75 per share, for an aggregate purchase price of approximately $11.2 million, pursuant to a stock purchase agreement, dated as of July 31, 2025 and amended on August 1, 2025, between the Company and Covidien (as amended, the "Medtronic Stock Purchase Agreement"). Pursuant to the terms of the Medtronic Stock Purchase Agreement, Covidien purchased an additional 132,282 shares of Common Stock on August 28, 2025 at a purchase price of $2.75 per share, for an aggregate purchase price of $363,775, as a result of the exercise by the underwriters of their option to purchase an additional 2,182,500 shares of Common Stock in the Company's public offering, which closed on August 4, 2025. The equity was purchased at a fair value consistent with the price paid by other investors at that time, and accordingly, the proceeds received were recorded as an equity investment.

Through September 30, 2026, there have been no amounts recognized as revenue under the Amended Medtronic Agreement.

4. Financial Instruments and Fair Value Measurements

The following tables summarize the Company's financial assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy:

	September 30, 2026			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets				
Money market fund (included in Cash and cash equivalents)	$ 13,569	$ —	$ —	$ 13,569
Corporate and government debt securities (included in Marketable securities)	—	74,146	—	74,146
Total assets	**$ 13,569**	**$ 74,146**	**$ —**	**$ 87,715**
Liabilities				
Derivative liability (Note 8)	—	—	1,593	1,593
Total liabilities	**$ —**	**$ —**	**$ 1,593**	**$ 1,593**

	December 31, 2025			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets				
Money market fund (included in Cash and cash equivalents)	$ 12,789	$ —	$ —	$ 12,789
Corporate and government debt securities (included in Marketable securities)	—	71,822	—	71,822
Total assets	**$ 12,789**	**$ 71,822**	**$ —**	**$ 84,611**
Liabilities				
Derivative liability (Note 8)	—	—	2,749	2,749
Total liabilities	**$ —**	**$ —**	**$ 2,749**	**$ 2,749**

The Level 2 assets consist of corporate and government debt securities which are valued using market observable inputs, including the current interest rate and other characteristics for similar types of investments, whose fair value may not represent actual transactions of identical securities. There were no transfers between Levels 1, 2 or 3 for the periods presented.

The Level 3 liabilities consist of the derivative liability associated with the Series A Preferred Stock, of which the fair values were

measured upon issuance of the Series A Preferred Stock and are remeasured to fair value at each reporting period. The valuation methodology and underlying assumptions are discussed further in Note 8 – *"Derivative Liability."* Significant change to the inputs used in determining the fair value would result in significant changes to the fair value measurement.

5. Marketable Securities and Strategic Investments

Marketable Securities

The following is a summary of the Company's marketable securities as of September 30, 2026 and December 31, 2025:

	September 30, 2026			
(in thousands)	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Corporate debt securities	$ 59,878	$ 4	$ (117)	$ 59,765
Government debt securities	14,421	—	(40)	14,381
Total	**$ 74,299**	**$ 4**	**$ (157)**	**$ 74,146**

	December 31, 2025			
(in thousands)	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Corporate debt securities	$ 69,308	$ 60	$ (2)	$ 69,366
Government debt securities	2,454	2	—	2,456
Total	**$ 71,762**	**$ 62**	**$ (2)**	**$ 71,822**

The Company believes it is more likely than not that its marketable securities in an unrealized loss position will be held until maturity or the recovery of the cost basis of the investment. To date, the Company has not recorded any allowance for credit losses on its investment securities. The Company determined that the unrealized losses were not attributed to credit risk but were primarily driven by the broader change in interest rates. As of September 30, 2026, approximately $787,000 of the Company's marketable securities had maturities of 12 to 36 months while the remaining marketable securities had maturities of less than 12 months.

For the three and nine months ended September 30, 2026 and 2025, the Company did not recognize any realized gains or losses on its marketable securities.

Strategic Investments

The Company's long-term strategic investments as of December 31, 2025 represented investments made in Vivasure in 2022, 2021 and 2020 that were originally recorded at cost. There were no observable price changes, other than as described below, or impairments identified during the nine months ended September 30, 2025 related to these investments.

On January 9, 2026, Haemonetics Corporation, a global medical technology company focused on delivering innovative solutions designed to improve patient outcomes, announced its acquisition of Vivasure. Vivasure was a strategic investment of the Company prior to its acquisition. During the nine months ended September 30, 2026, the Company received approximately $10.9 million of proceeds in association with the transaction and recognized a gain on the sale of strategic investments of $8.4 million. The Company may receive additional proceeds in the future associated with revenue earnouts based on the achievement of certain milestones.

6. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consists of the following:

(in thousands)	September 30, 2026	December 31, 2025
Equipment	$ 3,571	$ 2,743
Office furniture	459	444
Leasehold improvements	171	159
Property and equipment, gross	4,201	3,346
Less accumulated depreciation and amortization	(1,917)	(1,631)
Total Property and equipment, net	**$ 2,284**	**$ 1,715**

As of September 30, 2026, $965,000 of equipment is not yet in service and has not yet commenced depreciation.

Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consist of the following:

(in thousands)	September 30, 2026	December 31, 2025
Clinical trial accruals	$ 4,410	$ 4,151
Accrued compensation	1,920	4,160
Other accrued expenses	2,037	1,579
Total Accrued expenses and other liabilities	**$ 8,367**	**$ 9,890**

7. Common and Preferred Stock

Common Stock

The Company is authorized to issue up to 340,000,000 shares of Common Stock.

Preferred Stock

The Company is authorized to issue 10,000,000 shares of preferred stock with a par value of $0.0001 per share. The board of directors of the Company (the "Board") has the authority to issue preferred stock and to determine the rights, privileges, preferences, restrictions, and voting rights of those shares. As of September 30, 2026 and December 31, 2025, 200,000 shares of preferred stock were outstanding.

Series A Preferred Stock

On October 24, 2025, concurrent with the execution of the Termination and ROFR Agreement, the Company and Terumo Medical Corporation ("TMC") entered into a securities purchase agreement (the "Terumo Securities Purchase Agreement"), pursuant to which TMC purchased 200,000 shares of Series A Preferred Stock ("Preferred Shares") at a purchase price equal to $100.00 per share for gross proceeds to the Company of $20.0 million. The closing of the sale of the Preferred Shares pursuant to the Terumo Securities Purchase Agreement occurred on November 7, 2025.

The Series A Preferred Stock was accounted for as mezzanine equity in accordance with ASC 480 and the embedded conversion and redemption features were separated from the host instrument and recognized as derivative liability with change in fair value at each reporting period end recognized in the condensed consolidated statements of operations and comprehensive loss. (see Note 8 – *"Derivative Liability"*).

The Company utilized an option pricing valuation to determine the fair value of the Series A Preferred Stock at issuance. The valuation incorporated Level 3 inputs in the fair value hierarchy including the expected life of Series A Preferred Stock, expected volatility, and discount rate as well as probability-weighted outcomes. Assumptions used in the valuation also take into account the contractual terms as well as the quoted price of the Company's common stock in an active market. Significant changes in any of these inputs in isolation would result in significant changes to the fair value measurement.

A roll-forward of the Series A Preferred Stock activity is presented below for the nine months ended September 30, 2026 (in thousands):

Beginning balance, January 1, 2026	**$**	**9,808**
Adjustment to carrying value of Series A Preferred Stock		1,156
Ending balance, September 30, 2026	**$**	**10,964**

At-the-Market Offering and Shelf Registration Statement

On August 12, 2024, the Company entered into a sales agreement (the "Sales Agreement") with TD Securities (USA) LLC, as agent ("TD Cowen"), pursuant to which the Company may offer and sell, from time to time through TD Cowen, up to $100.0 million of shares of Common Stock (the "Offering") by any method permitted by law and deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended. The Offering is being made pursuant to a shelf registration statement, filed with the SEC on May 15, 2024 and declared effective on May 24, 2024 (the "Shelf Registration Statement"), a base prospectus, dated May 24, 2024, included as part of the Shelf Registration Statement, and a prospectus supplement, dated August 12, 2024 filed with the SEC pursuant to Rule 424(b)(5) on August 12, 2024.

During the three months ended September 30, 2026, the Company sold 1,219,499 shares of Common Stock under the Sales Agreement resulting in aggregate gross proceeds to the Company of approximately $6.2 million and net proceeds to the Company of approximately $6.0 million. During the nine months ended September 30, 2026, the Company sold 2,670,938 shares of Common Stock under the Sales Agreement resulting in aggregate gross proceeds to the Company of approximately $12.2 million and net proceeds to the Company of approximately $11.9 million. As of September 30, 2026, the Company had up to $86.2 million of Common Stock available to sell under the Sales Agreement.

8. Derivative Liability

The Company assessed the Series A Preferred Stock features to determine whether any features are required to be bifurcated and separately accounted for as an embedded derivative. The Company concluded that certain conversion and redemption features meet the requirements to be separately accounted for as a bifurcated derivative. The Series A Preferred Stock was accounted for as mezzanine equity in accordance with ASC 480 and the embedded conversion and redemption features were separated from the host instrument and recognized as derivative liabilities with change in fair value at each reporting period end recognized in the condensed consolidated statements of operations and comprehensive loss.

The Company performed a "with-and-without" scenario analysis to determine the fair value of the derivative liability by comparing the value of the Series A Preferred Stock including the bifurcated embedded derivatives to the value of the Series A Preferred Stock excluding them. The Company utilized an option pricing valuation with the expected life of Series A Preferred Stock, expected volatility, and discount rate as significant inputs as well as probability-weighted outcomes. Assumptions used in the valuation also take into account the contractual terms as well as the quoted price of the Common Stock in an active market. Significant changes in any of those inputs in isolation would result in significant changes to the fair value measurement.

The following table presents changes in Level 3 liabilities measured at fair value for the nine months ended September 30, 2026 (in thousands):

		September 30, 2026
Beginning balance, January 1, 2026	**$**	2,749
Change in the fair value of derivative liability		(1,156)
Ending balance, September 30, 2026	**$**	**1,593**

The option pricing valuation used to determine the fair value, used the following assumptions:

	September 30, 2026	December 31, 2025
Expected term (in years)	1.25	2.00
Expected volatility	69 %	80 %
Risk-free interest rate	4.53 %	3.41 %
Expected dividend yield	0 %	0 %
Market discount rate	24.61 %	14.79 %
Fair value of common stock	6.22	4.15

Each of these inputs is subjective and generally requires significant judgment and estimation by management:

Expected Term — The expected term represents the estimated time until the conversion or redemption events are achieved.

Expected Volatility — The Company derives volatility over the expected term using its own historical stock price volatility.

