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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, 2023

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 Global Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 10, 2023, the registrant had 35,743,972 shares of common stock, $0.0001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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;
- our ability to realize the anticipated benefits of the Business Combination (as defined in Part I, Item 1, Note 1, “Organization and Basis of Presentation,” in the notes to unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q);
- 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;
- 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 names 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 heading "Item 1A. Risk Factors" in Part II of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 (the "Q1 10-Q") and under the heading "Item 1A. Risk Factors" in Part II of this Quarterly Report on Form 10-Q, as well as elsewhere in this Quarterly Report on Form 10-Q. 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, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 19,078	$ 19,784
Marketable securities	89,410	63,915
Strategic investments, current portion	362	86
Accounts receivable, net	86	96
Inventory	137	276
Prepaid expenses and other current assets	1,116	533
Total current assets	110,189	84,690
Property and equipment, net	1,355	1,489
Right-of-use assets	1,714	2,187
Strategic investments, less current portion	2,495	2,495
Deposits and other assets	604	4,711
TOTAL ASSETS	$ 116,357	$ 95,572
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 3,150	$ 3,968
Accrued expenses and other liabilities	4,301	5,376
Operating lease liability, current portion	747	697
Warrant liability	—	2,089
Deferred revenue, current portion	3,676	6,436
Loan payable, current portion	9,599	—
Total current liabilities	21,473	18,566
Deferred revenue, less current portion	13,845	13,103
Loan payable, less current portion	—	9,490
Operating lease liability, less current portion	1,117	1,683
Other long-term liabilities	266	196
TOTAL LIABILITIES	36,701	43,038
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value per share; 10,000,000 shares authorized; none issued or outstanding at September 30, 2023 and December 31, 2022.	—	—
Common stock, $0.0001 par value per share; 340,000,000 shares authorized; 35,743,972 and 20,187,850 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively.	4	2
Additional paid-in capital	315,765	252,274
Accumulated other comprehensive loss	(77)	(8)
Accumulated deficit	(236,036)	(199,734)
TOTAL STOCKHOLDERS' EQUITY	79,656	52,534
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 116,357	$ 95,572

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,	
	2023	2022	2023	2022
Revenue:				
Partnership revenue	$ 271	$ 986	$ 2,018	$ 1,931
Product revenue	148	177	480	499
Total revenue	419	1,163	2,498	2,430
Expenses:				
Cost of product revenues	41	56	139	158
Research and development	8,558	5,899	25,311	14,402
Selling, general and administrative	6,344	5,275	16,073	10,699
Total expenses	14,943	11,230	41,523	25,259
Loss from operations	(14,524)	(10,067)	(39,025)	(22,829)
Other income (expense):				
Interest income (expense), net	915	63	2,741	(419)
Gain (loss) on fair value adjustment of warrant liability	—	36	(294)	(1,124)
Loss on debt extinguishment	—	—	—	(682)
Gain (loss) on fair value of strategic investments	293	(314)	276	1,196
Total other income (expense)	1,208	(215)	2,723	(1,029)
Net loss	$ (13,316)	$ (10,282)	$ (36,302)	$ (23,858)
Net loss per share				
Basic and diluted	$ (0.38)	$ (0.51)	$ (1.11)	$ (1.80)
Weighted-average shares used in computing net loss per share, basic and diluted	35,243,598	20,187,773	32,586,431	13,236,450
Comprehensive loss				
Net loss	$ (13,316)	$ (10,282)	$ (36,302)	$ (23,858)
Unrealized loss on marketable securities	19	—	(69)	—
Comprehensive loss	$ (13,297)	$ (10,282)	$ (36,371)	$ (23,858)

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance, January 1, 2023 (as previously reported)	35,694,179	$ 165,923	2,522,214	$ —	$ 86,353	$ (8)	$ (199,734)	$ (113,389)
Retroactive application of reverse capitalization (Note 3)	(35,694,179)	(165,923)	17,665,636	2	165,921	—	—	165,923
Balance, January 1, 2023 effect of Merger	—	—	20,187,850	2	252,274	(8)	(199,734)	52,534
Effect of Merger and recapitalization (refer to Note 3)	—	—	11,422,741	1	54,301	—	—	54,302
Reclassification of Legacy Orchestra common stock warrants to stockholders' equity	—	—	—	—	2,373	—	—	2,373
Unrealized loss on marketable securities	—	—	—	—	—	(27)	—	(27)
Stock-based compensation	—	—	—	—	1,489	—	—	1,489
Exercise of stock options	—	—	2,325	—	10	—	—	10
Exercise of warrants	—	—	128,231	—	11	—	—	11
Net loss	—	—	—	—	—	—	(10,940)	(10,940)
Balance, March 31, 2023	—	$ —	31,741,147	$ 3	$ 310,458	$ (35)	$ (210,674)	$ 99,752
Issuance of shares in settlement of earnout	—	—	3,999,987	1	—	—	—	1
Unrealized loss on marketable securities	—	—	—	—	—	(61)	—	(61)
Stock-based compensation	—	—	—	—	1,707	—	—	1,707
Exercise of stock options	—	—	15,500	—	64	—	—	64
Exercise of warrants	—	—	32,279	—	22	—	—	22
Forfeiture of restricted stock awards	—	—	(45,906)	—	—	—	—	—
Net loss	—	—	—	—	—	—	(12,046)	(12,046)
Balance, June 30, 2023	—	$ —	35,743,007	$ 4	$ 312,251	$ (96)	$ (222,720)	$ 89,439
Unrealized gain on marketable securities	—	—	—	—	—	19	—	19
Stock-based compensation	—	—	—	—	3,510	—	—	3,510
Exercise of stock options	—	—	965	—	4	—	—	4
Net loss	—	—	—	—	—	—	(13,316)	(13,316)
Balance, September 30, 2023	—	$ —	35,743,972	$ 4	$ 315,765	$ (77)	$ (236,036)	$ 79,656

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance, January 1, 2022 (as previously reported)	12,075,976	$ 51,452	2,185,297	$ —	$ 94,894	$ —	$ (166,126)	$ (71,232)
Retroactive application of reverse capitalization (Note 3)	(12,075,976)	(51,452)	6,636,983	1	51,451	—	—	51,452
Balance, January 1, 2022 effect of Merger	—	—	8,822,280	1	146,345	—	(166,126)	(19,780)
Stock-based compensation	—	—	—	—	70	—	—	70
Exercise of stock options	—	—	5,696	—	25	—	—	25
Exercise of warrants	—	—	68,588	—	230	—	—	230
Proceeds from private placement	—	—	1,240,169	—	25,262	—	—	25,262
Net loss	—	—	—	—	—	—	(5,729)	(5,729)
Balance, March 31, 2022	—	$ —	10,136,733	$ 1	$ 171,932	$ —	$ (171,855)	$ 78
Stock-based compensation	—	—	—	—	219	—	—	219
Exercise of stock options	—	—	21,442	—	92	—	—	92
Exercise of warrants	—	—	4,650	—	(151)	—	—	(151)
Proceeds from private placement financing	—	—	10,015,015	1	76,392	—	—	76,393
Shares issued pursuant to consulting agreement	—	—	9,300	—	38	—	—	38
Issuance of warrants pursuant to debt refinancing	—	—	—	—	178	—	—	178
Other	—	—	—	—	506	—	—	506
Net loss	—	—	—	—	—	—	(7,847)	(7,847)
Balance, June 30, 2022	—	$ —	20,187,140	$ 2	$ 249,206	$ —	$ (179,702)	$ 69,506
Stock-based compensation	—	—	—	—	2,223	—	—	2,223
Exercise of stock options	—	—	710	—	4	—	—	4
Proceeds from private placement financing	—	—	—	—	(23)	—	—	(23)
Net loss	—	—	—	—	—	—	(10,282)	(10,282)
Balance, September 30, 2022	—	$ —	20,187,850	$ 2	$ 251,410	$ —	$ (189,984)	$ 61,428

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,	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (36,302)	$ (23,858)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	215	152
Shares issued as compensation for consulting services	—	38
Stock-based compensation	6,706	2,512
Loss on fair value adjustment of warrant liability	294	1,124
Gain on fair value of strategic investments	(276)	(1,196)
Accretion and interest related to marketable securities	(3,181)	—
Loss on debt extinguishment	—	682
Non-cash lease expense	473	419
Amortization of deferred financing fees	109	127
Changes in operating assets and liabilities:		
Accounts receivable	10	25
Inventory	139	(262)
Prepaid expenses and other assets	(458)	(475)
Accounts payable, accrued expenses and other liabilities	(348)	2,294
Operating lease liabilities – current and non-current	(516)	(196)
Deferred revenue	(2,018)	(1,931)
Net cash used in operating activities	(35,153)	(20,545)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(81)	(537)
Sales of marketable securities	115,690	—
Purchases of marketable securities	(138,073)	(208)
Net cash used in investing activities	(22,464)	(745)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Repayment of debt financing, inclusive of debt extinguishment costs	—	(6,446)
Proceeds from Avenue term loan	—	10,000
Proceeds from exercise of warrants	23	79
Proceeds from exercise of stock options	78	121
Effect of merger, net of transaction costs (Note 3)	56,810	—
Proceeds from private placement financing	—	109,830
Deferred financing, offering and merger costs	—	(5,237)
Net cash provided by financing activities	56,911	108,347
Net (decrease) increase in cash and cash equivalents	(706)	87,057
Cash and cash equivalents, beginning of the period	19,784	9,938
Cash and cash equivalents, end of the period	$ 19,078	$ 96,995
Supplemental Disclosures of Cash Flow Information		
Cash paid during the nine months ended September 30:		
Interest	$ 1,098	$ 1,040
Non-cash financing activities:		
Deferred offering and merger costs in accounts payable and accrued expenses	—	5,682
Warrants issued pursuant to private placement financing	—	620
Warrants issued pursuant to debt financing	—	178

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") (formerly known as Health Sciences Acquisitions Corporation 2) is a biomedical innovation company accelerating high-impact technologies to patients through risk-reward sharing partnerships with leading 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 lead product candidate is BackBeat Cardiac Neuromodulation Therapy ("BackBeat CNT") for the treatment of hypertension ("HTN"), a significant risk factor for death worldwide. The Company is also developing Virtue Sirolimus AngioInfusion Balloon ("Virtue SAB") for the treatment of atherosclerotic artery disease, the leading cause of mortality worldwide.

Prior to January 26, 2023, the Company was a special purpose acquisition company formed for the purpose of entering into a merger, amalgamation, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses or entities. On January 26, 2023 (the "Closing Date"), the Company consummated the business combination contemplated by the Agreement and Plan of Merger, dated as of July 4, 2022 (as amended by Amendment No. 1 to Agreement and Plan of Merger, dated July 21, 2022, and Amendment No. 2 to Agreement and Plan of Merger, dated November 21, 2022, the "Merger Agreement") by and among Health Sciences Acquisitions Corporation 2, a special purpose acquisition company incorporated as a Cayman Islands exempted company in 2020 ("HSAC2"), HSAC Olympus Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of HSAC2 ("Merger Sub"), and Orchestra BioMed, Inc. ("Legacy Orchestra"). Pursuant to the Merger Agreement, (i) HSAC2 deregistered in the Cayman Islands in accordance with the Companies Act (2022 Revision) (As Revised) of the Cayman Islands and domesticated as a Delaware corporation in accordance with Section 388 of the Delaware General Corporation Law (the "Domestication") and (ii) Merger Sub merged with and into Legacy Orchestra, with Legacy Orchestra as the surviving company in the merger and, after giving effect to such merger, continuing as a wholly owned subsidiary of Orchestra (the "Merger" and, together with the Domestication and the other transactions contemplated by the Merger Agreement, the "Business Combination"). As part of the Domestication, the Company's name was changed from "Health Sciences Acquisitions Corporation 2" to "Orchestra BioMed Holdings, Inc." See Note 3 for additional information.

Legacy Orchestra, the Company's wholly owned subsidiary, 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, Legacy Orchestra concurrently completed its formation mergers (the "Formation Mergers") with Caliber Therapeutics, Inc., a Delaware corporation, BackBeat Medical, Inc., a Delaware Corporation, and FreeHold Surgical, Inc., a Delaware corporation. Legacy Orchestra completed the conversions of BackBeat Medical, Inc. to BackBeat Medical, LLC ("BackBeat"), a Delaware limited liability company, of FreeHold Surgical, Inc. to FreeHold Surgical, LLC ("FreeHold") and of Caliber Therapeutics, Inc. to Caliber Therapeutics, LLC ("Caliber"), a Delaware limited liability company, in 2019.

Caliber

Caliber Therapeutics, Inc. was incorporated in Delaware in October 2005 and began development of its lead product Virtue SAB in 2008. Virtue SAB is a patented drug/device combination product candidate for the treatment of artery disease that delivers a proprietary extended release formulation of sirolimus called SirolimusEFR to the vessel wall during balloon angioplasty without any coating on the balloon surface or the need for leaving a permanent implant such as a stent in the artery. In 2019, Legacy Orchestra entered into a distribution agreement with Terumo Medical Corporation ("Terumo") for global development and commercialization of Virtue SAB (the "Terumo Agreement") (See Note 4).

BackBeat

BackBeat Medical, Inc. was incorporated in Delaware in January 2010 and began development of its lead product BackBeat CNT that same year. BackBeat CNT is a patented implantable cardiac stimulation-based treatment for

hypertension that is designed to immediately, substantially and persistently lower blood pressure while simultaneously modulating autonomic nervous system responses that normally drive and maintain blood pressure higher. Refer to Note 5 for details regarding the Exclusive License and Collaboration Agreement, dated as of June 30, 2022, by and among, Legacy Orchestra, BackBeat and Medtronic, Inc. (an affiliate of Medtronic plc) (the "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 visual 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 regulation 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, 2022 has been derived from the audited financial statements at that date. Operating results and cash flows for the nine months ended September 30, 2023 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2023 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 interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements included in our report for the year ended December 31, 2022 together with the related notes thereto, filed as Exhibit 99.1 to the Company's Form 8-K/A filed with the SEC on March 24, 2023.

The Company has a limited operating history and the sales and income potential of its businesses and markets are unproven. As of September 30, 2023, the Company had an accumulated deficit of $236.0 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, 2023, 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 beyond 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, more specifically, on the progress of the Company's research and development programs.