Risk-Free Interest Rate — The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of the remeasurement and all thereafter for zero-coupon U.S. Treasury notes with maturities commensurate with the remaining term.

Expected Dividend Yield — The expected dividend yield is zero as the Company has not paid, and the Company does not anticipate paying, any dividends on the Common Stock in the foreseeable future.

Market Discount Rate – The Company utilizes the S&P corporate yield curve with a tenor commensurate with the expected term to estimate a discount rate applicable to the Company's credit risk.

Fair Value of Common Stock — The Company utilizes the price of its publicly-traded Common Stock as an input in determining the fair value of the derivative.

9. Warrants

The Company evaluates its outstanding warrants to determine if the instruments qualify for equity or liability classification.

Summarized Outstanding Warrants

The following table summarizes outstanding warrants to purchase shares of Common Stock as of September 30, 2026 and December 31, 2025:

	Number of Shares		Exercise Price	Remaining Term in Years
	September 30, 2026	December 31, 2025		
Equity-classified Warrants				
Pre-Funded Warrants[1]	3,886,331	5,136,363	$0.0001	N/A
Ligand Warrant (Note 13)	2,000,000	2,000,000	$3.67	8.84
Orchestra BioMed, Inc. Warrants[2]	507,841	507,841	$4.06 – $10.22	0.67 - 2.32
Hercules Warrants (Note 14)	167,598	167,598	$3.58	5.10
Avenue Warrants	27,707	27,707	$7.67	2.02
Non-employee Warrants (Note 10)	60,000	60,000	$4.69	3.42
Private Warrants Held by Sponsor[3]	750,000	750,000	$11.50	6.33
Officer and Director Warrants[4]	635,000	635,000	$11.50	6.33
Total Outstanding	8,034,477	9,284,509		

(1) In August 2025, the Company received $2.7499 per the Pre-Funded Warrant issued, or $14.1 million in aggregate proceeds. Each Pre-Funded Warrant may be exercised for $0.0001 per Pre-Funded Warrant. During the nine months ended September 30, 2026, 1,250,032 Pre-Funded Warrants were exercised in a cashless transaction.

(2) Represents warrants initially issued by Orchestra BioMed, Inc., which converted into warrants to acquire Common Stock in connection with the Business Combination (the "Orchestra BioMed, Inc. Warrants").

(3) The Sponsor purchased 1,500,000 warrants to purchase shares of HSAC2 in a private placement upon consummation of the HSAC2 initial public offering (the "Private Warrants"), 750,000 of which were forfeited by the Sponsor immediately prior to the closing of the Business Combination (the "Sponsor Forfeiture").

(4) Pursuant to the terms of the Business Combination, immediately following the Sponsor Forfeiture and prior to the closing of the Business Combination, HSAC2 issued 750,000 warrants to purchase Common Stock to eleven specified employees and directors of Orchestra (the "Officer and Director Warrants"). These Officer and Director Warrants have substantially similar terms to the forfeited Private Warrants, except they were subject to vesting provisions that expired in January 2026. There are fewer than 750,000 Officer and Director Warrants outstanding currently due to forfeitures by persons that resigned from the Company prior to the vesting of the Officer and Director Warrants.

10. Stock-Based Compensation

Orchestra BioMed Holdings, Inc. 2023 Equity Incentive Plan

On January 26, 2023, the Company adopted the Orchestra BioMed Holdings, Inc. 2023 Equity Incentive Plan (the "2023 Plan"), which permits the granting of incentive stock options, non-qualified options, stock appreciation rights, restricted stock, restricted stock units, performance awards and other stock-based award to employees, directors, and non-employee consultants and/or advisors. As of September 30, 2026, approximately 483,000 shares of Common Stock remained available for issuance pursuant to future awards under the 2023 Plan. The pool of available shares is automatically increased on the first day of each calendar year, beginning January 1, 2024 and ending January 1, 2032, by an amount equal to the lesser of (i) 4.8% of the outstanding shares of the Common Stock determined on a fully-diluted basis as of the immediately preceding December 31 and (ii) 3,036,722 shares of Common Stock, and (iii) such number of shares of Common Stock determined by the Board or the Compensation Committee prior to January 1st of a given year. Employees, consultants, and directors are eligible for awards granted under the 2023 Plan, which generally have a contractual life of up to 10 years and may be exercisable in cash or as otherwise determined by the Board. Vesting generally occurs over a period of not greater than four years.

Orchestra BioMed Holdings, Inc. 2025 New Hire Inducement Plan

In November 2025, the Company's Board of Directors adopted the 2025 New Hire Inducement Plan (the "Inducement Plan"). The Inducement Plan provides for the grant of nonstatutory stock options, stock appreciation rights, restricted stock, RSUs and other stock-based awards with respect to an aggregate of 950,000 shares of Common Stock (subject to adjustment as provided in the Inducement Plan). Awards under the Inducement Plan may only be granted to new employees who were not previously an employee or director of the Company or are commencing employment with the Company following a bona fide period of non-employment, in either case, as an inducement material to the individual's entering into employment with the Company and in accordance with the requirements of Nasdaq

Stock Market Rule 5635(c)(4). During the nine months ended September 30, 2026, the Company granted inducement equity awards to 21 new employees as a material inducement to acceptance of their respective employment consisting of stock options to purchase up to an aggregate of 338,500 shares of the Common Stock. As of September 30, 2026, there were approximately 498,000 shares remaining available for future issuance under the Inducement Plan.

Orchestra BioMed Holdings, Inc. 2026 Employee Stock Purchase Plan

In June 2026, the Company's shareholders approved the Orchestra BioMed Holdings, Inc. 2026 Employee Stock Purchase Plan (the "ESPP"). The ESPP allows eligible employees to acquire a stock ownership interest in Common Stock in consideration of the participating employees' continued services. Eligible employees will be entitled to purchase limited amounts of Common Stock at a discount during semi-annual offering periods. The per-share purchase price at the end of each offering period is equal to the lesser of 85% of the closing price of the Common Stock at (i) the beginning of the offering period or (ii) the end of the offering period. There were 750,000 shares reserved for issuance under the ESPP and no shares were issued under the 2026 ESPP during the nine months ended September 30, 2026.

Stock-based Compensation Expense

Total stock-based compensation related to option issuances was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2026	2025	2026	2025
Research and development	$ 660	$ 552	$ 1,791	$ 1,825
Selling, general and administrative	409	436	1,192	1,767
Total stock-based compensation	**$ 1,069**	**$ 988**	**$ 2,983**	**$ 3,592**

As of September 30, 2026, there was approximately $9.1 million of unrecognized stock-based compensation expense associated with the stock options noted above that is expected to be recognized over a weighted average period of approximately 2.8 years.

Total stock-based compensation related to restricted stock awards and restricted stock units was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2026	2025	2026	2025
Research and development	$ 429	$ 572	$ 1,555	$ 1,565
Selling, general and administrative	762	1,126	3,007	3,112
Total stock-based compensation	**$ 1,191**	**$ 1,698**	**$ 4,562**	**$ 4,677**

As of September 30, 2026, there was approximately $8.7 million of unrecognized restricted stock-based compensation expense associated with the restricted stock noted above that is expected to be recognized over a weighted average period of approximately 2.1 years.

On February 28, 2025, the Company issued equity-classified warrants to purchase 60,000 shares of Common Stock at an exercise price of $4.69 per share to non-employee consultants. The warrants were issued as consideration for entering into an agreement for future services. At the grant date, 6,000 became exercisable while the remaining vested ratably over eight months. Assumptions used were an expected term (in years) of 2.84, expected volatility of 110.1%, risk-free interest rate of 3.99%, expected dividend yield of 0%, and the fair value of Common Stock of $3.12.

Total stock-based compensation related to the employee stock purchase plan was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2026	2025	2026	2025
Research and development	$ 20	$ —	$ 20	$ —
Selling, general and administrative	6	—	6	—
Total stock-based compensation	**$ 26**	**$ —**	**$ 26**	**$ —**

Total stock-based compensation related to warrants was 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
Research and development	$ —	$ 120	$ 32	$ 361
Selling, general and administrative	—	207	39	598
Total stock-based compensation	**$ —**	**$ 327**	**$ 71**	**$ 959**

As of September 30, 2026, the stock-based compensation expense associated with the warrants noted above is fully recognized.

Stock Option Activity

The following table summarizes the stock option activity of the Company under the 2023 Plan and the Inducement Plan:

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Term (years)	Aggregate Intrinsic Value (000s)
Outstanding at January 1, 2026	7,199,571	$ 6.23	7.08	$ 1,963
Granted	1,735,434	3.93	—	—
Exercised	(12,278)	3.43	—	14
Forfeited/canceled	(349,904)	6.02	—	—
Outstanding September 30, 2026	**8,572,823**	**$ 5.78**	**7.04**	**$ 10,935**
Exercisable at September 30, 2026	**5,175,542**	**$ 6.89**	**5.84**	**$ 4,270**

The weighted average grant-date fair value of stock options granted during the nine months ended September 30, 2026 and 2025 was $3.34 and $2.12 per share, respectively.

Restricted Equity Awards Activity

The following table summarizes the restricted stock awards and restricted stock units activity of the Company under the 2023 Plan:

	Restricted Stock Awards/Units Outstanding	Weighted Average Grant Date Fair Value
Outstanding at January 1, 2026	2,300,651	$ 3.95
Granted	1,721,631	3.83
Vested	(661,598)	5.80
Forfeited/canceled	—	—
Outstanding September 30, 2026	3,360,684	$ 3.53

No performance-based restricted stock awards or units were granted during the nine months ended September 30, 2026. The fair value of restricted stock units vested during the three and nine months ended September 30, 2026 was approximately $611,000 and $3.8 million, respectively.

Determination of Stock Option Awards Fair Value

The estimated grant-date fair value of all the Company's option awards was calculated using the Black-Scholes option pricing model, based on the following weighted average assumptions:

	Nine Months Ended September 30,	
	2026	2025
Expected term (in years)	6.18	6.00
Expected volatility	111 %	81 %
Risk-free interest rate	3.94 %	3.91 %
Expected dividend yield	0 %	0 %
Fair value of common stock	3.34	3.05

The fair value of each stock option grant was determined by the Company using the methods and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment and estimation by management.

Expected Term — The expected term represents the period that stock-based awards are expected to be outstanding. The Company's historical share option exercise information is limited due to a lack of sufficient data points and did not provide a reasonable basis upon which to estimate an expected term. The expected term for option grants is therefore determined using the "simplified" method, as prescribed in the Securities and Exchange Commission's Staff Accounting Bulletin (SAB) No. 107. The simplified method deems the expected term to be the midpoint between the vesting date and the contractual life of the stock-based awards.

Expected Volatility — The Company derives volatility over the expected term using its own historical stock price volatility.

Risk-Free Interest Rate — The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the stock-based awards' expected term.

Expected Dividend Yield — The expected dividend yield is zero as the Company has not paid, and the Company does not anticipate paying, any dividends on the Common Stock in the foreseeable future.

Fair Value of Common Stock — The Company utilizes the price of its publicly-traded Common Stock to determine the grant date fair value of awards.

11. Leases

Office Lease

In August 2024, the Company entered into an additional addendum to the lease agreement for office space in New Hope, PA originally entered into by Orchestra BioMed, Inc. in December 2009 (as amended, the "New Hope Lease"). The New Hope Lease covers 8,052 square feet and will expire in September 2027. Monthly fees under the New Hope Lease range between $17,000 and $19,000 for the period from the August 2024 addendum through expiration.

In November 2019, Orchestra BioMed, Inc. entered into a new lease agreement for approximately 5,200 square feet of office space in New York, NY. In November 2022, Orchestra BioMed, Inc. entered into an amendment for this lease which increased the office space square footage to approximately 7,800 and amended the expiration to April 2028. Monthly fees range between $28,000 and $40,000 for the period from commencement through expiration.

In September 2024, the Company entered into a new lease for 6,496 square feet of office space in Fort Lauderdale, Florida. The agreement will expire in December 2027. The monthly fees commenced in November 2024, the commencement date of the agreement, and range between $16,000 and $17,000 for the period from commencement through expiration.

Operating cash flow supplemental information for the nine months ended September 30, 2026:

Cash paid for amounts included in the present value of operating lease liabilities was $791,000 during the nine months ended September 30, 2026 compared to $735,000 during the nine months ended September 30, 2025.

As of September 30, 2026:	
Weighted average remaining lease term – operating leases, in years	1.41
Weighted average discount rate – operating leases	9.92 %

Operating Leases

The components of lease expense were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2026	2025	2026	2025
Fixed operating expense	$ 200	$ 246	$ 601	$ 779
Short-term lease expense	44	46	132	178
Variable lease expense	28	35	87	85
	$ 272	**$ 327**	**$ 820**	**$ 1,042**

Variable lease costs consist primarily of common area maintenance costs, insurance and taxes which are paid based upon actual costs incurred by the lessor. The table below shows the future minimum rental payments, exclusive of taxes, insurance, and other costs, under the leases as of September 30, 2026:

Year ending December 31:	Operating Leases (in thousands)
2026 (remaining three months)	$ 225
2027	829
2028	159
2029	—
2030	—
Thereafter	—
Total future minimum lease payments	$ 1,213
Imputed interest	(78)
Total liability	**$ 1,135**

12. Related Party Transactions

In addition to transactions and balances related to cash and stock-based compensation to officers and directors, the Company had the following transactions and balances with related parties during the nine months ended September 30, 2026 and the year ended December 31, 2025:

As part of the Public Offering, on August 4, 2025, (i) entities associated with RTW Investments, LP (collectively, "RTW"), which beneficially owned approximately 21% of the Common Stock immediately prior to the Public Offering, purchased Pre-Funded Warrants exercisable for 3,636,363 shares of Common Stock and (ii) Perceptive Life Sciences Master Fund, Ltd, which beneficially owned approximately 12% of the Common Stock immediately prior to the Public Offering, purchased Pre-Funded Warrants exercisable for 1,500,000 shares of Common Stock. During the nine months ended September 30, 2026, RTW exercised 1,250,032 Pre-Funded Warrants on a cashless basis and received 1,250,000 shares of Common Stock.

In addition, transactions between the Company and Medtronic are disclosed in both Note 3 – *"Medtronic Agreement"* and Note 14 – *"Debt Financing."*

The Company had no other transactions or balances with current related parties during the nine months ended September 30, 2026.

13. Royalty Purchase Agreement

On July 31, 2025, the Company entered into a revenue participation right purchase and sale agreement (the "Royalty Purchase Agreement") with Ligand Pharmaceuticals Incorporated ("Ligand"). Under the terms of the Royalty Purchase Agreement, in exchange for payment of $35.0 million (the "Investment Amount"), less certain reimbursable expenses, Ligand acquired the right to receive tiered royalty

payments from the Company (the "Royalty Interest") with respect to revenue (including certain licensing revenue) received by the Company in a calendar year in connection with worldwide net product sales, or other product revenue received, by the Company and its licensees ("Annual Net Sales") of (a) AVIM Therapy (the "Primary Product") and (b) Virtue SAB (the "Secondary Product" and together with the Primary Product, the "Products") in the field of coronary artery treatment.

Pursuant to the Royalty Purchase Agreement, the Investment Amount was received in two tranches: (i) $20.0 million was received on August 4, 2025 and (ii) $15.0 million was received on May 1, 2026 (the "Second Installment"). In repayment of the Investment Amount, the Company will remit 17.0% of revenues related to the Products until an annual total of $17.0 million has been remitted to Ligand, thereafter the Company will remit (a) 4.0% of revenues related to the Primary Product in the field of HTN treatment and (b) 4.0% of revenues related to the Secondary Product in the field of coronary artery treatment.

The Royalty Interest in respect of Annual Net Sales of the Products will end on the date in which no Product is being developed or commercialized by or on behalf of the Company, any of its affiliates, or any of its or their licensees or distributors and Ligand has received the last Royalty Interest payment payable under the terms of the Royalty Purchase Agreement. The obligations arising under the Royalty Purchase Agreement are secured by security interests in, and pledges over, the Royalty Interest, the Revenue Participation Right (as defined in the Royalty Purchase Agreement) and the Company's interests in the Products and associated intellectual property rights, subject to certain agreed security principles, permitted liens and other customary exceptions and qualifications, and the security interests in the Products and associated intellectual property rights of the Company are subordinate in right of payment to the prior payment in full of the outstanding indebtedness under the 2024 LSA (as defined below). The Royalty Purchase Agreement contains customary representations, warranties and indemnities of the Company and Ligand, and customary covenants on the part of the Company.

In connection with the sale of the Royalty Interest, and pursuant to the terms of the Royalty Purchase Agreement, on August 4, 2025, the Company issued to Ligand a warrant (the "Ligand Warrant") to purchase up to 2,000,000 shares of the Common Stock (the "Ligand Warrant Shares"), at an exercise price equal to $3.67 per share. The exercise price of the Ligand Warrant and the number of Ligand Warrant Shares issuable upon exercise of the Ligand Warrant are subject to adjustments for stock splits, combinations, stock dividends or similar events. Pursuant to the terms of the Ligand Warrant, the Ligand Warrant Shares vested and became exercisable as follows: (i) 1,142,857 of the Ligand Warrant Shares (the "First Tranche") vested upon issuance; and (ii) 857,143 of the Ligand Warrant Shares vested on the date of payment of the Second Installment. The Ligand Warrant is exercisable for ten years from the date of issuance.

The Company accounted for its sale of royalty revenues to Ligand, pursuant to the Royalty Purchase Agreement, in accordance with ASC 470, *Debt*, which addresses situations in which an entity receives cash from an investor in return for an agreement to pay the investor a specified percentage of the revenue from a contractual right. The Company classified the proceeds received from the sale to Ligand as debt as the Company determined that it had significant continuing involvement in the generation of the cash flows to Ligand. Interest related to the Royalty Purchase Agreement will be recognized utilizing the effective interest method over the estimated term.

The Company's estimate of interest expense associated with the Royalty Interest resulted in an effective annual interest rate of approximately 21.3% as of September 30, 2026 and 23.1% as of December 31, 2025. This estimate contains significant assumptions that impact the interest expense that will be recognized over the royalty period. The Company will periodically assess the estimated amounts due and payable to Ligand and to the extent the amount or timing of such payments is materially different than the original estimates, an adjustment will be recorded prospectively to the condensed consolidated statements of operations and comprehensive loss. There are a number of factors that could materially affect the amount and timing of the royalty payments to be paid by the Company to Ligand and, correspondingly, the amount of interest expense recorded by the Company.

The following table shows the activity of the Royalty Purchase Agreement for the nine months ended September 30, 2026 (in thousands):

	September 30, 2026
Beginning balance, January 1, 2026	$ 16,482
Proceeds from the royalty purchase agreement	15,000
Non-cash interest expense on liability	5,313
Ending balance, September 30, 2026	$ 36,795

Total interest expense recorded on Royalty Interest during the three and nine months ended September 30, 2026 was approximately $2.2 million and $5.3 million, respectively. Total interest expense recorded on the Royalty Interest during the three and nine months ended September 30, 2025 was approximately $761,000.

14. Debt Financing

2025 Medtronic Loan Agreement

On July 31, 2025, the Company and its wholly-owned subsidiaries, Orchestra BioMed, Inc. and BackBeat, entered into a Loan Agreement with Medtronic (the "Medtronic Loan Agreement"), pursuant to which Medtronic agreed to extend a convertible loan to the Company in the aggregate original principal amount of $20.0 million (the "Medtronic Loan"). The Medtronic Loan is evidenced by a secured subordinated convertible promissory note (the "Medtronic Note") issued by the Company. The issuance of the Medtronic Note to Medtronic and the funding of the Medtronic Loan occurred on May 1, 2026 pursuant to the conditions described in the Medtronic Loan Agreement.

The Medtronic Note accrues simple interest at a rate of 11% per annum provided that no interest payments will be paid or due until April 27, 2031 (the "Maturity Date"). The Medtronic Note does not allow for prepayment without the prior consent of Medtronic. Unless earlier converted, or redeemed, the Medtronic Note will mature on the Maturity Date. In addition, the payment or other satisfaction of the obligations set forth in the Medtronic Loan Agreement are subordinate in right of payment to the prior payment in full of the senior obligations. The obligations arising under the Medtronic Loan Agreement and the Medtronic Note are secured by security interests in, and pledges over, the Company's assets, subject to certain agreed security principles, permitted liens and other customary exceptions and qualifications.

The principal balance of the Medtronic Note, together with all accrued and unpaid interest thereon (collectively, the "Balance") will automatically convert into a revenue share (the "Revenue Share Credit"), if FDA approval of a Medtronic device incorporating AVIM Therapy is achieved prior to the Maturity Date. Upon conversion of the then outstanding Balance the Company shall pay to Medtronic the Revenue Share Credit, which shall equal 15% of the revenue share amounts that the Company receives under the Amended Medtronic Agreement, until such time as the total Revenue Share Credit payments equal $40.0 million.

The Medtronic Loan Agreement contains customary representations, warranties and affirmative and negative covenants. In addition, the Medtronic Loan Agreement contains customary events of default that entitle Medtronic to cause the Company's indebtedness under the Note to become immediately due and payable, and to exercise remedies against the Company and the collateral securing the Loan. Upon the occurrence and for the duration of an event of default, an additional default interest rate equal to 2.0% per annum may apply to all obligations owed under the Loan Agreement.