2. Summary of Significant Accounting Policies

Reverse Recapitalization

The Business Combination is accounted for as a reverse recapitalization in accordance with U.S. GAAP (the "Reverse Recapitalization"). Under this method of accounting, HSAC2 is treated as the "acquired" company, and Legacy Orchestra

is treated as the acquirer for financial reporting purposes. Accordingly, for accounting purposes, the Business Combination was treated as the equivalent of Legacy Orchestra issuing stock for the net assets of HSAC2, accompanied by a recapitalization. As a result, the consolidated assets, liabilities and results of operations prior to the Reverse Recapitalization are those of Legacy Orchestra. Additionally, the shares and corresponding capital amounts and losses per share, prior to the Business Combination, have been retroactively restated based the exchange ratio established in the Merger Agreement (the "Exchange Ratio"). For additional information on the Business Combination and the Exchange Ratio, see Note 3 to these unaudited condensed consolidated financial statements.

Emerging Growth Company and Smaller Reporting Company Status

The Company is an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933 (the "Securities Act"), as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). As such, it is eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that an emerging growth company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, the Company, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of the Company's condensed consolidated financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

The Company will remain an emerging growth company until the earliest of (1) the last day of the fiscal year following the fifth anniversary of the closing of the initial public offering of HSAC2, (2) the last day of the fiscal year in which the Company has total annual gross revenue of at least $1.235 billion, (3) the last day of the fiscal year in which the Company is deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of the common stock of the Company ("Company Common Stock") held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year, or (4) the date on which the Company has issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

The Company is also a "smaller reporting company" as defined in the Exchange Act. The Company may continue to be a smaller reporting company even after the Company is no longer an emerging growth company. The Company may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) the market value of the Company's voting and non-voting Common Stock held by non-affiliates is less than $250.0 million measured on the last business day of the Company's second fiscal quarter, or (ii)(a) the Company's annual revenue is less than $100.0 million during the most recently completed fiscal year and (b) the market value of the Company's voting and non-voting Common Stock held by non-affiliates is less than $700.0 million measured on the last business day of the Company's second fiscal quarter.

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, the fair value of stock-based compensation, research and development costs incurred, the fair value of the warrant liability, and the estimated costs to complete the combined performance obligation pursuant to the Terumo Agreement (Note 4).

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 income (loss). 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 has made investments in affiliated companies and assesses whether the Company exerts significant influence over its strategic investments. The Company considers the nature and magnitude of its investment, any voting and protective rights it holds, 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 does not have the ability to exercise significant influence over its strategic investments.

The Company's strategic investments consist of equity investments in common stock of Motus GI Holdings, Inc. ("Motus GI"), a publicly-held company and related party, and preferred shares of Vivasure Medical Limited ("Vivasure"), a privately-held company and related party. The Company classifies strategic investments on its balance sheet as current assets if the assets are available for use for current operations, and the Company does not have a specific plan to hold the investments for a certain duration of time. The shares held of Motus GI represent equity securities with a readily determinable fair value and are required to be measured at fair value at each reporting period using readily determinable pricing available on a securities exchange, in accordance with the provisions of ASU 2016-01, Recognition and Measurement of Financial Assets and Liabilities. Therefore, the Company categorized the investments as current assets. The investments in Vivasure do not have readily determinable fair values and are 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 are not readily marketable, the Company categorized the investments as non-current assets. As of September 30, 2023 and December 31, 2022, the carrying value of the investments in Vivasure was $2.5 million.

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 Motus GI, marketable securities, and warrant liabilities at fair value. In addition, at September 30, 2023, the Company believed the carrying value of debt approximates fair value as the interest rates were reflective of the rate the Company could obtain on debt with similar terms and conditions. See Note 6 for additional information regarding fair value measurements.

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, 2023 and December 31, 2022, 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, 2023 and December 31, 2022, 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 our 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, generally three to five years. 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 statements of operations.

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.

Warrants

The Company evaluates its warrants to determine if the contracts qualify as liabilities in accordance with ASC 480-10, *Distinguishing Liabilities from Equity,* and ASC 815, *Derivatives and Hedging* ("ASC 815"). If the warrant is determined to meet the criteria to be liability classified, the warrant liability is marked-to-market each balance sheet date and recorded as a liability, with the change in fair value recorded in the Company's condensed consolidated statements of operations and comprehensive loss as gain (loss) on fair value adjustment of warrant liability within other income or expense.

In bundled transactions, the proceeds received from any debt instruments and liability classified warrants are allocated to the warrant at fair value first, and the residual value is then allocated to the debt instrument. Upon conversion or exercise of a warrant that is subject to liability treatment, the instrument is marked to fair value at the conversion or exercise date and the fair value is reclassified to equity. Equity classified warrants are recorded within additional paid-in capital at the time of issuance at fair value as of the issuance date and are not subject to subsequent remeasurement.

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 the Company expects to be entitled to. 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 are currently comprised of product revenue from the sale of FreeHold's intracorporeal organ retractors, and partnership revenues from the Terumo Agreement related to the development and commercialization of Virtue SAB.

Product Revenues

Product revenues related 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.

Partnership Revenues

To date, the Company's partnership revenues have related to the Terumo Agreement as further described in Note 4. In future periods, partnership revenues may also include revenues related to the Medtronic Agreement as discussed in Note 5.

The Company assessed whether the Terumo Agreement fell within the scope of ASC 808, *Collaborative Arrangements ("ASC 808")* based on whether the arrangement involved joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. The Company determined that the Terumo Agreement did not fall within the scope of ASC 808. The Company then analyzed the arrangement pursuant to the provisions of ASC 606 and determined that the arrangement represents a contract with a customer and is therefore within the scope of ASC 606.

The promised goods or services in the Terumo Agreement include (i) license rights to the Company's intellectual property, and (ii) research and development services. The Company also has optional additional items in the Terumo Agreement which are considered marketing offers and are accounted for as separate contracts with the customer if such

option is elected by the customer, unless the option provides a material right which would not be provided without entering into the contract. Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer. Promised goods or services are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources or (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct in the Terumo Agreement, the Company considered factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on their own or whether the required expertise is readily available.

The Company estimates the transaction price for the Terumo Agreement performance obligations based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration includes both fixed consideration and variable consideration. At the inception of the Terumo Agreement, as well as at each reporting period, the Company evaluates the amount of potential payments and the likelihood that the payments will be received. The Company utilizes either the most likely amount method or expected amount method to estimate the amount expected to be received based on which method better predicts the amount expected to be received. If it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price.

The Terumo Agreement contains development and regulatory milestone payments. At contract inception and at each reporting period, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect partnership revenues and earnings in the period of adjustment.

The Terumo Agreement also includes sales-based royalties and the license is deemed to be the predominant item to which the royalties relate. Accordingly, the Company will recognize royalty revenue when the related sales occur. To date, the Company has not recognized any royalty revenue under the arrangement.

The Company has determined that intellectual property licensed to Terumo and the research and development services to be provided through the premarket approval by the U.S. Food and Drug Administration (the “FDA”) for the in-stent restenosis (“ISR”) indication represent a combined performance obligation that is satisfied over time, and that the appropriate method of measuring progress for purposes of recognizing revenues relates to a proportional performance model that measures the proportional performance based on the costs incurred to date relative to the total costs expected to be incurred through the completion of the performance obligation. The Company evaluates the measure of progress at each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The Company receives payments from Terumo based on billing schedules established in the contract. Such billings for milestone related events have 10-day terms from the date the milestone is achieved, royalty payments are 20-day terms after the close of each quarter, any optional services are 20 days after receipt of an invoice and any sales of the SirolimusEFR are within 30 days after receipt of the shipping invoices. Upfront payments are recorded as deferred revenue upon receipt or when due until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the right to consideration is unconditional.

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 11). 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.

Net Loss Per Share

Basic and diluted net loss per share is calculated by dividing net loss by the weighted-average number of shares of 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 (Note 3) and unvested restricted stock awards and restricted stock units. Shares of Company Common Stock outstanding but subject to forfeiture and cancellation by the Company (e.g., the Forfeitable Shares (as defined in Note 3)) are excluded from the weighted-average number of shares until the period in which such shares are no longer subject to forfeiture. 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, 2023 and December 31, 2022, 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.

Deferred Offering and Merger Costs

Offering and merger costs, consisting of legal, accounting, printer and filing fees were deferred to be offset against proceeds received when the Business Combination was completed. As of December 31, 2022, there were $4.0 million of deferred transaction costs included in deposits and other assets on the accompanying condensed consolidated balance sheet. Upon the close of the Business Combination, these deferred costs were recorded against net proceeds in additional paid-in capital. For further discussion on the Business Combination, see Note 3.

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, 2023, the Company made $98,000 and $279,000, 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.

New Accounting Standards

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. During 2018 and 2019, the FASB also issued subsequent amendments to the initial guidance (collectively, "Topic 326"). Topic 326 requires organizations to measure all expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. The Company adopted ASU 2016-13 as of January 1, 2023. The adoption of ASU 2016-13 did not have a material impact on the Company's condensed consolidated financial statements.

3. Business Combination and Recapitalization

On January 26, 2023, Legacy Orchestra and HSAC2 consummated the Business Combination, with Legacy Orchestra surviving as a wholly owned subsidiary of HSAC2. As part of the Business Combination, HSAC2 changed its name to Orchestra BioMed Holdings, Inc. Upon the closing of the Business Combination (the "Closing"), the Company's certificate of incorporation provided for, among other things, a total number of authorized shares of capital stock of 350,000,000 shares, of which 340,000,000 shares were designated common stock, $0.0001 par value per share, and of which 10,000,000 shares were designated preferred stock, $0.0001 par value per share.

The Business Combination is accounted for as a reverse recapitalization in accordance with U.S. GAAP. Under this method of accounting, HSAC2 is treated as the "acquired" company and Legacy Orchestra is treated as the acquirer for financial reporting purposes. Accordingly, for accounting purposes, the Business Combination was treated as the equivalent of Legacy Orchestra issuing stock for the net assets of HSAC2, accompanied by a recapitalization. The net assets of HSAC2 are stated at historical cost, with no goodwill or intangible assets recorded.

In connection with the Business Combination, HSAC2 Holdings, LLC (the "Sponsor") agreed that 25% or 1,000,000 shares of its shares of Company Common Stock will be forfeited to the Company (the "Forfeitable Shares") on the first business day following the fifth anniversary of the Closing unless, as to 500,000 shares, the volume-weighted average price of the Company 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 Company 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"). Further, the Sponsor and HSAC2's other initial shareholders prior to HSAC2's initial public offering (the "HSAC2 IPO") agreed to subject (i) the 4,000,000 shares of Company Common Stock issued to HSAC2's initial shareholders prior to the HSAC2 IPO (the "Insider Shares") and (ii) the 450,000 shares of Company Common Stock purchased in a private placement simultaneously with the HSAC2 IPO (the "Private Shares") to a lock-up for up to 12 months following the Closing, and the Sponsor forfeited 50% of its 1,500,000 warrants in HSAC2 purchased upon consummation of the HSAC2 IPO (the "Private Warrants"), comprising 750,000 Private Warrants, for no consideration, immediately prior to the Closing (the "Sponsor Forfeiture"). Pursuant to

the terms of the Merger Agreement, immediately following the Sponsor Forfeiture and prior to the Closing, HSAC2 issued 750,000 warrants to purchase Company Common Stock to eleven specified employees and directors of Legacy Orchestra (the "Officer and Director Warrants"). The Officer and Director Warrants have substantially similar terms to the forfeited Private Warrants, except that 50% of the Officer and Director Warrants will become exercisable 24 months after the Closing and the remaining 50% will become exercisable 36 months after the Closing. On April 12, 2023, the Initial Milestone Event was achieved, and, as a result, 500,000 of the Forfeitable Shares are no longer subject to forfeiture.

In connection with the Business Combination, existing Legacy Orchestra stockholders also had the opportunity to elect to participate in an earnout (the "Earnout") pursuant to which each such electing stockholder (an "Earnout Participant") may receive a portion of additional contingent consideration of up to 8,000,000 shares of Company Common Stock in the aggregate ("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 will collectively be entitled to receive: (i) 4,000,000 shares of the Earnout Consideration, in the aggregate, in the event that, from the time beginning immediately after the Closing until the fifth anniversary of the Closing Date (the "Earnout Period"), the Initial Milestone Event occurs; and (ii) an additional 4,000,000 shares of the Earnout Consideration, in the aggregate, in the event that, during the Earnout Period, the Final Milestone Event occurs. Approximately, 91% of Legacy Orchestra 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) of 4,000,000 shares of Company Common Stock, resulting in a total of 3,999,987 shares of Company Common Stock being issued (less than 4,000,000 due to rounding).

Simultaneously with the execution of the Merger Agreement, HSAC2 and Legacy Orchestra entered into separate forward purchase agreements (each, as amended, a "Forward Purchase Agreement" and, together, the "Forward Purchase Agreements") with certain funds managed by RTW Investments, LP (the "RTW Funds") and Covidien Group S.à.r.l., an affiliate of Medtronic plc ("Medtronic" and the RTW Funds, each a "Purchasing Party"), pursuant to which each of the Purchasing Parties agreed to purchase $10 million of ordinary shares of HSAC2 ("HSAC2 Ordinary Shares") immediately prior to the Domestication (as defined below), less the dollar amount of HSAC2 Ordinary Shares holding redemption rights that the Purchasing Party acquired and held until immediately prior to the Domestication (such HSAC2 Ordinary Shares either purchased from HSAC2 or acquired and held until immediately prior to the Domestication, the "Forward Purchase Shares"). The RTW Funds completed their purchases of HSAC2 Ordinary Shares under their Forward Purchase Agreement on or before July 22, 2022. Medtronic completed approximately $9.9 million of purchases of HSAC2 Ordinary Shares under its Forward Purchase Agreement on or before January 20, 2023. Medtronic subsequently completed $0.1 million in purchases of HSAC2 Ordinary Shares and/or Company Common Stock on or before January 30, 2023.