The Company recognizes interest expense using the effective interest method over the estimated term of the arrangement. The effective interest rate is based on the Company's estimate of the timing and amount of future payments expected to be made under the arrangement. The total interest expense associated with the Medtronic Note resulted in an effective interest rate of 15.2% as of September 30, 2026. The Company will periodically assess the estimated amounts due and payable to Medtronic and to the extent the amount or timing of such payments is materially different than the original estimates, an adjustment will be recorded prospectively to the condensed consolidated statements of operations and comprehensive loss.

The obligations under the Medtronic Loan as of September 30, 2026 consisted of the following (in thousands):

		September 30, 2026
Beginning balance, January 1, 2026	$	—
Proceeds from note payable		20,000
Accrued interest expense on liability		1,152
Ending balance, September 30, 2026	$	21,152

The following table shows the amount of principal payments due pursuant to the Medtronic Loan by year:

Year ending December 31:	Principal Payments (in thousands)
2026 (remaining three months)	$ —
2027	—
2028	—
2029	—
2030	—
Thereafter	20,000
Total	**$ 20,000**

Total interest expense recorded on this facility during the three and nine months ended September 30, 2026 was approximately $711,000 and $1.2 million, respectively. No interest expense was recorded on this facility during the three and nine months ended September 30, 2025.

2024 Loan and Security Agreement

On November 6, 2024 (the "LSA Closing Date"), the Company and certain of its subsidiaries (together with the Company, the "Borrower") entered into a Loan and Security Agreement, by and among the Borrower, the several banks and other financial institutions or entities party thereto, as lenders (collectively, the "Hercules Lenders"), and Hercules Capital, Inc. ("Hercules"), as administrative agent and collateral agent for itself and the Hercules Lenders, as amended by that certain First Amendment to Loan and Security Agreement dated as of December 30, 2024, Second Amendment to Loan and Security Agreement dated as of July 31, 2025 and Third Amendment to the Loan and Security Agreement, dated as of April 6, 2026 (as amended, the "2024 LSA").

The 2024 LSA provides a secured term loan facility of up to $50.0 million in up to two tranches (collectively, the "Term Loans"), with the first tranche of $15.0 million drawn on the LSA Closing Date, and a second tranche of up to $35.0 million that may be borrowed by the Company in the discretion of the lender's investment committee.

Under the terms of the 2024 LSA, the initial date upon which the Company has to begin amortizing the Term Loans is June 1, 2028. The Term Loans accrue interest at a floating per annum rate equal to the greater of (i) (x) the "prime rate" as reported in The Wall Street Journal plus (y) 2.0%, and (ii) 9.50%. The repayment terms of the Term Loans include monthly payments over a 4-year period, consisting of an interest-only period expiring June 1, 2028, followed by six monthly principal payments plus interest. At the Company's option, the Company may prepay all or a portion of the outstanding Term Loans, subject to a prepayment premium equal to (a) 3.0% of the Term Loans being prepaid if the prepayment occurs during the twelve months following the LSA Closing Date, (b) 2.0% of the Term Loans being prepaid if the prepayment occurs after 12 months following the LSA Closing Date but on or prior to 24 months following the LSA Closing Date, and (c) 1.0% of the Term Loans being prepaid if the prepayment occurs after 24 months following the LSA Closing Date and prior to the maturity date. In addition, the Company will pay an end of term charge of 6.35% of the principal amount of the Term Loans upon the prepayment or repayment of the Term Loans and a facility charge of 0.75% upon any draws of the Term Loans.

In connection with the entry into the 2024 LSA, on the LSA Closing Date, the Company issued each of the Hercules Lenders a warrant to purchase Common Stock, which warrants were amended effective August 4, 2025 in connection with the Second Amendment to Loan and Security Agreement (as amended, each a "Hercules Warrant" and, collectively, the "Hercules Warrants"). Pursuant to the terms of the Hercules Warrants, each Hercules Lender can purchase that number of shares of Common Stock equal to (i)(x) 0.04, multiplied by (y) the aggregate principal amount of all Term Loan Advances (as defined in the 2024 LSA) made to the Company by the applicable Lender, divided by (ii) $3.58, which is the exercise price of the Hercules Warrants. Each Hercules Warrant is exercisable for seven years from the LSA Closing Date.

The 2024 LSA includes customary affirmative and negative covenants and representations and warranties, including a covenant against the occurrence of a "change in control," financial reporting obligations, and certain limitations on indebtedness, liens, investments, distributions (including dividends), collateral, transfers, mergers or acquisitions, taxes, corporate changes, and bank accounts. The 2024 LSA also includes customary events of default, including payment defaults, breaches of covenants following any applicable cure period, the occurrence of certain events that could reasonably be expected to have a "material adverse effect" as set forth in the 2024 LSA, cross

acceleration to third-party indebtedness and certain events relating to bankruptcy or insolvency. Upon the occurrence of an event of default, Hercules may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the 2024 LSA.

The Company must maintain Qualified Cash (as defined in the 2024 LSA), beginning on January 1, 2027 (subject to being extended to as late as January 1, 2028 depending on the Company's receipt of specified net cash proceeds from specified sources), in an amount greater than or equal to (x) the outstanding principal amount of the Term Loan Advances, multiplied by (y) the applicable Cash Coverage Percentage (as defined in the 2024 LSA), which percentage ranges from a minimum of 45% to a maximum of 75% of Term Loan Advances, depending upon the amount of Qualified Cash.

The following table shows the amount of principal payments due pursuant to the Term Loans by year:

Year ending December 31:	Principal Payments (in thousands)
2026 (remaining three months)	$ —
2027	—
2028	15,000
2029	—
Total	**$ 15,000**

Total interest expense recorded on these facilities during the three and nine months ended September 30, 2026 was approximately $488,000 and $1.5 million, respectively. Total interest expense recorded on these facilities during the three and nine months ended September 30, 2025 was approximately $482,000 and $1.4 million, respectively.

15. Segment Disclosures

The Company has one reportable segment, which consists of the development of clinical and preclinical product candidates through risk-reward sharing partnerships with leading medical device companies. The Company's CODM, its Chief Executive Officer, manages the Company's operations on a consolidated basis for the purpose of assessing performance and allocating resources based on net loss that also is reported on the condensed consolidated statement of operations and comprehensive loss as consolidated net loss. Net loss is used by the CODM to make key strategic and operational decisions. The measure of segment assets is reported on the condensed consolidated balance sheets as total consolidated assets. The majority of the Company's long-lived assets are held in the United States.

The following table presents selected financial information, including significant expenses regularly reviewed by the CODM, about the Company's single operating segment for the three and nine months ended September 30, 2026 and 2025:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
(in thousands)				
Partnership revenue	$ —	$ 721	$ —	$ 2,120
Product revenue	91	140	289	445
Expenses:				
Cost of product revenues	28	49	85	139
Non-clinical development costs	3,468	3,808	10,897	12,880
Clinical development costs	5,654	3,727	14,188	9,302
Personnel and consulting costs	9,188	6,817	26,799	20,483
Stock-based compensation	2,286	3,013	7,642	9,228
Depreciation and amortization expense	101	81	287	245
Other segment expenses, net[(1)]	2,662	3,679	8,119	8,849
Interest expense, net	2,463	515	5,052	385
Change in the fair value of derivative liability	(867)	—	(1,156)	—
Gain on sale of strategic investments	(6,142)	—	(8,428)	—
Net loss	$ (18,750)	$ (20,828)	$ (63,196)	$ (58,946)

(1) Other segment expenses primarily include general and administrative costs not presented in other line items.

16. Net Loss Per Share

Basic net loss per share of Common Stock is computed by dividing net loss less any adjustment to the carrying value of Series A Preferred Stock by the weighted-average number of shares of Common Stock which includes the weighted average effect of the Pre-Funded Warrants, for the purchase of shares of Common Stock, for which the remaining unfunded exercise price is $0.0001 per share. Shares of Common Stock outstanding but subject to forfeiture and cancellation by the Company are excluded from the weighted-average number of shares until the period in which such shares are no longer subject to forfeiture. In connection with the Business Combination, the Sponsor agreed that 25% or 1,000,000 of the shares of Common Stock held by the Sponsor (the "Forfeitable Shares") will be forfeited to the Company on the first business day following the fifth anniversary of the closing of the Business Combination (the "Closing"), unless, as to 500,000 shares, the volume-weighted average price of the Common Stock is greater than or equal to $15.00 per share over any 20 trading days within any 30-trading day period (the "Initial Milestone Event"), and as to the remaining 500,000 shares, the volume-weighted average price of the Common Stock is greater than or equal to $20.00 per share over any 20 trading days within any 30-trading day period (the "Final Milestone Event"). On April 12, 2023, the Initial Milestone Event was achieved and 500,000 of the Forfeitable Shares are no longer subject to forfeiture. However, the Final Milestone event has not occurred, and 500,000 Forfeitable Shares remain subject to forfeiture.

In connection with the Business Combination, existing Orchestra BioMed, Inc. stockholders had the opportunity to elect to participate in an earnout (the "Earnout") pursuant to which such each electing stockholder (each, an "Earnout Participant") may receive a portion of additional contingent consideration of up to 8,000,000 shares of Common Stock (the "Earnout Consideration"). Each Earnout Participant agreed to extend their applicable lock-up period from 6 months to 12 months after the Closing, pursuant to an Earnout Election Agreement and such Earnout Participants are collectively be entitled to receive: (i) 4,000,000 shares of the Earnout Consideration, in the event that, from the time beginning immediately after the Closing until the fifth anniversary of the Closing (the "Earnout Period"), the Initial Milestone Event occurs; and (ii) an additional 4,000,000 shares of the Earnout Consideration, in the event that, during the Earnout Period, the Final Milestone Event occurs. Approximately 91% of Orchestra BioMed, Inc. stockholders elected to participate in the Earnout. On April 12, 2023, the Initial Milestone Event was achieved, and each Earnout Participant was issued their Pro Rata Portion (as such term is defined in the merger agreement for the Business Combination) of 4,000,000 shares of Common Stock, resulting in a total of 3,999,987 shares of Common Stock being issued (less than 4,000,000 due to rounding).

Diluted net loss per share of Common Stock includes the effect, if any, from the potential exercise or conversion of securities, such as stock options, Orchestra BioMed, Inc. Warrants, Private Warrants, Officer and Director Warrants, Forfeitable Shares, Earnout Consideration, and Series A Preferred Stock, using the if-converted method, which would result in the issuance of incremental shares of Common Stock, unless their effect would be anti-dilutive.