Simultaneously with the execution of the Merger Agreement and Forward Purchase Agreements, HSAC2, Legacy Orchestra and the RTW Funds entered into a Backstop Agreement (the "Backstop Agreement"), pursuant to which the RTW Funds, jointly and severally, agreed to purchase such number of HSAC2 Ordinary Shares at a price of $10.00 per share to the extent that the amount of cash remaining in HSAC2's working capital and trust account as of immediately prior to the closing of the Merger was less than $60 million (which calculation excludes amounts received pursuant to Medtronic's Forward Purchase Agreement or are otherwise held in HSAC2's trust account established pursuant to the HSAC2 IPO (the "HSAC2 Trust Account") in respect of Medtronic's Forward Purchase Shares, but is inclusive of amounts received pursuant to the RTW Funds' Forward Purchase Agreement and otherwise held in the HSAC2 Trust Account in respect of the RTW Funds' Forward Purchase Shares). Pursuant to the Backstop Agreement, the RTW Funds purchased 1,808,512 HSAC2 Ordinary Shares on January 25, 2023, immediately prior to the Domestication.

Immediately prior to the closing of the Business Combination, each issued and outstanding share of Legacy Orchestra preferred stock (the "Legacy Orchestra Preferred Stock") was canceled and converted into shares of Legacy Orchestra common stock (the "Legacy Orchestra Common Stock") based on predetermined ratios (see Note 9).

Upon the consummation of the Business Combination, each issued and outstanding share of Legacy Orchestra Common Stock was canceled and converted into the right to receive shares of Company Common Stock based upon the Exchange Ratio. The shares and corresponding capital amounts and loss per share related to Legacy Orchestra Common Stock prior to the Business Combination have been retroactively restated to reflect the Exchange Ratio.

Outstanding stock options, whether vested or unvested, to purchase shares of Legacy Orchestra Common Stock ("Legacy Orchestra Options") granted under the Orchestra BioMed, Inc. 2018 Stock Incentive Plan ("2018 Plan") (see Note 11) converted into stock options to purchase shares of Company Common Stock upon the same terms and conditions that were in effect with respect to such stock options immediately prior to the Business Combination, after giving effect to the Exchange Ratio (the "Exchanged Options").

The following table details the number of shares of Company Common Stock issued immediately following the consummation of the Business Combination:

	Number of Shares
Common stock of HSAC2, outstanding prior to the Business Combination	6,762,117
Less: Redemption of HSAC2 shares	(1,597,888)
Common stock held by former HSAC2 shareholders	5,164,229
HSAC2 sponsor shares	4,450,000
Shares issued related to Backstop Agreement	1,808,512
Total shares outstanding prior to issuance of merger consideration to Legacy Orchestra stockholders	11,422,741
Shares issued to Legacy Orchestra stockholders – Company Common Stock[(1)]	20,191,338
Total shares of Company Common Stock immediately after Business Combination[(2)]	31,614,079

(1) The number of shares of common stock issued to Legacy Orchestra equity holders was determined based on (i) 2,522,214 shares of Legacy Orchestra Common Stock outstanding immediately prior to the closing of the Business Combination converted based on the Exchange Ratio and (ii) 35,694,179 shares of Legacy Orchestra Preferred Stock outstanding immediately prior to the Closing, which pursuant to their terms converted into Legacy Orchestra Common Stock immediately prior to the Closing and then converted into Company Common Stock based on the Exchange Ratio. All fractional shares were rounded down.

(2) Excludes 8,000,000 shares of Company Common Stock issued or to be issued based on satisfaction of the Initial Milestone Event and the Final Milestone Event. 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) of 4,000,000 shares of Company Common Stock, resulting in a total of 3,999,987 shares of Company Common Stock being issued (less than 4,000,000 due to rounding).

The following table reconciles the elements of the Business Combination to the Company's condensed consolidated statement of changes in stockholders' equity (deficit) (in thousands):

	Amount
Cash – HSAC2's trust (net of redemption)	$ 51,915
Cash – Backstop Agreement	18,085
Gross proceeds	70,000
Less: HSAC2 and Legacy Orchestra transaction costs paid	(15,698)
Effect of Business Combination, net of redemptions and transaction costs	$ 54,302

The $54.3 million above differs from the $56.8 million effect of the Business Combination on the condensed consolidated statements of cash flows, due to $2.5 million of transaction costs paid by Legacy Orchestra in 2022.

4. Terumo Agreement

In June 2019, Legacy Orchestra entered into the Terumo Agreement, pursuant to which Terumo secured global commercialization rights for Virtue SAB in coronary and peripheral vascular indications (the "Terumo Indications"). Under the Terumo Agreement, Legacy Orchestra received an upfront payment of $30 million and an equity commitment of up to $5 million of which $2.5 million was invested in June 2019 as part of the Legacy Orchestra Series B-1 financing and $2.5 million was invested in June 2022 as part of the Legacy Orchestra Series D-2 financing. The Company was initially eligible to receive up to $65 million in additional payments based on the achievement of certain development and regulatory milestones and is also eligible to earn royalties on future sales by Terumo based on royalty rates ranging from 10 – 15%. Of these milestone payments, $35 million relate to achieving certain milestones by specified target achievement dates. As of the issuance date of these financial statements, the target achievement date for two $5 million milestone payments has already passed. In addition, due to delays in the Company's Virtue SAB program resulting from the COVID-19 pandemic, supply chain issues and unexpected changes to regulatory requirements, including increased testing and other activities related to chemistry, manufacturing, and control, increased nonclinical and good laboratory practice

preclinical data requirements, including biocompatibility, as well as a requirement to repeat good laboratory practice preclinical studies already performed based on changes to source of component materials and a change in manufacturing site, the Company is unlikely to be able to complete the remaining time-based milestones by the specified target achievement dates to earn the remaining $25 million in time-based milestone payments pursuant to the Terumo Agreement.

As previously disclosed, the Company and Terumo have been negotiating for mutually agreeable adjustments to its current agreement with the purpose of restructuring milestone payments as well as making other potential material modifications to that agreement including additional financial commitments by Terumo to Orchestra and the Virtue SAB program. The Company has delayed initiation of its Virtue ISR-US pivotal study, for which it secured conditional IDE approval from the FDA on August 8, 2023, until such time as the Company restructures its partnership agreement with Terumo in a manner that provides the Company with a satisfactory amount of additional capital, whether from milestone payments or other financial arrangements. Initiation of the Virtue ISR-US pivotal study is currently targeted for 2024 pending ongoing negotiations with Terumo. If negotiations are not completed to the Company's satisfaction or to the satisfaction of Terumo, clinical study, product development, and commercialization plans for Virtue SAB may continue to be adversely impacted.

Pursuant to the terms of the Terumo Agreement, Legacy Orchestra licensed intellectual property rights to Terumo and the Company is primarily responsible for completing the development of the product in the United States through premarket approval by the FDA for the ISR indication. These research and development services to be provided by the Company include (i) manufacturing, testing and packaging the drug required for the clinical trials, (ii) supplying Terumo with information related to the design and manufacture of the delivery device and the technology transfer needed for Terumo to ultimately commence manufacture of the delivery device, and (iii) carrying out regulatory activities related to clinical trials in the United States for the ISR indication.

The Company has concluded that the license granted to Terumo is not distinct from the research and development services that will be provided to Terumo through the completion of the development of ISR indication, as Terumo cannot obtain the benefit of the license without the related research and development services. Accordingly, the Company will recognize revenues for this combined performance obligation over the estimated period of research and development services using a proportional performance model. The Company measures proportional performance based on the costs incurred relative to the total estimated costs of the research and development services.

In 2019, Legacy Orchestra received a total of $32.5 million from Terumo related to the stock purchase and the revenue generating elements of the Terumo Agreement. The Company recorded the estimated fair value of the shares of $2.5 million in stockholders' equity, as the value paid by Terumo is consistent with the value paid by other third-party stockholders in Legacy Orchestra's offering of its Series B-1 Preferred Stock. The Company allocated the remaining $30 million to the transaction price of the Terumo Agreement. The Company considers the future potential development and regulatory milestones to be variable consideration, which are fully constrained from the transaction price as of September 30, 2023 and December 31, 2022, as the achievement of such milestone payments are uncertain and highly susceptible to factors outside of the Company's control. The Company plans to re-evaluate the transaction price at each reporting period and as uncertain events are resolved or other changes in circumstances occur. In addition, the arrangement also includes sales-based royalties on product sales by Terumo subsequent to commercialization ranging from 10 - 15%, none of which have been recognized to date.

The Company recorded the $30 million upfront payment received from Terumo in 2019 within deferred revenue. The following table presents the changes in the Company's deferred revenue balance from the Terumo Agreement during the nine months ended September 30, 2023 and 2022:

Deferred Revenue – December 31, 2022 (in thousands)	$	19,539
Revenue recognized		(2,018)
Deferred Revenue – September 30, 2023	$	17,521
Deferred Revenue – December 31, 2021	$	22,401
Revenue recognized		(1,931)
Deferred Revenue – September 30, 2022	$	20,470

The Company's balance of deferred revenue contains the transaction price from the Terumo Agreement allocated to the combined license and research and development performance obligation, which was partially unsatisfied as of September 30, 2023. The Company expects to recognize approximately $3.7 million of its deferred revenue during the next twelve months and recognize the remaining approximately $13.8 million through the remainder of the performance period, which is currently estimated to be completed in 2028 and may be impacted by the actual clinical and regulatory timelines of the program.

As of each quarterly reporting date, the Company evaluates its estimates of the total costs expected to be incurred through the completion of the combined performance obligation and updates its estimates as necessary. For the three months ended September 30, 2023 and 2022, the expenses incurred related to the Terumo Agreement were approximately $3.4 million and $4.0 million, respectively. For the nine months ended September 30, 2023 and 2022, the expenses incurred related to the Terumo Agreement were approximately $11.7 million and $10.6 million, respectively. The estimated total costs associated with the Terumo Agreement through completion increased by approximately 7% as of September 30, 2023, as compared to the estimates as of December 31, 2022, and increased by approximately 10% as of September 30, 2022, as compared to the estimates as of December 31, 2021. While the Company believes it has estimated total costs associated with the Terumo Agreement through completion, these estimates encompass a broad range of expenses over a multi-year period and, as such, are subject to periodic changes as new information becomes available. The impact of the changes in estimates resulted in a reduction of partnership revenues of $558,000 and $10,000 for the three months ended September 30, 2023 and 2022, respectively, as compared to the amounts that would have been recorded based on the previous estimates. The impact of the changes in estimates resulted in a reduction of partnership revenues of $882,000 and $956,000 for the nine months ended September 30, 2023 and 2022, respectively, as compared to the amounts that would have been recorded based on the previous estimates. The impact of these changes in estimates on the net loss per share, basic and diluted, for the three months ended September 30, 2023 was an increase of $0.02 and no impact for the three months ended September 30, 2022. The impact of these changes in estimates on the net loss per share, basic and diluted, for the nine months ended September 30, 2023 and 2022 was an increase of $0.03 and $0.07, respectively.

The Company will also manufacture, or have manufactured, SirolimusEFR and has exclusive rights to sell it on a per unit basis to Terumo for use in the Virtue SAB product. The Company has determined that this promise does not contain a material right as the pricing is based on standalone selling prices. Through September 30, 2023, there have been no additional amounts recognized as revenue under the Terumo Agreement other than the recognition of a portion of the upfront payment described above.

5. Medtronic Agreement

In June 2022, Legacy Orchestra, BackBeat and Medtronic entered into the Medtronic Agreement for the development and commercialization of BackBeat CNT for the treatment of hypertension ("HTN") in patients indicated for a cardiac pacemaker (the "Primary Field"). Under the terms of the Medtronic Agreement, the Company will sponsor a multinational pivotal study to support regulatory approval of BackBeat CNT in the Primary Field and be financially responsible for development, clinical and regulatory costs associated with this pivotal study. Medtronic is currently working with the Company to integrate BackBeat CNT into its top-of-the-line, commercially available dual-chamber pacemaker system for use in the pivotal trial and will provide development, clinical and regulatory resources in support of the pivotal trial, for which the Company will reimburse Medtronic at cost.

Under the terms of the Medtronic Agreement, Medtronic will have exclusive rights to commercialize BackBeat CNT-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 BackBeat CNT-enabled device sold based on a formula of the higher of (1) a fixed dollar amount per BackBeat CNT-enabled device (amount varies materially on a country-by-country basis) or (2) a percentage of the BackBeat CNT-generated sales. Procedures using the BackBeat CNT-enabled pacemakers are expected to be billed under existing reimbursement codes.

Medtronic has a right of first negotiation through FDA approval of BackBeat CNT in the Primary Field, to expand its global rights to BackBeat CNT for the treatment of HTN patients not indicated for a pacemaker.

The Company assessed whether the Medtronic Agreement fell within the scope of ASC 808 and concluded that the 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 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 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, 2023, the Company incurred approximately $854,000 and $3.1 million, respectively, of research and development costs related to these reimbursements pursuant to the Medtronic Agreement, of which $1.4 million is included within accounts payable and accrued expenses in the Company's September 30, 2023 condensed consolidated balance sheet. During the three and nine months ended September 30, 2022, the Company incurred approximately $530,000 of research and development costs related to these reimbursements pursuant to the Medtronic Agreement.

Concurrently with the close of the Medtronic Agreement, Legacy Orchestra also received a $40 million investment from Medtronic in connection with Legacy Orchestra'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.

Through September 30, 2023, there have been no amounts recognized as revenue under the Medtronic Agreement.

6. 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, 2023			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets				
Money market fund (included in cash and cash equivalents)	$ 13,618	$ —	$ —	$ 13,618
Investment in Motus GI (see Note 7)	362	—	—	362
Marketable securities (Corporate and Government debt securities)	—	89,410	—	89,410
Total assets	$ 13,980	$ 89,410	$ —	$ 103,390

	December 31, 2022			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets				
Money market fund (included in cash and cash equivalents)	$ 8,708	$ —	$ —	$ 8,708
Investment in Motus GI (see Note 7)	86	—	—	86
Marketable securities (Corporate and Government debt securities)	—	63,915	—	63,915
Total assets	$ 8,794	$ 63,915	$ —	$ 72,709
Liabilities:				
Warrant liability (see Note 10)	$ —	$ —	$ 2,089	$ 2,089
Total liabilities	$ —	$ —	$ 2,089	$ 2,089

The Level 2 assets consist of government and corporate 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.

Prior to the closing of the Business Combination, the Company's warrant liability was measured at fair value on a recurring basis using unobservable inputs and were classified as Level 3 inputs, and any change in fair value was recognized as change in fair value of warrant liability in the Company's condensed consolidated statements of operations and comprehensive loss. As of the Closing Date, all Legacy Orchestra liability classified warrants were reclassified to equity. Refer to Note 10 for the valuation technique and assumptions used in estimating the fair value of the warrants and discussion on the change in classification.

The following table presents a roll-forward of the aggregate fair values of the Company's liabilities for which fair value is determined by Level 3 inputs (in thousands):

	Warrant Liability
Balance—December 31, 2022	$ 2,089
Warrants exercised prior to the Business Combination	(10)
Change in fair value of warrants	294
Warrants reclassified to equity	(2,373)
Balance—March 31, 2023	—
Balance—June 30, 2023	—
Balance—September 30, 2023	**$ —**

7. Marketable Securities and Strategic Investments

Marketable Securities

The following is a summary of the Company's marketable securities as of September 30, 2023 and December 31, 2022:

	September 30, 2023			
(in thousands)	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Corporate debt securities	$ 25,625	$ —	$ (24)	$ 25,601
Government debt securities	63,862	1	(54)	63,809
Total	**$ 89,487**	**$ 1**	**$ (78)**	**$ 89,410**

	December 31, 2022			
(in thousands)	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Corporate debt securities	$ 52,242	$ 7	$ —	$ 52,249
Government debt securities	11,681	—	(15)	11,666
Total	**$ 63,923**	**$ 7**	**$ (15)**	**$ 63,915**

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.

For the nine months ended September 30, 2023, the Company recognized realized losses on its marketable securities of $102,000 but did not recognize any realized gains or losses for the three months ended September 30, 2023. For the three and nine months ended September 30, 2022, the Company did not recognize any realized gains or losses on its marketable securities.

Strategic Investments

The Company values the Motus GI investment by measuring fair value using the listed share price on the Nasdaq Capital Market on each valuation date.

Aggregate gains of $293,000 and $276,000 for the three and nine months ended September 30, 2023, respectively, were recorded to adjust the strategic investments in equity securities of Motus GI to its fair value of $362,000 at September 30, 2023. This was primarily the result of an agreement entered into on September 12, 2023 between the Company and Motus GI to exchange previously held royalty certificates, which had a de minimis carrying value, for 701,522 additional shares of Motus GI common stock. Aggregate losses of $327,000 and $707,000 during the three and nine months ended September 30, 2022, respectively, were recorded to adjust the strategic investments in equity securities of Motus GI to its fair value of $86,000 at December 31, 2022, which is classified as strategic investments within current assets on the accompanying condensed consolidated balance sheets.

The Company's long-term strategic investments as of September 30, 2023 represent investments made in Vivasure in 2020, 2021 and 2022 that were originally recorded at cost. There were no observable price changes, other than as described below, or impairments identified during the three and nine months ended September 30, 2023 or the three and nine months ended September 30, 2022 related to these investments.

In May 2022, Vivasure announced a Series D private placement, in which it received a material investment from Haemonetics Corporation, a new strategic investor. In conjunction with a €30 million investment in Vivasure, Haemonetics Corporation also secured an option to acquire Vivasure based on the achievement of certain milestones. As a result, Legacy Orchestra's existing convertible redeemable notes converted into Series D Preferred Stock of Vivasure in May 2022. The investment in the Vivasure Series D Preferred Stock represents an observable price change in an orderly transaction for an identical instrument of the same issuer, and accordingly, the Company recognized a gain on its strategic investment in Vivasure of $1.9 million in the second quarter of 2022. This amount represents a portion of the previously impaired investment balance described below.

During the fourth quarter of 2019, the Company identified indicators of impairment of Vivasure strategic investments held at that time as a result of adverse changes in Vivasure's business operations, including liquidity concerns. As a result, the Company recorded an impairment charge in the fourth quarter of 2019 of $5.8 million, which represents the cumulative impairment charges recorded on Vivasure strategic investments to date.

8. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consists of the following:

(in thousands)	September 30, 2023	December 31, 2022
Equipment	$ 1,783	$ 1,712
Office furniture	367	364
Leasehold improvements	198	191
Property and equipment, gross	2,348	2,267
Less accumulated depreciation and amortization	(993)	(778)
Total Property and equipment, net	**$ 1,355**	**$ 1,489**

Depreciation and amortization expense was $71,000 and $54,000 for the three months ended September 30, 2023 and 2022, respectively. Depreciation and amortization expense was $215,000 and $152,000 for the nine months ended September 30, 2023 and 2022, respectively.

Accrued Expenses

Accrued expenses consist of the following:

(in thousands)	September 30, 2023	December 31, 2022
Accrued compensation	$ 2,571	$ 2,480
Clinical trial accruals	956	1,003
Other accrued expenses	774	1,893
Total accrued expenses	**$ 4,301**	**$ 5,376**

9. Common and Preferred Stock

Common Stock

The Company is authorized to issue up to 340,000,000 shares of Company Common Stock, par value $0.0001 per share.

As discussed in Note 3, the Company has retroactively adjusted the shares issued and outstanding prior to January 26, 2023 to give effect to the Exchange Ratio to determine the number of shares of Company Common Stock into which they were converted.

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, 2023, no shares of preferred stock were outstanding.

10. Warrants

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

Private Warrants

Prior to the Merger, HSAC2 had outstanding 1,500,000 Private Warrants, which were issued in connection with the HSAC2 IPO to the Sponsor. Each Private Warrant entitles the holder thereof to purchase one share of Company Common Stock at a price of $11.50 per share, subject to adjustment as provided therein. The Private Warrants became exercisable 30 days after the completion of the Business Combination and will expire five years after the completion of the Business Combination. Each Private Warrant is non-redeemable and may be exercised on a cashless basis. Since these warrants are indexed to the Company's publicly traded common stock, they are classified within equity.

As described in Note 3, the Sponsor and HSAC2's other initial shareholders prior to the HSAC2 IPO agreed to subject (i) the 4,000,000 Insider Shares and (ii) the 450,000 Private Shares to a lock-up for up to 12 months following the Closing and the Sponsor forfeited 50% of its 1,500,000 Private Warrants, comprising 750,000 Private Warrants, for no consideration, immediately prior to the Closing. Pursuant to the terms of the Merger Agreement, immediately following the Sponsor Forfeiture and prior to the Closing, HSAC2 issued 750,000 Officer and Director Warrants to eleven specified employees and directors of Legacy Orchestra. The Officer and Director Warrants have substantially similar terms to the forfeited Private Warrants, except that 50% of the Officer and Director Warrants will become exercisable 24 months after the Closing and the remaining 50% will become exercisable 36 months after the Closing.

Assumed Legacy Orchestra Warrants

Prior to the close of the Business Combination, the majority of Legacy Orchestra's warrants (the "Legacy Orchestra Warrants") were required to be accounted for as liabilities as certain features within the warrant agreements contained features that were not considered "fixed for fixed" pursuant to ASC 815, and therefore, the fair value of the warrant liability was marked-to-market at each balance sheet date, with the change in fair value recorded in the Company's condensed consolidated statements of operations and comprehensive loss within other income (expense). Upon the close of the Business Combination, all liability classified Legacy Orchestra Warrants became equity classified on that date, as the warrant agreements became "fixed for fixed." As a result, the warrant liability was fair valued and adjusted from $2.1 million as of December 31, 2022 to $2.4 million as of January 26, 2023, and then subsequently reclassified into stockholders' equity. In addition, Legacy Orchestra also had outstanding other equity classified warrants recorded within additional paid-in capital at the time of issuance at fair value that were not subject to subsequent remeasurement.

The Company calculates the fair value of the outstanding warrant liability at each reporting date by estimating the equity value of the Company, and then utilizing option pricing models to allocate the total equity value to the shares and warrants outstanding. The inputs used in the valuation models for the Company's warrant liability are as follows:

	Period from January 1, 2023 to January 26, 2023	September 30, 2022
Expected volatility	44 – 49 %	42 – 45 %
Risk-free interest rate	3.60 – 4.80 %	3.30 – 4.10 %
Remaining term in years	0.35 – 5.00	0.67 – 5.13
Exercise price of common warrants	$1.08 – $30.11	$1.08 – $30.11
Exercise price of Legacy preferred warrants	—	—
Common stock price	$10.63	$9.18
Legacy preferred stock price	—	—
Expected dividend yield	0 %	0 %

The Company's warrant liability related to Legacy Orchestra warrant activity rollforward is as follows, with the warrants having been converted to reflect the effect of the Merger:

(in thousands, except share data)	Preferred Warrants	Common Warrants	Amount
Balance December 31, 2022	—	1,327,074	$ 2,089
Warrants exercised prior to the business combination	—	(1,163)	(10)
Change in fair value of warrants as of January 26, 2023	—	—	294
Warrants reclassified to equity	—	(1,325,911)	(2,373)
Balance March 31, 2023	—	—	—
Balance June 30, 2023	—	—	—
Balance September 30, 2023	—	—	$ —

(in thousands, except share data)	Preferred Warrants	Common Warrants	Amount
Balance December 31, 2021	206,997	1,189,162	$ 635
Exercise of warrants	—	(68,587)	(156)
Change in the fair value of warrants	—	—	145
Balance March 31, 2022	206,997	1,120,575	624
Exercise of warrants	—	(4,650)	(15)
Forfeiture of warrants	—	(4,650)	(38)
Issuance of warrants related to Legacy Orchestra preferred stock financing	—	159,965	620
Amendments of existing warrants	(206,997)	206,997	810
Other	—	(150,000)	(335)
Change in the fair value of warrants	—	—	243
Balance June 30, 2022	—	1,328,237	1,909
Balance September 30, 2022	—	1,328,237	$ 1,909

Private Warrants and Assumed Legacy Orchestra Warrants

The following table summarizes outstanding warrants to purchase shares of Company Common Stock as of September 30, 2023 and December 31, 2022:

	Number of Shares			
	September 30, 2023	December 31, 2022	Exercise Price	Term
Liability-classified Warrants				
Legacy Orchestra Warrants	—	1,327,074	$0.50 – $14.00	0.10 – 4.50
Equity-classified Warrants				
Legacy Orchestra Warrants	509,258	250,000	$0.50 – $14.00	0.10 – 8.75
Private Warrants Held by Sponsor	750,000	1,500,000	$11.50	4.32 – 4.57
Private Warrants Held by Employees (Note 11)	675,000	—	$11.50	4.32
	1,934,258	1,750,000		
Total Outstanding	1,934,258	3,077,074		

11. Stock-Based Compensation

As of September 30, 2023, the only equity compensation plan from which the Company may currently issue new awards is the Company's 2023 Equity Incentive Plan (the "2023 Plan"), as more fully described below.

Orchestra BioMed, Inc. 2018 Stock Incentive Plan

Prior to the Merger, Legacy Orchestra maintained the 2018 Plan, under which Legacy Orchestra granted incentive stock options, non-qualified stock options and restricted stock awards to its employees and certain non-employees, including consultants, advisors and directors. The maximum aggregate shares of Legacy Orchestra Common Stock that was subject to awards and issuable under the 2018 Plan was 5.2 million shares prior to the Merger. Employees, consultants, and directors were eligible for awards granted under the 2018 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 three years.

As described in Note 3, in connection with the Merger, each Legacy Orchestra Option that was outstanding and unexercised immediately prior to the time that the Merger became effective (the "Effective Time") (whether vested or unvested) was assumed by the Company and converted into an option to purchase an adjusted number of shares of Company Common Stock at an adjusted exercise price per share, based on the Exchange Ratio, and will continue to be governed by substantially the same terms and conditions, including vesting, as were applicable to the former option. Each Exchanged Option is exercisable for a number of whole shares of Company Common Stock equal to the product of the number of shares of Legacy Orchestra Common Stock underlying such Legacy Orchestra Options multiplied by the Exchange Ratio, and the per share exercise price of such Exchanged Option is equal to the quotient determined by dividing the exercise price per share of the Legacy Orchestra Option by the Exchange Ratio. Following the closing of the Merger, no new awards may be made under the 2018 Plan.

The Company accounted for the Exchanged Options as a modification of the existing options. Incremental compensation costs, measured as the excess, if any, of the fair value of the modified options over the fair value of the original options immediately before its terms are modified, is measured based on the fair value of the underlying shares and other pertinent factors at the modification date. The impact of the option modifications were de minimis.

Orchestra BioMed Holdings, Inc. 2023 Equity Incentive Plan

At the Effective Time, the Company adopted 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, 2023, 3,561,678 shares of Company Common Stock are authorized for issuance pursuant to awards under the 2023 Plan.

The pool of available shares will be 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 our 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.

In addition, any awards outstanding under the 2018 Plan upon the Closing, after adjustment for the Business Combination, remain outstanding. If any of those awards subsequently expire, terminate, or are surrendered or forfeited for any reason without issuance of shares after the closing of the Business Combination, the shares of Company Common Stock underlying those awards will automatically become available for issuance under the 2023 Plan.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2023	2022	2023	2022
Research and development	$ 391	$ 101	$ 1,206	$ 192
Selling, general and administrative	610	2,092	1,979	2,199
Total stock-based compensation	$ 1,001	$ 2,193	$ 3,185	$ 2,391

As of September 30, 2023, there was approximately $7.6 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 three 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)	2023	2022	2023	2022
Research and development	$ 643	$ —	$ 643	$ —
Selling, general and administrative	1,595	30	2,142	121
Total stock-based compensation	$ 2,238	$ 30	$ 2,785	$ 121

As of September 30, 2023, there was approximately $10.6 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 two years.

As previously discussed in Note 3 and Note 10, pursuant to the terms of the Merger Agreement, immediately following the Sponsor Forfeiture and prior to the Closing, the Company issued 750,000 warrants to purchase Company Common Stock to eleven specified employees and directors of Legacy Orchestra (the “Officer and Director Warrants”). The Officer and Director Warrants have substantially similar terms to the forfeited Private Warrants, except that 50% of the Officer and Director Warrants will become exercisable 24 months after the Closing and the remaining 50% will become exercisable 36 months after the Closing. The estimated grant-date fair value of these warrant awards issued concurrent with the close of the Business Combination was calculated using the Black-Scholes option pricing model. Assumptions used were an expected term (in years) of 5.00, expected volatility of 50%, risk-free interest rate of 3.54%, expected dividend yield of 0%, and fair value of common stock of $10.63. During the nine months ended September 30, 2023, 75,000 of these warrants were forfeited resulting in a remaining 675,000 warrants outstanding.