The following outstanding potentially dilutive securities have been excluded from the calculation of diluted net loss per share for the three and nine months ended September 30, 2026 and September 30, 2025, as their effect is anti-dilutive:

	Nine Months Ended September 30,	
	2026	2025
Stock options	8,572,823	7,143,824
Common stock warrants	4,148,146	4,173,146
Unvested restricted stock units	3,360,684	2,627,131
Series A Preferred Stock	1,666,666	—
Forfeitable Shares	500,000	500,000
Earnout Consideration	4,000,000	4,000,000
Employee stock purchase plan	80,332	—
Total	**22,328,651**	**18,444,101**

17. Subsequent Events

Public Offering

On November 9, 2026, the Company closed an underwritten public offering of 17,250,000 shares of Common Stock at a price to the public of $5.00 per share, resulting in net proceeds to the Company of approximately $80.5 million (including proceeds from the

underwriters' full exercise of their option to purchase additional shares), after deducting underwriting discounts and commissions and estimated offering expenses.

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

Unless otherwise indicated or the context otherwise requires, references to "Orchestra," "Orchestra's," the "Company," "we," "its" and "our" refer to Orchestra BioMed Holdings, Inc. and its consolidated subsidiaries. All references to years, unless otherwise noted, refer to the Company's fiscal years, which end on December 31.

The following discussion should be read together with "Special Note Regarding Forward-Looking Statements" and the Company's unaudited condensed consolidated financial statements, together with the related notes thereto, included elsewhere in this Quarterly Report on Form 10-Q (the "Consolidated Financial Statements"), and the Company's audited consolidated financial statements, together with the related notes thereto, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2025 filed with the SEC on March 12, 2026.

Overview

We are a biomedical innovation company accelerating high-impact technologies to patients through risk-reward sharing collaborations with market-leading global medical device companies. Our partnership-enabled business model focuses on forging strategic collaborations with leading medical device companies to drive successful global commercialization of products we develop. We are led by a highly accomplished, multidisciplinary management team and a board of directors with extensive experience in all phases of therapeutic device development. Our business was formed in 2018 by assembling a pipeline of multiple late-stage clinical product candidates originally developed by our founding team.

Our two flagship product candidates – Atrioventricular Interval Modulation Therapy ("AVIM Therapy") and Virtue® Sirolimus AngioInfusion™ Balloon ("Virtue SAB") – are currently undergoing pivotal clinical trials for their lead indications, each representing multi-billion-dollar annual global market opportunities.

AVIM Therapy is a bioelectronic treatment for hypertension ("HTN"), the leading risk factor for death worldwide, and is designed to be delivered by a pacemaker and achieve immediate, substantial and sustained reductions in blood pressure in patients with hypertensive heart disease. We have an exclusive license and strategic collaboration agreement with Medtronic Inc. (an affiliate of Medtronic plc) ("Medtronic"), one of the largest medical device companies in the world and the global leader in cardiac pacing therapies, for the development and commercialization of AVIM Therapy for the treatment of uncontrolled HTN in patients indicated for a cardiac pacemaker. We are actively conducting a double-blind, randomized, global pivotal trial (the "BACKBEAT Trial"). As of October 31, 2026, we enrolled 349 randomized patients with uncontrolled HTN who are indicated for a dual-chamber pacemaker. Assuming primary endpoints are met, we and Medtronic plan to submit primary endpoint data as a late-breaking clinical trial presentation at Heart Rhythm 2027 in May, the premier global scientific meeting for electrophysiologists and cardiologists who implant pacemakers and care for pacemaker-indicated patients. Following this, Medtronic is expected to submit a Premarket Approval application supplement to the FDA, as well as applications to other global regulatory agencies. AVIM Therapy has received two FDA Breakthrough Device Designations ("BDDs").

Virtue SAB is a highly differentiated, first-of-its-kind, non-coated drug delivery AngioInfusion balloon system designed to infuse a large liquid dose of our proprietary extended-release formulation of sirolimus, SirolimusEFR™, for the treatment of atherosclerotic artery disease, the leading cause of mortality worldwide. Virtue SAB has been granted BDD by the FDA for the treatment of coronary in-stent restenosis, coronary small vessel disease and below-the-knee peripheral artery disease, in each case, within specified parameters. We are actively enrolling patients in the Virtue SAB in the Treatment of Coronary In-Stent Restenosis ("ISR") Trial (the "Virtue Trial") for our global investigational device exemption ("IDE") pivotal trial comparing Virtue SAB head-to-head with Boston Scientific Corporation's commercially available AGENT™ paclitaxel-coated balloon. Designed to support regulatory approval of Virtue SAB, the Virtue Trial is expected to enroll 740 patients in the United States with enrollment expected to be completed by the end of 2027. We cannot provide assurance that we will be able to complete enrollment of the Virtue Trial in the timeframe we anticipate.

Since Orchestra BioMed, Inc.'s inception, we have devoted the substantial majority of our resources to research and development and clinical activities in support of our product development and collaboration efforts. We have funded our operations primarily through the issuance of our common stock, convertible preferred stock, and warrants, as well as proceeds from the Business Combination, our prior Terumo Agreement (as defined below) and the Termination and ROFR Agreement (as defined below), borrowings under debt arrangements, the sale of future revenues, sale of strategic investments, and, to a lesser extent, product revenue from our subsidiary, FreeHold Surgical, LLC ("FreeHold"). We had $101.9 million in cash and cash equivalents and marketable securities at September 30, 2026, comprised of $27.8 million in cash and cash equivalents and $74.1 million in marketable securities. We have incurred

net losses each year since inception. Our net losses were $63.2 million and $58.9 million for the nine months ended September 30, 2026 and 2025, respectively. We expect to continue to incur significant losses for the foreseeable future. As of September 30, 2026, we had an accumulated deficit of $425.8 million.

Orchestra BioMed, Inc., our wholly owned subsidiary, was incorporated in Delaware in 2017 and completed a recapitalization and mergers with Caliber Therapeutics, Inc., a Delaware corporation that has, among other things, the rights to the Virtue SAB product candidate and BackBeat Medical, Inc., ("BackBeat") a Delaware Corporation that has, among other things, the rights to the AVIM Therapy product candidate, in 2018. Orchestra BioMed, Inc. completed the conversions of Caliber Therapeutics, Inc. to Caliber Therapeutics, LLC, a Delaware limited liability company, and BackBeat Medical, Inc. to BackBeat Medical, LLC, a Delaware limited liability company, in 2019.

We were incorporated in the Cayman Islands in 2020, as a special purpose acquisition company under the name Health Sciences Acquisitions Corporation 2 ("HSAC2"). On January 26, 2023, Orchestra BioMed, Inc., our wholly owned subsidiary, and HSAC2 consummated a business combination pursuant to which, among other things, Orchestra BioMed, Inc. became a wholly owned subsidiary of HSAC2 and HSAC2 changed its name to Orchestra BioMed Holdings, Inc. (the "Business Combination"). HSAC2 Holdings, LLC was the sponsor of HSAC2 prior to the Business Combination.

Recent Developments

Public Offering

On November 9, 2026, we closed an underwritten public offering of 17,250,000 shares of our common stock at a price to the public of $5.00 per share, resulting in net proceeds to us of approximately $80.5 million (including proceeds from the underwriters' full exercise of their option to purchase additional shares), after deducting underwriting discounts and commissions and estimated offering expenses.

Transcatheter Cardiovascular Therapeutics

In November 2026, Virtue SAB was featured in a presentation at Transcatheter Cardiovascular Therapeutics ("TCT") 2026 delivered by Allen Jeremias, MD, Co-Principal Investigator of the Virtue Trial. Dr. Jeremias reviewed Virtue SAB's differentiated mechanism of action, published preclinical data showing sirolimus tissue concentrations exceeding drug-eluting stent and drug-coated balloon benchmarks through the critical healing period, three-year results from the SABRE pilot study in coronary ISR, including a target lesion failure rate of 14.3% with no additional target lesion revascularizations between years one and three, and the design of the Virtue Trial.

R&D Day Announcement

In October 2026, we announced plans to host an R&D Day on November 12, 2026, in New York City and via live webcast, featuring presentations by Company leadership, leading cardiologists and clinical trial investigators. The event will focus on the clinical and treatment burden associated with uncontrolled HTN in pacemaker-indicated patients and restenosis in coronary stent interventions, the potential for AVIM Therapy and Virtue SAB to address these unmet needs, key upcoming clinical milestones and the commercial potential of AVIM Therapy and Virtue SAB.

BACKBEAT Trial Enrollment Milestone

We completed enrollment in the BACKBEAT Trial with 349 randomized patients across 92 clinical sites in 15 countries with approximately 50% of patients from the US. We are now focused on completing the three-month follow-up period and preparing for primary endpoint data analysis. See "Overview" above in this Item 2 for additional information regarding the BACKBEAT Trial and anticipated clinical and regulatory milestones.

Components of Our Results of Operations

Partnership Revenue

Previously, our partnership revenues related to our former distribution agreement with Terumo Corporation ("Terumo Corporation") and Terumo Medical Corporation ("TMC" and, collectively with Terumo Corporation, "Terumo") for global development and

commercialization of Virtue SAB in coronary and peripheral vascular indications (the "Terumo Agreement"). In future periods, partnership revenues may include revenues related to the Exclusive License and Collaboration Agreement, dated as of June 30, 2022, by and among, Orchestra BioMed, Inc., BackBeat Medical, LLC and Medtronic, discussed in Note 3 – *"Medtronic Agreement"* to the Consolidated Financial Statements.

Orchestra BioMed, Inc., and its wholly owned subsidiary BackBeat, entered into an Exclusive License and Collaboration Agreement, dated as of June 30, 2022, with Medtronic for the development and commercialization of AVIM Therapy for the treatment of pacemaker-indicated patients with uncontrolled HTN despite the use of anti-hypertensive medications (the "Medtronic Agreement"). On July 31, 2025, our wholly owned subsidiaries, Orchestra BioMed, Inc. and BackBeat, and Medtronic entered into an amendment to the Medtronic Agreement, which became effective on August 4, 2025 (the "Medtronic Agreement Amendment"), to provide, among other things, a development and commercialization framework for future AVIM-therapy integration into a dual-chamber leadless pacemaker. Pursuant to the Medtronic Agreement Amendment, we will be required, among other things, to reimburse Medtronic for certain expenses incurred in connection with the integration of AVIM-therapy into Medtronic's dual-chamber leadless pacemaker, up to a specified cap, to the extent Medtronic elects to pursue such integration.

We have determined that the arrangement set forth in the Medtronic Agreement as amended by the Medtronic Agreement Amendment (the "Amended Medtronic Agreement") is a collaboration within the scope of ASC 808, Collaborative Arrangements ("ASC 808"). In addition, we concluded that Medtronic is a customer for a good or service that is a distinct unit of account, and therefore, the transactions set forth in the Amended Medtronic Agreement should be accounted for under ASC 606. Through September 30, 2026, there have been no amounts recognized as revenue under the Amended Medtronic Agreement.

Product Revenue

Product revenues related to sales of FreeHold's intracorporeal organ retractors and such revenues are recognized at a point-in-time upon the shipment of the product to the customer given payment terms are typically 30 days. FreeHold products are currently only sold in the United States.

Cost of Product Revenue and Gross Margin

Cost of product revenue consists primarily of costs of finished goods components for use in FreeHold's products and assembled, warehoused and inventoried by a third-party vendor. We expect the cost of finished goods product revenue to increase in absolute terms as our revenue grows.

Our gross margin has been, and will continue to be, affected by a variety of factors, including finished goods manufactured component parts, as well as the cost to assemble and warehouse the FreeHold product finished goods inventory.

Research and Development Expenses

Research and development expenses consist of applicable personnel, consulting, materials and clinical study expenses. Research and development expenses include:

- Certain personnel-related expenses, including salaries, benefits, bonus, travel and stock-based compensation;
- Cost of clinical studies to support new products and product enhancements, including expenses for clinical research organizations and site payments;
- Product device materials and drug supply, and manufacturing used for internal research and development, and clinical activities;
- Allocated overhead including facilities and information technology expenses; and
- Cost of outside consultants who assist with device and drug development, regulatory affairs, clinical affairs and quality assurance.

Research and development costs are expensed as incurred. Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical studies. In the future, we expect research and development expenses may increase in absolute dollars as we continue to develop new products, enhance existing products and technologies, initiate clinical studies, manufacture drug supply for internal research and development and clinical trial supply and perform activities related to obtaining additional regulatory approvals. We do not track expenses by product candidate, unless tracking such expenses is required pursuant to the revenue recognition model for a collaborative arrangement.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist of personnel-related expenses, including salaries, benefits, bonus, travel and stock-based compensation. Other selling, general and administrative expenses include professional services fees, including legal, audit, investor/public relations, and insurance costs, outside consultants costs, employee recruiting and training costs, and non-income taxes. Moreover, we incur and expect to continue to incur additional expenses associated with operating as a public company, including legal, accounting, insurance, exchange listing and U.S. Securities and Exchange Commission ("SEC") compliance, and investor relations expenses. We expect quarterly selling, general and administrative expenses to continue to increase as we conduct additional clinical trials and expand our operations as a public company.

Interest (Expense) Income, Net

Interest (expense) income, net reflects the income generated from marketable securities during the year. Interest expense is attributable to loan interest and interest related to the Royalty Purchase Agreement.

On July 31, 2025, we entered into a revenue participation right purchase and sale agreement (the "Royalty Purchase Agreement") with Ligand Pharmaceuticals Incorporated ("Ligand"). Under the terms of the Royalty Purchase Agreement, in exchange for payment of $35.0 million (the "Investment Amount"), less certain reimbursable expenses, Ligand acquired the right to receive tiered royalty payments from us (the "Royalty Interest") with respect to revenue (including certain licensing revenue) received by us in a calendar year in connection with worldwide net product sales, or other product revenue received by, by us and our licensees ("Annual Net Sales") of (a) AVIM Therapy (the "Primary Product") and (b) Virtue SAB (the "Secondary Product" and together with the Primary Product, the "Products") in the field of coronary artery treatment. Our estimate of this total interest expense associated with the Royalty Interest resulted in an effective annual interest rate of approximately 21.3% as of September 30, 2026. This estimate contains significant assumptions that impact both the amount recorded at execution and the interest expense that will be recognized over the royalty period. We will periodically assess the estimated amounts due and payable to Ligand and to the extent the amount or timing of such payments is materially different than the original estimates, an adjustment will be recorded prospectively to increase or decrease interest expense. There are a number of factors that could materially affect the amount and timing of the royalty payments to be paid by us to Ligand and, correspondingly, the amount of interest expense recorded by us.

On November 6, 2024 (the "LSA Closing Date"), we and certain of our subsidiaries (collectively, the "Borrower") entered into a Loan and Security Agreement, by and among the Borrower, the several banks and other financial institutions or entities party thereto, as lenders (collectively, the "Hercules Lenders"), and Hercules Capital, Inc. ("Hercules"), as administrative agent and collateral agent for itself and the Hercules Lenders, as amended by that certain First Amendment to Loan and Security Agreement dated as of December 30, 2024, Second Amendment to Loan and Security Agreement dated as of July 31, 2025 and Third Amendment to Loan and Security Agreement, dated as of April 6, 2026 (as amended, the "2024 LSA") .

The 2024 LSA provides a secured term loan facility of up to $50.0 million in up to two tranches (collectively, the "Term Loans"), with the first tranche of $15.0 million drawn on the LSA Closing Date, and a second tranche of up $35.0 million that may be borrowed by us in the discretion of the lender's investment committee.

Under the terms of the 2024 LSA, the initial date upon which we have to begin amortizing Term Loans is June 1, 2028. The Term Loans accrue interest at a floating per annum rate equal to the greater of (i) (x) the "prime rate" as reported in The Wall Street Journal plus (y) 2.0%, and (ii) 9.50%. The repayment terms of the Term Loans include monthly payments over a 4-year period, consisting of an interest-only period expiring June 1, 2028, followed by six monthly principal payments plus interest. At our option, we may prepay all or a portion of the outstanding Term Loans, subject to a prepayment premium equal to (a) 3.0% of the Term Loans being prepaid if the prepayment occurs during the twelve months following the LSA Closing Date, (b) 2.0% of the Term Loans being prepaid if the prepayment occurs after 12 months following the LSA Closing Date but on or prior to 24 months following the LSA Closing Date, and (c) 1.0% of the Term Loans being prepaid if the prepayment occurs after 24 months following the LSA Closing Date and prior to the maturity date. In addition, we will pay an end of term charge of 6.35% of the principal amount of the Term Loans upon the prepayment or repayment of the Term Loans and a facility charge of 0.75% upon any draws of the Term Loans. Refer to Note 14 – *"Debt Financing"* to the Consolidated Financial Statements.

On July 31, 2025, we and our wholly-owned subsidiaries, Orchestra BioMed, Inc. and BackBeat, entered into a Loan Agreement with Medtronic (the "Medtronic Loan Agreement"), pursuant to which Medtronic agreed to extend a convertible loan to us in the aggregate original principal amount of $20.0 million (the "Medtronic Loan"). The Medtronic Loan is evidenced by a secured subordinated convertible promissory note (the "Medtronic Note") issued by us. The issuance of the Medtronic Note to Medtronic and the funding of the Medtronic Loan occurred on May 1, 2026 pursuant to the conditions described in the Medtronic Loan Agreement. The Medtronic Note accrues simple interest at a rate of 11% per annum provided that no interest payments will be paid or due until the Maturity Date.

The Medtronic Note does not allow for prepayment without the prior consent of Medtronic. Unless earlier converted, or redeemed, the Medtronic Note will mature on April 27, 2031 (the "Maturity Date"). In addition, the payment or other satisfaction of the obligations set forth in the Medtronic Loan Agreement are subordinate in right of payment to the prior payment in full of the senior obligations. The obligations arising under the Medtronic Loan Agreement and the Medtronic Note are secured by security interests in, and pledges over, the Company's assets, subject to certain agreed security principles, permitted liens and other customary exceptions and qualifications.

The principal balance of the Medtronic Note, together with all accrued and unpaid interest thereon (collectively, the "Balance") will automatically convert into a revenue share (the "Revenue Share Credit"), if FDA approval of a Medtronic device incorporating AVIM Therapy is achieved prior to the Maturity Date. Upon conversion of the outstanding Balance, we shall pay to Medtronic the Revenue Share Credit, which shall equal 15% of the revenue share amounts that we receive under the Amended Medtronic Agreement, until such time as the total Revenue Share Credit payments equal $40.0 million.

We recognize interest expense using the effective interest method over the estimated term of the arrangement. The effective interest rate is based on our estimate of the timing and amount of future payments expected to be made under the arrangement. The total interest expense associated with the Medtronic Note resulted in an effective interest rate of 15.2% as of September 30, 2026. We will periodically assess the estimated amounts due and payable to Medtronic and to the extent the amount or timing of such payments is materially different than the original estimates, an adjustment will be recorded prospectively to the condensed consolidated statements of operations and comprehensive loss.

Change in the fair value of derivative liability

In November 2025, we sold 200,000 shares of Series A Preferred Stock at a purchase price equal to $100.00 per share for gross proceeds of $20.0 million. We concluded that certain conversion and redemption features meet the requirements to be separately accounted for as a bifurcated derivative. As a result, we bifurcated the Series A Preferred Stock between (i) the host contract, which was accounted for within mezzanine equity, and (ii) the bifurcated derivative liabilities related to those conversion and redemption features. The bifurcated derivatives are remeasured to fair value at each reporting period with changes in fair value recorded in the condensed consolidated statement of operations and comprehensive loss.

Gain on Sale of Strategic Investments

The gain on sale of strategic investments represents a change in the preferred shares and convertible notes of Vivasure Medical Limited ("Vivasure"), a privately-held company and related party, and fair value of our investment in common stock holdings of a previously publicly-held company. On January 9, 2026, Haemonetics Corporation, a global medical technology company focused on delivering innovative solutions designed to improve patient outcomes, announced its acquisition of Vivasure. Vivasure was a strategic investment of

ours prior to its acquisition. In connection with the transaction, we recognized a gain on the sale of strategic investments of $8.4 million. We may receive additional proceeds in the future associated with revenue earnouts based on the achievement of certain milestones.

Previously, the investments in Vivasure did not have readily determinable fair values and were recorded at cost, less any impairment, plus or minus changes resulting from observable price changes in orderly transactions for identical or similar investments of the same issuer, in accordance with the provisions of ASU 2016-01.