Total stock-based compensation related to warrants was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2023	2022	2023	2022
Research and development	$ 120	$ —	$ 328	$ —
Selling, general and administrative	150	—	408	—
Total stock-based compensation	$ 270	$ —	$ 736	$ —

As of September 30, 2023, there was approximately $2.8 million of unrecognized stock-based compensation expense associated with the warrants noted above that is expected to be recognized over a weighted average period of approximately three years.

Stock Option Activity

The following table summarizes the stock option activity of the Company under the 2018 Plan and the 2023 Plan:

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2023	7,868,448	3.51	8.35	—
Retroactive application of Reverse Recapitalization (Note 3)	(4,209,620)	4.05	—	—
Outstanding at January 1, 2023, effect of Merger	3,658,828	7.56	8.35	—
Granted	1,080,875	8.19	—	—
Exercised	(18,790)	4.17	—	—
Forfeited/canceled	(141,848)	9.22	—	—
Outstanding September 30, 2023	4,579,065	7.72	8.03	$ 7,495
Exercisable at September 30, 2023	2,432,159	6.90	6.97	$ 5,794

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

	Restricted Stock Awards/Units Outstanding
Outstanding January 1, 2023	158,589
Granted	1,695,222
Vested	(67,689)
Forfeited/canceled	(45,901)
Outstanding September 30, 2023	1,740,221

During the nine months ended September 30, 2023, the Company granted 1,695,222 restricted stock units at a weighted-average grant date fair value of $7.42, all of which were service-based restricted stock awards. No performance-based restricted stock awards were granted in the nine months ended September 30, 2023.

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,	
	2023	2022
Expected term (in years)	6.09	6.00
Expected volatility	46 %	49 %
Risk-free interest rate	3.86 %	2.96 %
Expected dividend yield	0 %	0 %
Fair value of common stock	$ 8.19	$ 8.58

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 expected volatility was derived from the historical stock volatilities of comparable peer public companies within the Company's industry that are considered to be comparable to the Company's business over a period equivalent to the expected term of the stock-based awards since there has been no trading history of the Legacy Orchestra Common Stock and limited trading history of the Company Common Stock.

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 neither the Company nor Legacy Orchestra has paid, and the Company does not anticipate paying, any dividends on its common stock in the foreseeable future.

Fair Value of Common Stock — Prior to the Business Combination, as the Legacy Orchestra Common Stock has not historically been publicly traded, its board of directors periodically estimated the fair value of the Company's common stock considering, among other things, contemporaneous valuations of its common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Subsequent to the Business Combination, the Company utilizes the price of its publicly-traded Company Common Stock to determine the grant date fair value of awards.

12. Leases

Office Lease

In January 2019, Legacy Orchestra entered into an additional addendum to the lease agreement for office space in New Hope, PA originally entered into in December 2009 (as amended, the "New Hope Lease"). The New Hope Lease covers 8,052 square feet and will expire in September 2024. Monthly fees will be between $9,000 and $19,000 for the period from commencement through expiration.

In November 2019, Legacy Orchestra entered into a new lease agreement for approximately 5,200 square feet of office space in New York, NY. The lease will expire in March 2028. Monthly fees will be between $28,000 and $30,000 for the period from commencement through expiration.

In January 2020, Legacy Orchestra entered into an agreement for the use of portions of the office space of Motus GI, a related party, in Fort Lauderdale, Florida. The agreement will expire in September 2024. The monthly fee commenced on the month following the date of agreement. Monthly fees will be between $12,000 and $17,000 for the period from commencement through expiration.

In May 2022, Legacy Orchestra amended the agreement with Motus GI for a larger portion of the office space and extended the expiration date to November 2024. Monthly fees will be between $7,000 and $23,000 for the period from commencement of the amendment to expiration. The amount paid is estimated to be proportionate to the percentage of space used by the Company applied to the monthly rent obligated to be paid by Motus GI to their landlord.

Operating cash flow supplemental information for the nine months ended September 30, 2023:

Cash paid for amounts included in the present value of operating lease liabilities was $669,000 during the nine months ended September 30, 2023 compared to $579,000 during the nine months ended September 30, 2022.

As of September 30, 2023:	
Weighted average remaining lease term – operating leases, in years	3.60
Weighted average discount rate – operating leases	6.25 %

Operating Leases

Rent/lease expense for office and lab space was approximately $209,000 and $198,000, respectively, for the three months ended September 30, 2023 and 2022. Rent/lease expense for office and lab space was approximately $626,000 and $552,000 for the nine months ended September 30, 2023 and 2022, respectively. The table below shows the future minimum rental payments, exclusive of taxes, insurance, and other costs, under the leases as of September 30, 2023:

Year ending December 31:	Operating Leases (in thousands)
2023 (remaining three months)	$ 208
2024	727
2025	352
2026	352
2027	352
Thereafter	88
Total future minimum lease payments	$ 2,079
Imputed interest	(215)
Total liability	$ 1,864

13. 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 year ended 2022 and the nine months ended September 30, 2023:

Vivasure Investments

In December 2020 and 2021, and April 2022, Legacy Orchestra invested in Vivasure, a related party, $183,000, $213,000, and $208,000, respectively, in the form of unsecured convertible redeemable notes. The unsecured convertible redeemable notes converted into Series D preferred stock of Vivasure in May of 2022 (Note 7).

Motus GI Investments

On September 12, 2023, Motus GI, a related party, and the Company entered into an agreement to terminate the rights of previously held royalty certificates in exchange for 701,522 additional shares of Motus GI common stock (Note 7).

14. Debt Financing

In June 2022, Legacy Orchestra entered into a Loan and Security Agreement with Avenue Venture Opportunities Fund I and II (the “2022 Loan and Security Agreement”). The terms of the 2022 Loan and Security Agreement include a term loan of up to $20 million available in two tranches with the first tranche of $10 million that was drawn at closing in June of 2022, and a second tranche of $10 million available at closing of the Legacy Orchestra Series D-2 Preferred Stock financing was not drawn. Additionally, the Company may have access to a third tranche of $30 million subject to certain financing milestones. The term loan matures on June 1, 2026. In addition, the lender has the right, at its discretion, but not the obligation, to convert any portion of the outstanding principal amount of the loans up to $5 million into shares of Company Common Stock at a price per share equal to $12.00 (the “Conversion Option”), subject to adjustment; provided, however, the Conversion Option shall not be exercised by lender during the six (6) month period after completion of the Business Combination.

Pursuant to the terms of the 2022 Loan and Security Agreement, Legacy Orchestra issued Avenue Venture Opportunities Fund I and II warrants that will be exercisable for 100,000 shares of Company Common Stock, and the estimated fair value of the warrants of $178,000 was recorded as debt discount on the date of issuance and is being

amortized to interest expense over the term of the 2022 Loan and Security Agreement. In addition, other financing costs totaling $405,000 were also recorded as debt discount and is being amortized to interest expense over the term of the facility.

The term loan accrues interest at a floating per annum rate equal to the Wall Street Journal prime rate plus 6.45%. The rate in effect at September 30, 2023 was 15.0%. The repayment terms of the loan include monthly payments over a 4-year period, consisting of an initial 2-year interest-only period, followed by 24 monthly principal payments of $417,000 plus interest. In addition, there is a final payment equal to 4.25% of the initial commitment amount of $20 million, which will be accrued over the term of the loan using the effective-interest method.

Concurrent with the closing of the 2022 Loan and Security Agreement, Legacy Orchestra terminated and repaid an existing 2019 Loan and Security Agreement with Silicon Valley Bank (the "2019 Loan and Security Agreement"), which resulted in a loss on extinguishment of $682,000. Pursuant to the terms of the 2019 Loan and Security Agreement, Legacy Orchestra issued Silicon Valley Bank a warrant that, to the extent Legacy Orchestra made draws on the 2019 Loan and Security Agreement, was exercisable for a number of shares of Legacy Orchestra Common Stock equal to 2% of the amount drawn divided by the exercise price of $1.33 per share of Legacy Orchestra Common Stock. As a result of the draw in December of 2020, Legacy Orchestra issued 150,000 Legacy Orchestra Common Stock warrants to Silicon Valley Bank, and the estimated fair value of the warrants of $544,000 was recorded as debt discount on the date of issuance and was being amortized to interest expense over the term of the credit facility. These warrants have been exercised and are no longer outstanding.

The term loan accrued interest at a floating per annum rate equal to the greater of (i) the Wall Street Journal prime rate plus 1.00% or (ii) 6.25%. In addition, there was a final payment equal to 8.25% of the original aggregate principal amount which accrued over the term of the loan using the effective-interest method.

Total interest expense recorded on these facilities during the three months ended September 30, 2023 and September 30, 2022 was approximately $469,000 and $387,000, respectively. Total interest expense recorded on these facilities during the nine months ended September 30, 2023 and September 30, 2022 was approximately $1.4 million and $880,000, respectively.

The following table shows the amount of principal payments due pursuant to the term loan under the 2022 Loan and Security Agreement by year:

Period ending September 30:	Principal Payments (in thousands)
2023 (remaining three months)	$ —
2024	2,500
2025	5,000
2026	2,500
Total	$ 10,000

The term loan under the 2022 Loan and Security Agreement is secured by all of the Company's assets, excluding intellectual property and certain other assets. The loan contains customary affirmative and restrictive covenants, including the Company's ability to enter into fundamental transactions, incur additional indebtedness, grant liens, pay any dividend or make any distributions to its holders, make investments, merge or consolidate with any other person or engage in transactions with the Company's affiliates, but does not include any financial covenants. On October 6, 2023, the 2022 Loan and Security Agreement was repaid in full and terminated. Refer to Note 16, Subsequent Events.

15. Net Loss Per Share

Basic net loss per share of Company Common Stock is computed by dividing net loss by the weighted-average number of shares of Company Common Stock. Shares of Company Common Stock outstanding but subject to forfeiture and cancellation by the Company (e.g., the Forfeitable Shares – see Note 3) are excluded from the weighted-average number of shares until the period in which such shares are no longer subject to forfeiture.

As discussed in Note 3, in connection with the Business Combination, existing Legacy Orchestra stockholders had the opportunity to elect to participate in the Earnout pursuant to which each such Earnout Participant may receive a portion of additional contingent consideration of up to 8,000,000 shares of Earnout Consideration. 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) of 4,000,000 shares of Company Common Stock, resulting in a total of 3,999,987 shares of Company Common Stock being issued (less than 4,000,000 due to rounding). Additionally, 500,000 of the Forfeitable Shares are no longer subject to forfeiture as a result of the Initial Milestone Event.

Diluted net loss per share of Company Common Stock includes the effect, if any, from the potential exercise or conversion of securities, such as stock options, Legacy Orchestra Warrants and Private Warrants, and Forfeitable Shares and Earnout Consideration, which would result in the issuance of incremental shares of Company 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, 2023 and September 30, 2022, as their effect is anti-dilutive:

	Nine Months Ended September 30,	
	2023	2022
Stock options	4,579,065	1,578,316
Company common stock warrants	1,934,258	1,328,237
Unvested restricted stock awards	1,740,221	168,108
Conversion option	416,667	—
Forfeitable shares	500,000	—
Earnout consideration	4,000,000	—
Total	13,170,211	3,074,661

16. Subsequent Events

On October 6, 2023, the Company terminated and repaid the 2022 Loan and Security Agreement (as defined in Note 14 above). In connection with the repayment and termination, the Company repaid $10 million of principal and issued warrants to purchase 27,707 shares of Company Common Stock at an exercise price of $7.67 per share in lieu of a cash payment of approximately $212,500 due with respect to certain fees under the 2022 Loan and Security Agreement. The Company also paid approximately $849,000 of net interest, prepayment fees, and legal fees.

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 as Exhibit 99.1 to the Company's Current Report on Form 8-K/A filed with the Securities and Exchange Commission on March 24, 2023.

Closing of Business Combination

Prior to January 26, 2023, the Company was a special purpose acquisition company formed for the purpose of entering into a merger, amalgamation, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses or entities. On January 26, 2023, we consummated the business combination contemplated by the Agreement and Plan of Merger, dated as of July 4, 2022 (as amended by Amendment No. 1 to Agreement and Plan of Merger, dated July 21, 2022, and Amendment No. 2 to Agreement and Plan of Merger, dated November 21, 2022, the "Merger Agreement") by and among Health Sciences Acquisitions Corporation 2, a special purpose acquisition company incorporated as a Cayman Islands exempted company in 2020 and Orchestra's predecessor ("HSAC2"), HSAC Olympus Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of HSAC2 ("Merger Sub"), and Orchestra BioMed, Inc. ("Legacy Orchestra"). Pursuant to the Merger Agreement, (i) HSAC2 deregistered in the Cayman Islands in accordance with the Companies Act (2022 Revision) (As Revised) of the Cayman Islands and domesticated as a Delaware corporation in accordance with Section 388 of the Delaware General Corporation Law (the "Domestication") and (ii) Merger Sub merged with and into Legacy Orchestra, with Legacy Orchestra as the surviving company in the merger and, after giving effect to such merger, continuing as a wholly owned subsidiary of Orchestra (the "Merger" and, together with the Domestication and the other transactions contemplated by the Merger Agreement, the "Business Combination"). As part of the Domestication, we changed our name from "Health Sciences Acquisitions Corporation 2" to "Orchestra BioMed Holdings, Inc." On January 27, 2023, our common stock ("Company Common Stock") began trading on The Nasdaq Global Market under the symbol "OBIO." For additional information, see Note 3 to the Consolidated Financial Statements.

Reverse Recapitalization

The Business Combination is accounted for as a reverse recapitalization (the "Reverse Recapitalization") in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Under this method of accounting, HSAC2 is treated as the "acquired" company and Legacy Orchestra is treated as the acquirer for financial reporting purposes. As a result, the consolidated assets, liabilities and results of operations prior to the Reverse Recapitalization are those of Legacy Orchestra. Additionally, the shares and corresponding capital amounts and losses per share, prior to the Business Combination, have been retroactively restated based on the exchange ratio established in the Merger Agreement (the "Exchange Ratio"). For additional information on the Business Combination and the Exchange Ratio, see Note 3 to the Consolidated Financial Statements.

Overview

We are a biomedical innovation company accelerating high-impact technologies to patients through risk-reward sharing partnerships with leading 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 lead product candidate is BackBeat Cardiac Neuromodulation Therapy ("BackBeat CNT") for the treatment of hypertension ("HTN"), the leading risk factor for death worldwide. We have an exclusive license and collaboration agreement with Medtronic,

Inc. for the development and commercialization of BackBeat CNT for the treatment of HTN in patients indicated for a cardiac pacemaker. We are also developing the Virtue Sirolimus AngioInfusion Balloon ("Virtue SAB") for the treatment of atherosclerotic artery disease, the leading cause of mortality worldwide. We have a strategic collaboration with Terumo Medical Corporation ("Terumo") for the development and commercialization of Virtue SAB for the treatment of coronary and peripheral artery disease.