Results of Operations

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

The following table presents our statement of operations data for the nine months ended September 30, 2026 and 2025, and the dollar and percentage change between the two periods (in thousands):

	Nine Months Ended September 30,			
	2026	2025	Change $	Change %
Revenue:				
Partnership revenue	$ —	$ 2,120	$ (2,120)	(100)%
Product revenue	289	445	(156)	(35)%
Total revenue	289	2,565	(2,276)	(89)%
Expenses:				
Cost of product revenues	85	139	(54)	(39)%
Research and development	50,105	41,362	8,743	21 %
Selling, general and administrative	17,827	19,625	(1,798)	(9)%
Total expenses	68,017	61,126	6,891	11 %
Loss from operations	(67,728)	(58,561)	(9,167)	(16)%
Other income (expense):				
Interest expense, net	(5,052)	(385)	(4,667)	(1,212)%
Change in the fair value of derivative liability	1,156	—	1,156	100 %
Gain on sale of strategic investments	8,428	—	8,428	100 %
Total other income (expense)	4,532	(385)	4,917	1277 %
Net loss	$ (63,196)	$ (58,946)	$ (4,250)	(7)%

Partnership Revenue

Partnership revenue decreased by $2.1 million, or 100%, in the nine months ended September 30, 2026 from $2.1 million for the nine months ended September 30, 2025. Partnership revenue related to the recognition of the combined performance obligation for the license granted to Terumo and the ongoing research and development services over the estimated performance period for the Virtue SAB coronary ISR indication, using a proportional performance model, based on the costs incurred relative to the total estimated costs of the research and development services. Prior to the termination of the Terumo Agreement, as of each quarterly reporting date, we evaluated our estimates of the total costs expected to be incurred through the completion of the combined performance obligation and updated our estimates as necessary. On October 24, 2025, we and Terumo entered into a termination and right of first refusal agreement (the "Termination and ROFR Agreement"), which superseded and terminated the Terumo Agreement, and we no longer have any performance obligations under the Terumo Agreement.

For the nine months ended September 30, 2025, the expenses incurred related to the Terumo Agreement were $10.1 million. The estimated total costs associated with the Terumo Agreement through completion as of September 30, 2025 were similar compared to the estimates as of December 31, 2024.

Product Revenue

Product revenue decreased by $156,000, or approximately 35%, to $289,000 in the nine months ended September 30, 2026 from $445,000 for the nine months ended September 30, 2025.

Product revenue primarily consisted of the sale of FreeHold Duo and Trio intracorporeal organ retractors and revenue is recognized when product is shipped to customers. The decrease in product revenue was due to a decrease in the purchase volume. There were no changes to the per unit sale price in either period between the periods presented.

Cost of Product Revenue

Cost of product revenue decreased by $54,000, or approximately 39%, to $85,000 in the nine months ended September 30, 2026 from $139,000 for the nine months ended September 30, 2025. The decrease was primarily due to lower sales volume of FreeHold Duo and Trio intracorporeal organ retractors.

Research and Development Expenses

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

	Nine Months Ended September 30,	
	2026	2025
Personnel and consulting costs	$ 24,765	$ 18,965
Non-clinical development costs	11,152	13,095
Clinical development costs	14,188	9,302
Total research and development expenses	**$ 50,105**	**$ 41,362**

Research and development expenses increased by $8.7 million, or approximately 21%, to $50.1 million for the nine months ended September 30, 2026 from $41.4 million for the nine months ended September 30, 2025. This is primarily due to an increase in support of ongoing work to advance the BACKBEAT Trial and the Virtue Trial. The increase included an increase in personnel-related expenses of $6.2 million due to increased headcount and consulting costs, an increase of $4.9 million in clinical development costs, partially offset by a decrease of $1.9 million in non-clinical development costs associated with research and development program costs, supplies, and testing and a decrease of stock based compensation of $353,000.

The total research and development expenses summarized above include $10.0 million for the nine months ended September 30, 2025 related to the Terumo Agreement, which was terminated in October 2025.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased by $1.8 million, or approximately 9%, to $17.8 million for the nine months ended September 30, 2026 from $19.6 million for the nine months ended September 30, 2025. The decrease primarily resulted from a decrease of $1.2 million in stock-based compensation and a decrease of $1.2 million in legal and professional fees partially offset by an increase in investor relations expense of $544,000.

Interest Expense, Net

Interest expense, net increased by $4.7 million, or approximately 1212%, to $5.1 million of interest expense for the nine months ended September 30, 2026, from $385,000 of interest expense for the nine months ended September 30, 2025. The net interest expense in the 2026 period consisted primarily of monthly interest expense resulting from the 2024 LSA, the Medtronic Note, and the Royalty Purchase Agreement partially offset by interest earned from marketable securities. The net interest expense in the 2025 period consisted primarily of monthly interest expense resulting from the 2024 LSA and Royalty Purchase Agreement, partially offset by interest earned from marketable securities.

Change in the fair value of derivative liability

The derivative liability of the Series A Preferred Stock was remeasured to a fair value of $1.6 million as of September 30, 2026. We recognized a gain of $1.2 million for the nine months ended September 30, 2026 primarily due to changes in the fair value inputs and assumptions used in the valuation model since the measurement at December 31, 2025.

Gain on Sale of Strategic Investments

On January 9, 2026, Haemonetics Corporation, a global medical technology company focused on delivering innovative solutions designed to improve patient outcomes, announced its acquisition of Vivasure. During the nine months ended September 30, 2026, the Company received approximately $10.9 million of proceeds in connection with the transaction and recognized a gain on the sale of strategic investments of $8.4 million for the nine months ended September 30, 2026.

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

The following table presents our statement of operations data for the three months ended September 30, 2026 and 2025, and the dollar and percentage change between the two periods (in thousands):

	Three Months Ended September 30,			
	2026	2025	Change $	Change %
Revenue:				
Partnership revenue	$ —	$ 721	$ (721)	(100)%
Product revenue	91	140	(49)	(35)%
Total revenue	91	861	(770)	(89)%
Expenses:				
Cost of product revenues	28	49	(21)	(43)%
Research and development	17,734	14,027	3,707	26 %
Selling, general and administrative	5,625	7,098	(1,473)	(21)%
Total expenses	23,387	21,174	2,213	10 %
Loss from operations	(23,296)	(20,313)	(2,983)	(15)%
Other income (expense):				
Interest expense, net	(2,463)	(515)	(1,948)	(378)%
Change in the fair value of derivative liability	867	—	867	100 %
Gain on sale of strategic investments	6,142	—	6,142	100 %
Total other income (expense)	4,546	(515)	5,061	983 %
Net loss	$ (18,750)	$ (20,828)	$ 2,078	10 %

Partnership Revenue

Partnership revenue decreased by $721,000, or 100%, in the three months ended September 30, 2026 from $721,000 for the three months ended September 30, 2025. Partnership revenue related to the recognition of the combined performance obligation for the license granted to Terumo and the ongoing research and development services over the estimated performance period for the Virtue SAB coronary ISR indication, using a proportional performance model, based on the costs incurred relative to the total estimated costs of the research and development services. Prior to the termination of the Terumo Agreement, as of each quarterly reporting date, we evaluated our estimates of the total costs expected to be incurred through the completion of the combined performance obligation and updated our estimates as necessary. On October 24, 2025, we entered the Termination and ROFR Agreement, which superseded and terminated the Terumo Agreement, and we no longer have any performance obligations under the Terumo Agreement.

For the three months ended September 30, 2025, the expenses incurred related to the Terumo Agreement were $3.3 million. The estimated total costs associated with the Terumo Agreement through completion decreased by approximately 0.3% as of September 30, 2025 as compared to the estimates as of June 30, 2025.

Product Revenue

Product revenue decreased by $49,000, or approximately 35%, to $91,000 in the three months ended September 30, 2026 from $140,000 for the three months ended September 30, 2025.

Product revenue primarily consisted of the sale of FreeHold Duo and Trio intracorporeal organ retractors and revenue is recognized when product is shipped to customers. The decrease in product revenue was due to a decrease in the purchase volume. There were no changes to the per unit sale price in either period between the periods presented.

Cost of Product Revenue

Cost of product revenue decreased by $21,000, or approximately 43%, to $28,000 in the three months ended September 30, 2026 from $49,000 for the three months ended September 30, 2025. The decrease was primarily due to lower sales volume of FreeHold Duo and Trio intracorporeal organ retractors.

Research and Development Expenses

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

	Three Months Ended September 30,	
	2026	2025
Personnel and consulting costs	$ 8,522	$ 6,421
Non-clinical development costs	3,558	3,879
Clinical development costs	5,654	3,727
Total research and development expenses	**$ 17,734**	**$ 14,027**

Research and development expenses increased by $3.7 million, or approximately 26%, to $17.7 million for the three months ended September 30, 2026, from $14.0 million for the three months ended September 30, 2025. This is primarily due to an increase in support of ongoing work to advance the BACKBEAT Trial and the Virtue Trial. The increase included an increase in personnel-related expenses of $2.2 million due to increased headcount and consulting costs and an increase of $1.9 million in clinical development costs and, partially offset by a decrease of $321,000 in non-clinical development costs associated with research and development program costs, supplies, and testing.

The total research and development expenses summarized above include $3.2 million for the three months ended September 30, 2025 related to the Terumo Agreement, which was terminated in October 2025.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased by $1.5 million, or approximately 21%, to $5.6 million for the three months ended September 30, 2026, from $7.1 million of expense for the three months ended September 30, 2025. The decrease primarily resulted from a decrease of $1.5 million in legal and professional fees.

Interest Expense, Net

Interest expense, net increased by $1.9 million, or approximately 378%, to $2.5 million of net interest expense for the three months ended September 30, 2026, from $515,000 of net interest expense for the three months ended September 30, 2025. The net interest expense in the 2026 period consisted primarily of monthly interest expense resulting from the 2024 LSA, the Medtronic Note and the Royalty Purchase Agreement partially offset by interest earned from marketable securities. The net interest expense in the 2025 period consisted primarily of monthly interest expense resulting from the 2024 LSA partially offset by interest earned from marketable securities.

Change in the fair value of derivative liability

The derivative liability of the Series A Preferred Stock was remeasured to a fair value of $1.6 million as of September 30, 2026. We recognized a gain of $867,000 for the three months ended September 30, 2026 primarily due to changes in the fair value inputs and assumptions used in the valuation model since the measurement at June 30, 2026.

Gain on Sale of Strategic Investments

On January 9, 2026, Haemonetics Corporation, a global medical technology company focused on delivering innovative solutions designed to improve patient outcomes, announced its acquisition of Vivasure. For the three months ended September 30, 2026, we received additional proceeds and recognized a corresponding gain on the sale of strategic investments of approximately $6.1 million.

Liquidity and Capital Resources

Overview

From inception through September 30, 2026, we have incurred significant operating losses and negative cash flows from our operations. Our net losses were $63.2 million and $58.9 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, we had an accumulated deficit of $425.8 million. We have funded our operations primarily through the issuance of our common stock, convertible preferred stock, and warrants, as well as proceeds from the Business Combination, the prior Terumo Agreement and the Termination and ROFR Agreement, borrowings under debt arrangements, the sale of future revenues, the sale of strategic investments, and, to a lesser extent, revenue from FreeHold products. We had $101.9 million in cash and cash equivalents and marketable securities at September 30, 2026, comprised of $27.8 million in cash and cash equivalents and $74.1 million in marketable securities. Cash and cash equivalents consisted primarily of bank deposits and money market funds while short-term marketable securities consisted primarily of our investments in corporate and government debt securities.