Since Legacy Orchestra's inception, we have devoted the substantial majority of our resources to performing 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 convertible preferred stock and proceeds from the Business Combination, as well as through proceeds from our distribution agreement (the "Terumo Agreement") with Terumo, borrowings under debt arrangements and, to a lesser extent, from product revenue from our subsidiary, FreeHold Surgical, LLC. ("FreeHold"). We have raised a cumulative $166.8 million in gross proceeds through the issuance of convertible preferred stock, $70.0 million in gross proceeds from the Business Combination, and have received $30.0 million from the Terumo Agreement through September 30, 2023. We have incurred net losses each year since inception. Our net losses were $13.3 million and $10.3 million for the three months ended September 30, 2023 and 2022, respectively, and $36.3 million and $23.9 million for the nine months ended September 30, 2023 and 2022, respectively. We expect to continue to incur significant losses for the foreseeable future. As of September 30, 2023, we had an accumulated deficit of $236.0 million.

Legacy Orchestra, 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., a Delaware Corporation that has, among other things, the rights to the Backbeat CNT product candidate, in 2018. Legacy Orchestra 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.

Recent Developments

On September 19, 2023, we announced that the U.S. Food and Drug Administration (the "FDA") granted us IDE approval to initiate our planned BACKBEAT (BradycArdia paCemaKer with atrioventricular interval modulation for Blood prEssure treAtmenT) pivotal study (the "BACKBEAT pivotal study") of BackBeat CNT, also known as Atrioventricular Interval Modulation ("AVIM") therapy, to treat hypertension in patients indicated for a pacemaker. We currently expect to initiate enrollment of the BACKBEAT pivotal study before the end of 2023 following completion of clinical trial initiation activities, including clinical center Institutional Review Board approvals.

On August 8, 2023, we announced that the FDA granted us investigational device exemption approval with conditions to initiate our planned Virtue ISR-US pivotal study evaluating the efficacy and safety of Virtue SAB for the treatment of patients with coronary in-stent restenosis ("ISR"). The conditional approval permits us to initiate enrollment of the Virtue ISR-US pivotal study following completion of clinical trial initiation activities, including clinical center Institutional Review Board approvals. We are also required to submit additional information to the FDA.

As previously disclosed, the Company and Terumo have been negotiating for mutually agreeable adjustments to its current agreement with the purpose of restructuring milestone payments as well as making other potential material modifications to that agreement including additional financial commitments by Terumo to Orchestra and the Virtue SAB program. We have delayed initiation of our Virtue ISR-US pivotal study, for which we secured conditional IDE approval from the FDA on August 8, 2023, until such time as we restructure our partnership agreement with Terumo in a manner that provides us with a satisfactory amount of additional capital, whether from milestone payments or other financial arrangements. Initiation of the Virtue ISR-US pivotal study is currently targeted for 2024 pending ongoing negotiations with Terumo. If negotiations are not completed to the Company's satisfaction or to the satisfaction of Terumo, clinical study, product development, and commercialization plans for Virtue SAB may continue to be adversely impacted.

On October 6, 2023, we terminated and repaid the 2022 Loan and Security Agreement (as defined below). In connection with the repayment and termination, we repaid $10 million of principal and issued warrants to purchase 27,707 shares of Company Common Stock at an exercise price of $7.67 per share in lieu of a cash payment of approximately

$212,500 due with respect to certain fees under the 2022 Loan and Security Agreement. We also paid approximately $849,000 of net interest, prepayment fees, and legal fees.

Components of Our Results of Operations

Partnership Revenue

To date, our partnership revenues have related to the Terumo Agreement described below. In future periods, partnership revenues may also include revenues related to the Exclusive License and Collaboration Agreement, dated as of September 30, 2022, by and among, Legacy Orchestra, BackBeat Medical, LLC and Medtronic, Inc. (an affiliate of Medtronic plc) (the "Medtronic Agreement"), discussed in Note 5, *Medtronic Agreement*, to the Consolidated Financial Statements.

Legacy Orchestra entered into the Terumo Agreement in June 2019, and has determined that the arrangement represents a contract with a customer and is therefore in scope of ASC 606, *Revenues from Contracts with Customers* ("ASC 606"). Under the Terumo Agreement, Legacy Orchestra received an upfront payment of $30.0 million in 2019 and an equity commitment of up to $5 million of which $2.5 million was invested in June 2019 as part of the Legacy Orchestra Series B-1 financing and $2.5 million was invested in June 2022 as part of the Legacy Orchestra Series D-2 financing.

Under the Terumo Agreement, we were initially eligible for certain milestone payments in the amount of $65 million from Terumo upon completion of certain minimum enrollments in clinical studies, making certain filings and submissions, and obtaining certain regulatory approvals and certifications, and are also eligible to earn royalties on future sales by Terumo based on royalty rates ranging from 10 - 15%. Of these milestone payments, $35 million relate to achieving certain milestones by specified target achievement dates. As of the date of this Quarterly Report on Form 10-Q, we have already passed the target achievement dates for two $5 million milestone payments, in each case, without achieving the related milestones. In addition, due to delays in our Virtue SAB program resulting from the COVID-19 pandemic, supply chain issues and unexpected regulatory delays and requirements, including increased testing and other activities related to chemistry, manufacturing, and control, increased nonclinical and good laboratory practice preclinical data requirements, including biocompatibility, as well as a requirement to repeat good laboratory practice preclinical studies already performed based on changes to source of component materials and a change in manufacturing site, that caused us to amend our original project plan, we are unlikely to be able to complete the remaining time-based milestones by the specified target achievement dates to earn the remaining $25 million in time-based milestone payments pursuant to the Terumo Agreement. Further, Terumo has the right to terminate the agreement, or certain of its obligations thereunder, if certain milestones are not achieved.

As previously disclosed, the Company and Terumo have been negotiating for mutually agreeable adjustments to its current agreement with the purpose of restructuring milestone payments as well as making other potential material modifications to that agreement including additional financial commitments by Terumo to Orchestra and the Virtue SAB program. We have delayed initiation of our Virtue ISR-US pivotal study, for which we secured conditional IDE approval from the FDA on August 8, 2023, until such time as we restructure our partnership agreement with Terumo in a manner that provides us with a satisfactory amount of additional capital, whether from milestone payments or other financial arrangements. Initiation of the Virtue ISR-US pivotal study is currently targeted for 2024 pending ongoing negotiations with Terumo. If negotiations are not completed to the Company's satisfaction or to the satisfaction of Terumo, clinical study, product development, and commercialization plans for Virtue SAB may continue to be adversely impacted.

We recorded the $30.0 million upfront payment received in 2019 from Terumo within deferred revenue and are recognizing the upfront payment over time based on a proportional performance model based on the costs incurred to date relative to the total costs expected to be incurred through the completion of the development of the Coronary in ISR indication, for which we are primarily responsible. We have recognized $12.5 million in cumulative partnership revenues from 2019 through September 30, 2023. There were no other proceeds received pursuant to the Terumo Agreement from 2019 through September 30, 2023.

In June 2022, Legacy Orchestra entered into the Medtronic Agreement for the development and commercialization of BackBeat CNT for the treatment of HTN in patients indicated for a cardiac pacemaker. We have determined that the

arrangement is a collaboration within the scope of *ASC 808, Collaborative Arrangements* ("ASC 808"). In addition, we concluded that Medtronic, Inc., an affiliate of Medtronic plc ("Medtronic"), is a customer for a good or service that is a distinct unit of account, and therefore, the transactions in the Medtronic Agreement should be accounted for under ASC 606. Through September 30, 2023, there have been no amounts recognized as revenue under the 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 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 and 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 to 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. We expect quarterly selling, general and administrative expenses, excluding stock-based compensation expense, to continue to increase as a public company.

Interest Income (Expense), Net

Interest income reflects the income generated from marketable securities during the year. Interest expense is attributable to loan interest.

In June 2022, Legacy Orchestra entered into a loan and security agreement (the "2022 Loan and Security Agreement") with Avenue Venture Opportunities Fund, L.P. ("Avenue I") and Avenue Venture Opportunities Fund II, L.P. ("Avenue II," and, collectively with Avenue I, "Avenue"). As part of the 2022 Loan and Security Agreement, Legacy Orchestra paid off the balance of the 2019 Loan and Security Agreement (as defined below) with Silicon Valley Bank. The terms of the 2022 Loan and Security Agreement included a term loan of up to $20 million available in two tranches with the first tranche of $10 million that was drawn at closing in June of 2022, and a second tranche of $10 million available at closing of the Series D-2 Financing that was not drawn. Additionally, we may have had access to a third tranche of $30 million subject to certain financing milestones. The term loan had a maturity date of June 1, 2026 and accrued interest at a floating per annum rate equal to the Wall Street Journal prime rate plus 6.45%. The rate in effect at September 30, 2023 was 15.0%. As discussed above, on October 6, 2023, the 2022 Loan and Security Agreement was repaid in full and terminated. Refer to Note 14 to our Condensed Consolidated Financial Statements.

In December 2019, Legacy Orchestra entered into a Loan and Security Agreement with Silicon Valley Bank for a term loan as described in Note 14 to our Condensed Consolidated Financial Statements (the "2019 Loan and Security Agreement"). The 2019 Loan and Security Agreement provided Legacy Orchestra with capital for development and general corporate purposes. On December 31, 2020, Legacy Orchestra borrowed $10 million under the 2019 Loan and Security Agreement.

Gain (Loss) on Fair Value Adjustment of Warrant Liability

Certain of Legacy Orchestra's outstanding warrants contained features that required the warrants to be accounted for as liabilities. The warrants were subject to re-measurement at each balance sheet date with gains and losses reported through Legacy Orchestra's condensed consolidated statements of operations and comprehensive loss as gain (loss) on fair value adjustment of warrant liability. Upon closing of the Business Combination, all liability classified warrants of Legacy Orchestra became equity classified on that date as they are now considered "fixed for fixed."

Gain (Loss) on Fair Value of Strategic Investments

The gain (loss) on fair value of strategic investments represents a change in the fair value of our investment in Motus GI Holdings, Inc. ("Motus GI"), a publicly-held company and related party, and preferred shares and convertible notes of Vivasure Medical Limited ("Vivasure"), a privately-held company and related party. The shares held of Motus GI represent equity securities with a readily determinable fair value and are required to be measured at fair value at each reporting period using readily determinable pricing available on a securities exchange, in accordance with the provisions of ASU 2016-01, *Recognition and Measurement of Financial Assets and Liabilities*. The investments in Vivasure do not have readily determinable fair values and are 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.

On September 12, 2023, Motus GI and the Company entered into an agreement, pursuant to which the royalty certificates were amended to terminate the rights of royalty certificate holders to receive royalties in exchange for shares of Motus GI common stock. As a result of the Amendment Agreement, we received 701,522 shares of Motus GI common stock in exchange for our royalty certificates, which had a de minimis carrying value.

Results of Operations

Comparison of the Nine Months Ended September 30, 2023 and 2022

The following table presents our statement of operations data for the nine months ended September 30, 2023 and 2022, and the dollar and percentage change between the two periods (in thousands):

	Nine Months Ended September 30,			
	2023	2022	Change $	Change %
Revenue:				
Partnership revenue	$ 2,018	$ 1,931	$ 87	5 %
Product revenue	480	499	(19)	(4)%
Total revenue	2,498	2,430	68	3 %
Expenses:				
Cost of product revenues	139	158	(19)	(12)%
Research and development	25,311	14,402	10,909	76 %
Selling, general and administrative	16,073	10,699	5,374	50 %
Total expenses	41,523	25,259	16,264	64 %
Loss from operations	(39,025)	(22,829)	(16,196)	(71)%
Other income (expense):				
Interest income (expense), net	2,741	(419)	3,160	754 %
Loss on fair value adjustment of warrant liability	(294)	(1,124)	830	74 %
Loss on debt extinguishment	—	(682)	682	100 %
Gain on fair value of strategic investments	276	1,196	(920)	(77)%
Total other income (expense)	2,723	(1,029)	3,752	365 %
Net loss	$ (36,302)	$ (23,858)	$ (12,444)	(52)%

Partnership Revenue

Partnership revenue increased by $87,000, or approximately 5%, to $2.0 million in the nine months ended September 30, 2023 from $1.9 million for the nine months ended September 30, 2022. Partnership revenue relates 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. As of each quarterly reporting date, we evaluate our estimates of the total costs expected to be incurred through the completion of the combined performance obligation and update our estimates as necessary.

For the nine months ended September 30, 2023 and 2022, the expenses incurred related to the Terumo Agreement were approximately $11.7 million and $10.6 million, respectively. The estimated total costs associated with the Terumo Agreement through completion increased by approximately 7% as of September 30, 2023 as compared to the estimates as of December 31, 2022, and increased by approximately 10% as of September 30, 2022, as compared to the estimates as of December 31, 2021.

While we believe we have estimated total costs associated with the Terumo Agreement through completion, these estimates encompass a broad range of expenses over a multi-year period and, as such, are subject to periodic changes as new information becomes available.

Product Revenue

Product revenue decreased by $19,000, or approximately 4%, to $480,000 in the nine months ended September 30, 2023 from $499,000 for the nine months ended September 30, 2022.

Product revenue 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 primarily due to a decrease in the

purchase volume of FreeHold Duo and Trio intracorporeal organ retractors. There were no changes to the per unit sale price in either period presented.

Cost of Product Revenue

Cost of product revenue decreased by $19,000, or approximately 12%, to $139,000 in the nine months ended September 30, 2023 from $158,000 for the nine months ended September 30, 2022. The decrease was primarily due to decreased production costs 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, 2023 and 2022 (in thousands):

	Nine Months Ended September 30,	
	2023	2022
Personnel and consulting costs	$ 12,928	$ 6,234
Non-clinical development costs	9,377	6,663
Clinical development costs	3,006	1,505
Total research and development expenses	$ 25,311	$ 14,402

Research and development expenses increased by $10.9 million, or approximately 76%, to $25.3 million for the nine months ended September 30, 2023 from $14.4 million for the nine months ended September 30, 2022. This is primarily due to an increase in support of ongoing work to advance BackBeat CNT and Virtue SAB into planned pivotal studies and included an increase in personnel related expenses of $4.7 million due to increased headcount and associated expenses, along with increased stock-based compensation of $2.0 million, an increase of $2.7 million in non-clinical development costs, and an increase of $1.5 million in research and development program costs, supplies, and testing.