Funding Requirements

We intend to prioritize spending on our two flagship product candidates as we focus on continued execution of the BACKBEAT Trial for AVIM Therapy and the Virtue Trial for Virtue SAB. Expenses will primarily support clinical study costs as well as other research and development activities.

Based on internally prepared budget estimates that reflect our operating priorities, we anticipate that our cash and cash equivalents, and marketable securities are sufficient to fund our operations through 2028. The amount and timing of our future funding requirements may change from this current estimate and are dependent on many factors, including the cost and pace of execution of clinical studies and research and development activities, the strength of results from clinical studies and other research, development and manufacturing efforts, and any future impact of Qualified Cash commitments under the 2024 LSA. There are no assurances that any of these factors will be favorable to us, and we may need to seek additional sources of liquidity to meet our funding requirements earlier than current estimates, including the issuance of new equity, and/or other financing structures. In this regard, as of the date of this Quarterly Report, we may sell up to $86.2 million of shares of our common stock under the sales agreement (the "Sales Agreement") we entered into with TD Securities (USA) LLC ("TD Cowen") pursuant to which we may offer and sell, from time to time through TD Cowen, shares of our common stock by any method permitted by law and deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended (the "Securities Act").

Our future viability is dependent on our ability to raise additional capital to finance our operations. Our inability to raise capital as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies. There can be no assurance that our current operating plan will be achieved or that additional funding will be available on terms acceptable to us, or at all.

Pursuant to, among other things, contractual obligations entered into in connection with the Business Combination, we have registered the resale of approximately 18.6 million shares of our common stock pursuant to a registration statement filed with the SEC, which became effective on May 9, 2024 (the "Resale Registration Statement"). The sale of our common stock pursuant to the Resale Registration Statement may result in a decline in the value of our common stock, which may make it more difficult and more dilutive to the existing holders of our common stock to raise funds from the sale of our equity securities.

Cash Flows

The following table summarizes our cash flow data for the periods indicated (in thousands):

	Nine Months Ended September 30,	
	2026	2025
Net cash used in operating activities	$ (61,038)	$ (46,693)
Net cash provided by (used in) investing activities	7,974	(9,229)
Net cash provided by financing activities	46,135	75,673
Net (decrease) increase in cash and cash equivalents	**$ (6,929)**	**$ 19,751**

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

Net Cash Flows from Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2026 was $61.0 million and primarily consisted of our net loss of $63.2 million and changes in net operating assets and liabilities of $2.9 million, partially offset by non-cash charges of $5.1 million. Our non-cash charges primarily consisted of stock-based compensation of $7.6 million, non-cash interest expense on liability related to the Royalty Purchase Agreement of $5.3 million and accrued interest expense on liability related to the note payable of $1.2 million, partially offset by the gain on the sale of strategic investments of $8.4 million. The net change in operating assets and liabilities was primarily due to a decrease in accounts payable, accrued expenses and other liabilities of $2.5 million and operating lease liabilities of $552,000.

Net cash used in operating activities for the nine months ended September 30, 2025 was $46.7 million and primarily consisted of our net loss of $58.9 million, partially offset by non-cash charges of $10.3 million and changes in net operating assets and liabilities of $1.9 million. Our non-cash charges primarily consisted of stock-based compensation of $9.2 million, partially offset by $491,000 related to accretion and interest of marketable securities. The net change in operating assets and liabilities was primarily due to an increase in accounts payable, accrued expenses and other liabilities of $4.3 million, partially offset by a decrease in deferred revenue of $2.1 million.

Net Cash Flows from Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2026 was $8.0 million, which primarily consisted of the sales of $60.5 million of marketable securities and the sale of strategic investments of $10.9 million, partially offset by the purchases of $62.6 million of marketable securities and purchases of property and equipment of $836,000.

Net cash used in investing activities for the nine months ended September 30, 2025 was $9.2 million, which primarily consisted of the purchase of $50.7 million of marketable securities and purchases of property and equipment of $456,000, partially offset by the sale of $41.9 million of marketable securities.

Net Cash Flows from Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2026 was $46.1 million, which primarily consisted of $20.0 million of proceeds from the Medtronic Loan, $15.0 million of proceeds from the royalty purchase agreement and $11.9 million of proceeds from the sale of our common stock pursuant to the Sales Agreement, partially offset by $778,000 used to settle taxes associated with restricted stock vesting.

Net cash provided by financing activities for the nine months ended September 30, 2025 was $75.7 million, which primarily consisted of $57.8 million of proceeds from the sale of common stock and the pre-funded warrants, net of issuance costs and $20.0 million of proceeds from the sale of future royalties, partially offset by $1.1 million of deferred financing costs related to the Royalty Purchase Agreement and $1.1 million used to settle taxes associated with restricted stock vesting.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of September 30, 2026 (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease obligations	$ 1,213	$ 901	$ 312	$ —	$ —
2024 LSA Debt, principal and interest[1]	18,787	1,445	17,342	—	—
Medtronic Debt, principal and interest[2]	31,000	—	—	31,000	—
Total	**$ 51,000**	**$ 2,346**	**$ 17,654**	**$ 31,000**	**$ —**

(1) In November 2024, we entered into the 2024 LSA with Hercules, as amended. The 2024 LSA will mature in November 2028. Refer to Note 14 to the Consolidated Financial Statements for additional information.

(2) In July 2025, we entered into the Medtronic Loan Agreement which will mature in April 2031. Refer to Note 14 to the Consolidated Financial Statements for additional information.

We enter into agreements in the normal course of business with clinical research organizations for work related to clinical trials and with vendors for preclinical studies and other services and products for operating purposes, which are cancelable at any time by us, generally upon 30 days prior written notice. These payments are not included in the above table of contractual obligations and commitments.

Critical Accounting Policies and Estimates

Our financial statements are prepared in accordance with U.S. GAAP. The preparation of the financial statements in conformity with U.S. GAAP requires our management to make a number of estimates and assumptions relating to the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the period. We evaluate our significant estimates on an ongoing basis, including estimates related to the total costs expected to be incurred though the completion of the combined performance obligation of the Terumo Agreement (prior to its termination in October 2025), changes in the fair value of the derivative liability, effective interest expense related to the Royalty Purchase Agreement, research and development prepayments, accruals and related expenses and stock-based compensation. We base our estimates on historical experience and on various other assumptions that we believe to be 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. Actual results could differ from those estimates.

Our critical accounting policies are described in the MD&A section of our Form 10-K for the year ended December 31, 2025 filed with the SEC on March 12, 2026. There have been no material changes to our critical accounting policies during the nine months ended September 30, 2026.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 – *"Summary of Significant Accounting Policies,"* to the Consolidated Financial Statements.

Smaller Reporting Company Status

We are a "smaller reporting company" as defined in Rule 12b-2 promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). As a smaller reporting company, we will continue to not be required to comply with the auditor attestation requirements of Section 404(a) of the Sarbanes-Oxley Act of 2002 as long as (a) our annual revenue is less than $100.0 million during the most recently completed fiscal year and (b) the market value of our voting and non-voting common stock held by non-affiliates is less than $700.0 million as of the last business day of the second quarter of such fiscal year. We may also take advantage of certain reduced disclosure

requirements as a smaller reporting company, including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We will be able to take advantage of these scaled disclosures for so long as (i) the market value of our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or (ii)(a) our annual revenue is less than $100.0 million during the most recently completed fiscal year and (b) the market value of our voting and non-voting common stock held by non-affiliates is less than $700.0 million as of the last business day of the second quarter of such fiscal year.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures.

We maintain "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), that are designed to provide reasonable assurance that information required to be disclosed by us in the reports that 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.

Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2026, the end of the period covered by this Quarterly Report. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2026.

Changes in Internal Control Over Financial Reporting.

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended September 30, 2026 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitation on the Effectiveness of Internal Control.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures, or our internal controls, will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in various claims and legal proceedings that arise in the ordinary course of our business. We are not currently a party to any material legal proceedings and are not aware of any pending or threatened legal proceeding against us that we believe would have a material adverse effect on our business, operating results or financial condition.

Item 1A. Risk Factors.

For information regarding factors that could affect our results of operations, financial condition and liquidity, see the risk factors discussed in Part I, Item 1A in the 2025 10-K. There have been no material changes to the risk factors previously disclosed in Part I, Item 1A in the 2025 10-K.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Rule 10b5-1 Trading Arrangements

During the three months ended September 30, 2026, no director or officer (as defined in Rule 16a-1(f) promulgated under the Exchange Act) informed us of the adoption or termination of a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement", as those terms are defined in Item 408 of Regulation S-K.

Item 6. Exhibits.

Exhibit	Description
3.1	Certificate of Incorporation of Orchestra BioMed Holdings, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the SEC on January 31, 2023).
3.2	Certificate of Designation of Series A Convertible Preferred Stock, dated November 6, 2025 (incorporated by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 10, 2025)
3.3	Amended and Restated Bylaws of Orchestra BioMed Holdings, Inc. (incorporated by reference to Exhibit 3.2 to the Quarterly Report on Form 10-Q filed with the SEC on August 12, 2024).
31.1+	Certification of Chief Executive Officer, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of Chief Financial Officer, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*+	Certification of Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*+	Certification of Chief 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.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

\+ Filed herewith.

* Furnished herewith. This exhibit shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section. Such exhibit shall not be deemed incorporated into any filing under the Securities Act or the Exchange Act.

SIGNATURES

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

ORCHESTRA BIOMED HOLDINGS, INC.

Dated: November 10, 2026

/s/ Andrew Taylor
Andrew Taylor
Chief Financial Officer
(Principal Financial 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, David P. Hochman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Orchestra BioMed Holdings, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (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.

Dated: November 10, 2026

/s/ David P. Hochman
David P. Hochman
Chief Executive Officer
(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, Andrew Taylor, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Orchestra BioMed Holdings, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (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.

Dated: November 10, 2026

/s/ Andrew Taylor
Andrew Taylor
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Orchestra BioMed Holdings, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David P. Hochman, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §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; and

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

Dated: November 10, 2026

/s/ David P. Hochman
David P. Hochman
Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to Orchestra BioMed Holdings, Inc. and will be retained by Orchestra BioMed Holdings, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

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

In connection with the Quarterly Report of Orchestra BioMed Holdings, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Andrew Taylor, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §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; and

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

Dated: November 10, 2026

/s/ Andrew Taylor
Andrew Taylor
Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to Orchestra BioMed Holdings, Inc. and will be retained by Orchestra BioMed Holdings, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.