The total research and development expenses summarized above include $11.7 million for the nine months ended September 30, 2023 and $10.6 million for the nine months ended September 30, 2022 related to the Terumo Agreement. The increase of $1.1 million is due to increased expense activity related to the Terumo Agreement during the 2023 period.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $5.4 million, or approximately 50%, to $16.1 million for the nine months ended September 30, 2023, from $10.7 million of expense for the nine months ended September 30, 2022. The increase was primarily due to an increased stock-based compensation of $2.2 million, and an increase of $3.3 million of accounting, finance, legal, investor relations and public relations expenses incurred in connection with the overall growth of the business and in preparation for becoming and being a public company.

Interest Income (Expense), Net

Interest income (expense), net, increased by $3.2 million, or approximately 754%, to $2.7 million of income for the nine months ended September 30, 2023, from $419,000 of expense for the nine months ended September 30, 2022. The net interest income in the 2023 period consisted primarily of interest earned from marketable securities offset by monthly interest expense incurred resulting from the 2022 Loan and Security Agreement. The net interest expense in the 2022 period consisted primarily of interest expense incurred resulting from the December 31, 2020 drawdown of the $10.0 million tranche from the 2019 Loan and Security Agreement.

Loss on Fair Value Adjustment of Warrant Liability

The loss on fair value adjustment of warrant liability was a loss of $294,000 for the nine months ended September 30, 2023, as compared to a loss of $1.1 million for the nine months ended September 30, 2022. The change year over year is primarily a result of the change in the fair value of our outstanding warrants due to an increase in the fair value of the

underlying common stock. There were no additional charges for the adjustment of fair value for warrant liability after the three months ended March 31, 2023 as it had been settled in the first quarter with the close of the Business Combination.

Loss on Debt Extinguishment

The loss on debt extinguishment was $682,000 for the nine months ended September 30, 2022. The loss was due to recognition of unamortized debt discount as well as early termination payments related to the early termination and repayment of the 2019 Loan and Security Agreement in June 2022.

Gain on Fair Value of Strategic Investments

The gain on fair value of strategic investments was $276,000 for the nine months ended September 30, 2023, as compared to a gain of $1.2 million for the nine months ended September 30, 2022. The amounts recognized for the nine months ended September 30, 2023 related to the change in fair value in our common stock holdings of Motus GI due to receiving an additional 701,522 shares in exchange for previously held royalty certificates, which had a de minimis carrying value. The amount recognized for the nine months ended September 30, 2022, relates to a gain on our strategic investment in Vivasure of $1.9 million, partially offset by the change in fair value in our common stock holdings of Motus GI. The gain on our strategic investment in Vivasure was attributable to an observable price change for an identical investment due to a new third-party investment. Therefore, the investment was measured at fair value and a gain was recognized.

Comparison of the Three Months Ended September 30, 2023 and 2022

The following table presents our statement of operations data for the three months ended September 30, 2023 and 2022, and the dollar and percentage change between the two periods (in thousands):

	Three Months Ended September 30,			
	2023	2022	Change $	Change %
Revenue:				
Partnership revenue	$ 271	$ 986	$ (715)	$ (73)%
Product revenue	148	177	(29)	(16)%
Total revenue	419	1,163	(744)	(64)%
Expenses:				
Cost of product revenues	41	56	(15)	(27)%
Research and development	8,558	5,899	2,659	45 %
Selling, general and administrative	6,344	5,275	1,069	20 %
Total expenses	14,943	11,230	3,713	33 %
Loss from operations	(14,524)	(10,067)	(4,457)	(44)%
Other income (expense):				
Interest income, net	915	63	852	1352 %
Gain on fair value adjustment of warrant liability	—	36	(36)	(100)%
Gain (loss) on fair value of strategic investments	293	(314)	607	193 %
Total other income (expense)	1,208	(215)	1,423	662 %
Net loss	$ (13,316)	$ (10,282)	$ (3,034)	$ (30)%

Partnership Revenue

Partnership revenue decreased by $715,000, or approximately 73%, to $271,000 in the three months ended September 30, 2023 from $986,000 for the three months ended September 30, 2022. Partnership revenue relates 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. As of

each quarterly reporting date, we evaluate our estimates of the total costs expected to be incurred through the completion of the combined performance obligation and update our estimates as necessary.

For the three months ended September 30, 2023 and 2022, the expenses incurred related to the Terumo Agreement were approximately $3.4 million and $4.0 million, respectively. The estimated total costs associated with the Terumo Agreement through completion increased by approximately 4% as of September 30, 2023 as compared to the estimates as of June 30, 2023, and increased by less than 1% as of September 30, 2022, as compared to the estimates as of June 30, 2022.

While we believe we have estimated total costs associated with the Terumo Agreement through completion, these estimates encompass a broad range of expenses over a multi-year period and, as such, are subject to periodic changes as new information becomes available.

Product Revenue

Product revenue decreased by $29,000, or approximately 16%, to $148,000 in the three months ended September 30, 2023 from $177,000 for the three months ended September 30, 2022.

Product revenue 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 primarily due to a decrease in the purchase volume of FreeHold Duo and Trio intracorporeal organ retractors. There were no changes to the per unit sale price in either period presented.

Cost of Product Revenue

Cost of product revenue decreased by $15,000, or approximately 27%, to $41,000 in the three months ended September 30, 2023 from $56,000 for the three months ended September 30, 2022. The decrease was primarily due to decreased production costs 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, 2023 and 2022 (in thousands):

	Three Months Ended September 30,	
	2023	2022
Personnel and consulting costs	$ 4,839	$ 2,326
Non-clinical development costs	2,776	2,977
Clinical development costs	943	596
Total research and development expenses	$ 8,558	$ 5,899

Research and development expenses increased by $2.7 million, or approximately 45%, to $8.6 million for the three months ended September 30, 2023, from $5.9 million for the three months ended September 30, 2022. This is primarily due to an increase in support of ongoing work to advance BackBeat CNT and Virtue SAB into planned pivotal studies and included an increase in personnel related expenses of $1.5 million due to increased headcount and associated expenses, along with increased stock-based compensation of $1.1 million.

The total research and development expenses summarized above include $3.4 million for the three months ended September 30, 2023 and $4.0 million for the three months ended September 30, 2022 related to the Terumo Agreement. The decrease of $586,000 is due to decreased expense activity related to the Terumo Agreement during the 2023 period.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $1.1 million, or approximately 20%, to $6.3 million for the three months ended September 30, 2023, from $5.3 million of expense for the three months ended September 30, 2022.

The increase was primarily due to an increase of $1.2 million of accounting, finance, legal, investor relations and public relations expenses incurred in connection with the overall growth of the business and the costs of being a public company.

Interest Income (Expense), Net

Interest income (expense), net, for the three months ended September 30, 2023 was income of $915,000 compared to income of $63,000 for the three months ended September 30, 2022. The increase in net interest income in the 2023 period consisted primarily of increased interest earned from marketable securities offset by monthly interest expense incurred resulting from the 2022 Loan and Security Agreement.

Gain on Fair Value Adjustment of Warrant Liability

The gain on fair value adjustment of warrant liability was $36,000 for the three months ended September 30, 2022. There were no additional charges for the adjustment of fair value for warrant liability in the three months ended September 30, 2023 as it had been settled in the first quarter with the close of the Business Combination.

Gain (Loss) on Fair Value of Strategic Investments

The gain on fair value of strategic investments was $293,000 for the three months ended September 30, 2023, as compared to a loss of $314,000 for the three months ended September 30, 2022. The amounts recognized for the three months ended September 30, 2023 related to the change in fair value in our common stock holdings of Motus GI due to receiving an additional 701,522 shares in exchange for previously held royalty certificates, which had a de minimis carrying value. The loss recognized for the three months ended September 30, 2022 relates to a change in fair value in our common stock holdings of Motus GI.

Liquidity and Capital Resources

From inception through September 30, 2023, we have incurred significant operating losses and negative cash flows from our operations. Our net losses were $36.3 million and $23.9 million for the nine months ended September 30, 2023 and September 30, 2022, respectively. As of September 30, 2023, we had an accumulated deficit of $236.0 million. We have funded our operations primarily through the issuance of convertible preferred stock and proceeds from the Business Combination, as well as through proceeds from the Terumo Agreement, borrowings under debt arrangements and, to a lesser extent, from FreeHold product revenue. We have raised a cumulative $166.8 million in gross proceeds through the issuance of convertible preferred stock, $70.0 million in gross proceeds from the Business Combination, and have received $30.0 million from the Terumo Agreement through September 30, 2023. We had $19.1 million in cash and cash equivalents at September 30, 2023, which consisted primarily of bank deposits and money market funds. We also had $89.4 million of short-term marketable securities at September 30, 2023, which consisted primarily of our investments in corporate and government debt securities.

Funding Requirements

We have reevaluated our planned operating expenses in an effort to 1) prioritize planned spending related to our BackBeat CNT (AVIM therapy) program and the execution of our BACKBEAT pivotal study, for which we announced IDE approval from the FDA on September 19, 2023; and 2) reduce or limit planned spending over the next 12-18 months related to our Virtue SAB program and the execution of our Virtue ISR-US pivotal study, for which we announced conditional IDE approval from the FDA on August 8, 2023. With regard to our Virtue SAB program and our planned Virtue ISR-US pivotal study, we have delayed initiation of this study until such time as we restructure our partnership agreement with Terumo in a manner that provides us with a satisfactory amount of additional capital, whether from milestone payments or other financial arrangements, which additional capital we may not receive. As a result, we currently expect operating expenses related to Virtue SAB to decrease during the next 12-18 months. With regard to our BackBeat CNT program and our planned BACKBEAT pivotal study, we currently expect operating expenses to increase to support clinical study costs as well as additional research and development expenses in support of future potential regulatory approval and commercialization of AVIM therapy-enabled Medtronic pacemakers.

Based on revised internally prepared budget estimates that reflect these updated operating priorities, we anticipate that our cash, cash equivalents, marketable securities, and potential future proceeds described below are sufficient to fund our operations into the second half of 2026. The amount and timing of our future funding requirements may change from this current estimate and is 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, as well as the potential receipt of revenues or other payments or investments under a restructured Terumo Agreement, the Medtronic Agreement and/or future collaborations, and the realization of cash from the sale of some or all of our strategic holdings, most notably, Vivasure Medical. 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 further potential cost cutting associated with our Virtue SAB program, the issuance of new equity, drawdowns on new loan facilities, and/or other financing structures.

Cash Flows

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

	Nine Months Ended September 30,	
	2023	2022
Net cash used in operating activities	$ (35,153)	$ (20,545)
Net cash used in investing activities	(22,464)	(745)
Net cash provided by financing activities	56,911	108,347
Net (decrease) increase in cash and cash equivalents	$ (706)	$ 87,057

Comparison of the Nine Months Ended September 30, 2023 and 2022

Net Cash Flows from Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2023 was $35.2 million and primarily consisted of our net loss of $36.3 million and changes in net operating assets and liabilities of $3.2 million, which was offset by non-cash charges of $4.3 million. Our non-cash charges primarily consisted of a loss on fair value adjustment of warrant liability of $294,000 and stock-based compensation of $6.7 million, offset by $3.2 million related to accretion and interest of marketable securities. The net change in operating assets and liabilities was primarily due to a decrease in accounts payable and accrued expenses of $348,000, an increase in prepaid expenses and other assets of $458,000, and a decrease in deferred revenue of $2.0 million.

Net cash used in operating activities for the nine months ended September 30, 2022, was $20.5 million and primarily consisted of our net loss of $23.9 million, and changes in net operating assets and liabilities of $545,000, which was offset by non-cash charges of $3.9 million. Our non-cash charges primarily consisted of a loss on fair value adjustment of warrant liability of $1.1 million, loss on debt extinguishment of $682,000, stock-based compensation of $2.5 million, amortization of deferred financing costs of $127,000 and non-cash lease expense of $419,000, offset by a $1.2 million gain on the fair value of strategic investments. The net change in operating assets and liabilities were primarily due to a decrease in deferred revenue of $1.9 million and an increase in prepaid expenses and other assets of $475,000, offset by an increase in accounts payable, accrued expenses and other liabilities of $2.3 million.

Net Cash Flows from Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2023 was $22.5 million, which primarily consisted of the purchase of $138.1 million of marketable securities offset by the sale of $115.7 million of marketable securities.

Net cash used in investing activities for the nine months ended September 30, 2022, was $745,000, which consisted of the purchase of $537,000 of property and equipment and the purchase of $208,000 of strategic investments.

Net Cash Flows from Financing Activities

Net cash provided by financing activities of $56.9 million for the nine months ended September 30, 2023 was primarily attributable to net proceeds from the Business Combination. For additional information, see Note 3 to the Consolidated Financial Statements.

Net cash provided by financing activities of $108.3 million for the nine months ended September 30, 2022, was attributable to gross proceeds from the private placement financing totaling $110 million, and proceeds from the 2022 Loan and Security Agreement with Avenue Venture Opportunities Fund I and II of $10 million. These proceeds were offset by $5.2 million of deferred financing costs and principal repayment of $6.4 million, inclusive of debt extinguishment costs, from the termination of the 2019 Loan and Security Agreement with Silicon Valley Bank.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of September 30, 2023 (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease obligations	$ 2,079	$ 840	$ 711	$ 528	$ —
Debt, principal and interest[(1)]	13,443	2,738	10,705	—	—
Total	$ 15,522	$ 3,578	$ 11,416	$ 528	$ —

(1) In June 2022, Legacy Orchestra entered into the 2022 Loan and Security Agreement with Avenue. As part of the 2022 Loan and Security Agreement, Legacy Orchestra paid off the balance of the 2019 Loan and Security Agreement with Silicon Valley Bank. On October 6, 2023, the 2022 Loan and Security Agreement was repaid in full and terminated. Accordingly, as of the date of this Quarterly Report on Form 10-Q, we do not have any debt outstanding. Refer to Note 14, Debt Financing, to our Condensed Consolidated Financial Statements.

In addition, 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, 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.

We believe that the accounting policies described below involve a significant degree of judgment and complexity. Accordingly, we believe these are the most critical to aid in fully understanding and evaluating our financial condition and results of operations. For further information, see Note 2 to the Consolidated Financial Statements.

Revenue Recognition

We recognize revenue under the core principle according to ASC 606 to depict the transfer of control to our customers in an amount reflecting the consideration we expect to be entitled to. In order to achieve that core principle, we apply 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.

Our revenues are currently comprised of product revenue from the sale of FreeHold's intracorporeal organ retractors and partnership revenues under the Terumo Agreement related to the development and commercialization of Virtue SAB.

Product Revenues

Product revenues related 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.

Partnership Revenues

To date, our partnership revenues have related to the Terumo Agreement described below. In future periods, partnership revenues may also include revenues related to the Medtronic Agreement, discussed in Note 5 to the Consolidated Financial Statements.

Legacy Orchestra entered into the Terumo Agreement as further described in Note 4 to the Consolidated Financial Statements. We assessed whether the Terumo Agreement fell within the scope of ASC 808 based on whether the arrangement involved joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. We determined that the Terumo Agreement did not fall within the scope of ASC 808. We then analyzed the arrangement pursuant to the provisions of ASC 606 and determined that the arrangement represents a contract with a customer and is therefore within the scope of ASC 606.

The promised goods or services in the Terumo Agreement include (i) license rights to our intellectual property and (ii) research and development services. We also have optional additional items in the Terumo Agreement, which are considered marketing offers and are accounted for as separate contracts with the customer if such option is elected by the customer, unless the option provides a material right which would not be provided without entering into the contract. Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer. Promised goods or services are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources or (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct in the Terumo Agreement, we considered factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on their own or whether the required expertise is readily available.

We estimate the transaction price for the Terumo Agreement performance obligations based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration includes both fixed consideration and variable consideration. At the inception of the Terumo Agreement, as well as at each reporting period, we evaluate the amount of potential payment and the likelihood that the payments will be received. We utilize either the most likely amount method or expected amount method to estimate the amount expected to be received based on which method better predicts the amount expected to be received. If it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price.

The Terumo Agreement contains development and regulatory milestone payments. At contract inception and at each reporting period, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. At the end of each subsequent

reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect partnership revenues and earnings in the period of adjustment.

The Terumo Agreement also includes sales-based royalties and the license is deemed to be the predominant item to which the royalties relate. Accordingly, we will recognize royalty revenue when the related sales occur. To date, we have not recognized any royalty revenue under the arrangement.

We have determined that intellectual property licensed to Terumo and the research and development services to be provided through the premarket approval by the FDA for the ISR indication represent a combined performance obligation that is satisfied over time, and that the appropriate method of measuring progress for purposes of recognizing revenues relates to a proportional performance model that measures the proportional performance based on the costs incurred to date relative to the total costs expected to be incurred through the completion of the performance obligation. We evaluate the measure of progress at each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

In the nine months ended September 30, 2023, we updated our estimates of the total costs expected to be incurred through the completion of the combined performance obligation. The impact of the changes in estimates resulted in a reduction in partnership revenues of $882,000, which resulted in a $0.03 effect on net loss per share, basic and diluted. In the nine months ended September 30, 2022, the impact of the changes in estimates resulted in reduction of partnership revenues of $956,000, which resulted in a $0.07 effect on net loss per share, basic and diluted.

We receive payments from Terumo based on billing schedules established in the contract. Such billings for milestone related events have 10-day terms from the date the milestone is achieved, royalty payments are 20-day terms after the close of each quarter, any optional services are 20 days after receipt of an invoice and sales of SirolimusEFR are within 30 days after receipt of the shipping invoices. Upfront payments are recorded as deferred revenue upon receipt or when due until we perform our obligations under these arrangements. Amounts are recorded as accounts receivable when the right to consideration is unconditional.

In June 2022, Legacy Orchestra, BackBeat Medical, LLC and Medtronic entered into the Medtronic Agreement for the development and commercialization of BackBeat CNT for the treatment of HTN in patients indicated for a cardiac pacemaker. We determined that the arrangement is a collaboration within the scope of ASC 808. In addition, we concluded Medtronic is a customer for a good or service that is a distinct unit of account, and therefore the transactions in the Medtronic Agreement should be accounted for under ASC 606. Through September 30, 2023, there have been no amounts recognized as revenue under the Medtronic Agreement.

Research and Development Prepayments, Accruals and Related Expenses

We incur costs of research and development activities conducted by our third-party service providers, which include the conduct of preclinical and clinical studies. We are required to estimate our 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 our service providers. We determine 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 us or the services are performed. Accruals are recorded for the amounts of services provided that have not yet been invoiced.

Warrants

We evaluate our warrants to determine if the contracts qualify as liabilities in accordance with ASC 480-10, *Distinguishing Liabilities from Equity,* and ASC 815, *Derivatives and Hedging*. If the warrant is determined to meet the criteria to be liability classified, the warrant liability is marked-to-market each balance sheet date and recorded as a liability,

with the change in fair value recorded in our condensed consolidated statements of operations and comprehensive loss as gain (loss) on fair value adjustment of warrant liability within other income or expense.

In bundled transactions, the proceeds received from any debt instruments and liability classified warrants are allocated to the warrant at fair value first, and the residual value is then allocated to the debt instrument. Upon conversion or exercise of a warrant that is subject to liability treatment, the instrument is marked to fair value at the conversion or exercise date and the fair value is reclassified to equity. Equity classified warrants are recorded within additional paid-in capital at the time of issuance at fair value as of the issuance date and are not subject to subsequent remeasurement.

Stock-Based Compensation

We account for share-based payments at fair value. The fair value of stock options is measured using the Black-Scholes option-pricing model and the fair value of restricted stock is measured based on the fair value of the Company Common Stock underlying the award as of the grant date, described further below. For share-based awards that vest subject to the satisfaction of a service requirement, the fair value measurement date for stock-based compensation awards is the date of grant and the expense is recognized on a straight-line basis, over the vesting period. We account for forfeitures as they occur.

Prior to the Business Combination, due to the absence of an active market for Legacy Orchestra's common stock, Legacy Orchestra utilized methodologies, approaches, and assumptions consistent with the American Institute of Certified Public Accountants' Audit and Accounting Practice Guide: Valuation of Privately-Held Company Equity Securities Issued as Compensation to estimate the fair value of its common stock. The fair value of Legacy Orchestra's common stock was determined based upon a variety of factors, including valuations of Legacy Orchestra's common stock performed with the assistance of independent third-party valuation specialists; Legacy Orchestra's stage of development and business strategy, including the status of research and development efforts of its product candidates, and the material risks related to its business and industry; Legacy Orchestra's business conditions and projections; Legacy Orchestra's results of operations and financial position, including its levels of available capital resources; the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies; the lack of marketability of Legacy Orchestra's common stock as a private company; the prices of Legacy Orchestra's convertible preferred stock sold to investors in arm's length transactions and the rights, preferences and privileges of its convertible preferred stock relative to those of its common stock; the likelihood of achieving a liquidity event for the holders of Legacy Orchestra's common stock, such as an initial public offering or a sale of Legacy Orchestra given prevailing market conditions; trends and developments in its industry; the hiring of key personnel and the experience of management; and external market conditions affecting the life sciences and biotechnology industry sectors. Significant changes to the key assumptions underlying the factors used could result in different fair values of Legacy Orchestra's common stock at each valuation date. In determining the exercise prices for options granted and fair value of restricted stock, we have considered the fair value of the common stock as of the grant date.

Prior to the Business Combination, valuation analyses were conducted utilizing a probability weighted expected return method, in which the probability of a public company scenario was considered via either an initial public offering or special purpose acquisition company transaction. Subsequent to the Business Combination, fair value was determined by market prices of the Company Common Stock.

We classify stock-based compensation expense in our condensed consolidated statements of operations and comprehensive loss in the same manner in which the award recipients' payroll costs are classified or in which the award recipients' service payments are classified.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model, which is based on the 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. Our historical share option exercise information is limited due to a lack of sufficient data points and does 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 SEC'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 expected volatility was derived from the historical stock volatilities of comparable peer public companies within our industry that are considered to be comparable to our business over a period equivalent to the expected term of the stock-based awards, since there was no trading history of Legacy Orchestra's common stock and limited trading history of the Company Common Stock.

- *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 neither the Company nor Legacy Orchestra has paid, and we do not anticipate paying, any dividends on the Company Common Stock in the foreseeable future.

- *Common Stock Valuation* — Prior to the Business Combination, given the absence of a public trading market for Legacy Orchestra's common stock, Legacy Orchestra's board of directors considered numerous subjective and objective factors to determine the best estimate of fair value of Legacy Orchestra's common stock underlying the stock options granted to its employees and non-employees. In determining the grant date fair value of Legacy Orchestra's common stock, Legacy Orchestra's board considered, among other things, contemporaneous valuations of its common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Following the Business Combination, our board of directors determines the fair value of the Company Common Stock based on the closing price of the Company Common Stock on or around the date of grant.

During the three months ended September 30, 2023 and 2022, stock-based compensation was $3.5 million and $2.2 million, respectively. During the nine months ended September 30, 2023 and 2022, stock-based compensation was $6.7 million and $2.4 million, respectively. As of September 30, 2023, we had approximately $21.0 million of total unrecognized stock-based compensation, which we expect to recognize over a weighted-average period of approximately 3 years.

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.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933 (the "Securities Act"), as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). As such, we are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Securities Exchange Act

of 1934, as amended (the "Exchange Act")) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that an emerging growth company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We have elected not to opt out of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our Consolidated Financial Statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used.

We will remain an emerging growth company until the earliest of (1) the last day of the fiscal year following the fifth anniversary of the closing of the initial public offering of HSAC2, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (3) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of the Company Common Stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year, or (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) the market value of our voting and non-voting Company 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 Company Common Stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures.

Upon the closing of the Merger on January 26, 2023, the sole business conducted by us is the business previously conducted by Legacy Orchestra. Also, as a result of the Merger, the internal control over financial reporting utilized by Legacy Orchestra prior to the Business Combination became the internal control over financial reporting of the combined company.

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, 2023, the end of the period covered by this Quarterly Report on Form 10-Q. 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, 2023.

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, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, except that management has added resources to its accounting department and implemented a number of process changes to improve the overall control environment as a result of Legacy Orchestra becoming a public company.

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 error 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.

Our operations and financial results are subject to various risks and uncertainties, including those described under the heading "Item 1A. Risk Factors" in the Q1 10-Q, which could adversely affect our business, financial condition, results of operations, liquidity and the trading price of our common stock. Except as set forth below, there have been no material changes from the risk factors previously disclosed in the Q1 10-Q.

We did not meet the target achievement dates relating to certain milestone payments, and we may not meet other target achievement dates relating to additional milestone payments, under our manufacturing and distribution agreement with Terumo, which may have an adverse effect on our relationship with Terumo and our results of operations

In June 2019, we entered into a strategic partnership with Terumo (the "Terumo Partnership") for the manufacture and distribution of our product Virtue SAB. Under the agreement with Terumo, we were initially eligible for certain milestone payments in the amount of $65 million from Terumo upon completion of certain minimum enrollments in clinical studies, making certain filings and submissions, and obtaining certain regulatory approvals and certifications. Of these milestone payments, $35 million relate to achieving certain milestones by specified target achievement dates, and, as of the date of this Quarterly Report on Form 10-Q, we have already passed the target achievement dates for two $5 million milestone payments, in each case, without achieving the related milestones. In addition, due to delays in our Virtue SAB program resulting from the COVID-19 pandemic, supply chain issues and unexpected regulatory delays and requirements, we are unlikely to be able to complete the remaining time-based milestones by the specified target achievement dates to earn the remaining $25 million in time-based milestone payments pursuant to our agreement with Terumo. Our failure to earn milestone payments under our agreement with Terumo will have an adverse effect on our results of operations.

Further, Terumo has the right to terminate the agreement, or certain of its obligations thereunder, if certain milestones are not achieved. If Terumo elects to terminate the agreement, our development and commercialization plans for Virtue SAB could be adversely impacted, and this could have a material adverse effect on our business, financial condition, results of operations and prospects.

As previously disclosed, the Company and Terumo have been negotiating for mutually agreeable adjustments to its current agreement with the purpose of restructuring milestone payments as well as making other potential material modifications to that agreement including additional financial commitments by Terumo to Orchestra and the Virtue SAB program. we have delayed initiation of our Virtue ISR-US pivotal study, for which we secured conditional IDE approval from the FDA on August 8, 2023, until such time as we restructure our partnership agreement with Terumo in a manner that provides us with a satisfactory amount of additional capital, whether from milestone payments or other financial arrangements. Initiation of the Virtue ISR-US pivotal study is currently targeted for 2024 pending ongoing negotiations with Terumo. If negotiations are not completed to the Company's satisfaction or to the satisfaction of Terumo, clinical study, product development, and commercialization plans for Virtue SAB may continue to be adversely impacted.

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.

On November 9, 2023, Mr. Geoffrey Smith notified the Company of his resignation as a director of the Company, effective immediately. Mr. Smith served as a member of the Audit Committee of the Board of Directors (the "Board") and as a member of the Compensation Committee of the Board. Mr. Smith's resignation was not the result of any disagreement with the Company.

Rule 10b5-1 Trading Arrangements

During the three months ended September 30, 2023, no director or officer (as defined in Rule 16a-1(f) of the Exchange Act) informed us of the adoption or termination a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement", as each term is defined in Item 408(c) 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	Bylaws of Orchestra BioMed Holdings, Inc. (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K filed with the SEC on January 31, 2023).
4.1	Common Stock Warrant, issued by Orchestra BioMed Holdings, Inc. to Avenue Venture Opportunities Fund, L.P., dated October 6, 2023 (incorporated by reference to Exhibit 4.14 to the Company's Form S-1 filed with the SEC on October 10, 2023).
4.2	Common Stock Warrant, issued by Orchestra BioMed Holdings, Inc. to Avenue Venture Opportunities Fund II, L.P., dated October 6, 2023 (incorporated by reference to Exhibit 4.15 to theCompany's Form S-1 filed with the SEC on October 10, 2023).
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.

* 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 13, 2023

/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 13, 2023

/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 13, 2023

/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, 2023 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 13, 2023

/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, 2023 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 13, 2023

/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.