Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2024

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 May 9, 2024, the registrant had 35,788,497 shares of common stock, $0.0001 par value per share, outstanding.

Table of Contents

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 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");
- our ability to fund our operations into the second half of 2026 based on our cash, cash equivalents, marketable securities, and potential future payments or revenues discussed under the heading "Liquidity and Capital Resources—Funding Requirements" in Item 2 (Management's Discussion and Analysis of Financial Condition and Results of Operations) of this Quarterly Report on Form 10-Q;
- 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 I of our Annual Report on Form 10-K for the year ended December 31, 2023 (the "2023 10-K"), 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)

	March 31, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 23,324	$ 30,559
Marketable securities	51,691	56,968
Strategic investments, current portion	23	68
Accounts receivable, net	67	99
Inventory	115	146
Prepaid expenses and other current assets	1,209	1,274
Total current assets	76,429	89,114
Property and equipment, net	1,309	1,279
Right-of-use assets	1,501	1,555
Strategic investments, less current portion	2,495	2,495
Deposits and other assets	894	769
TOTAL ASSETS	$ 82,628	$ 95,212
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 3,354	$ 2,900
Accrued expenses and other liabilities	3,526	5,149
Operating lease liability, current portion	465	649
Deferred revenue, current portion	3,071	2,510
Total current liabilities	10,416	11,208
Deferred revenue, less current portion	13,865	14,923
Operating lease liability, less current portion	1,159	1,038
TOTAL LIABILITIES	25,440	27,169
STOCKHOLDERS' EQUITY		
Preferred stock, $ 0.0001 par value per share; 10,000,000 shares authorized; none issued or outstanding at March 31, 2024 and December 31, 2023.	—	—
Common stock, $ 0.0001 par value per share; 340,000,000 shares authorized; 35,784,997 and 35,777,412 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively.	4	4
Additional paid-in capital	319,509	316,903
Accumulated other comprehensive loss	(8)	(10)
Accumulated deficit	(262,317)	(248,854)
TOTAL STOCKHOLDERS' EQUITY	57,188	68,043
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 82,628	$ 95,212

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 March 31,	
	2024	**2023**
Revenue:		
Partnership revenue	$ 497	$ 1,019
Product revenue	123	145
Total revenue	620	1,164
Expenses:		
Cost of product revenues	34	44
Research and development	9,112	8,254
Selling, general and administrative	5,897	4,411
Total expenses	15,043	12,709
Loss from operations	(14,423)	(11,545)
Other income (expense):		
Interest income, net	1,016	885
Loss on fair value adjustment of warrant liability	—	(294)
(Loss) gain on fair value of strategic investments	(45)	14
Other expense	(11)	—
Total other income	960	605
Net loss	$ (13,463)	$ (10,940)
Net loss per share		
Basic and diluted	$ (0.38)	$ (0.40)
Weighted-average shares used in computing net loss per share, basic and diluted	35,777,877	27,643,549
Comprehensive loss		
Net loss	$ (13,463)	$ (10,940)
Unrealized gain (loss) on marketable securities	2	(27)
Comprehensive loss	$ (13,461)	$ (10,967)

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, 2024	—	$ —	35,777,412	$ 4	$ 316,903	$ (10)	$ (248,854)	$ 68,043
Unrealized gain on marketable securities	—	—	—	—	—	2	—	2
Stock-based compensation	—	—	—	—	2,588	—	—	2,588
Exercise of stock options	—	—	7,585	—	18	—	—	18
Net loss	—	—	—	—	—	—	(13,463)	(13,463)
Balance, March 31, 2024	—	$ —	35,784,997	$ 4	$ 319,509	$ (8)	$ (262,317)	$ 57,188

	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	165,922	—	—	165,924
Balance, January 1, 2023 effect of Merger	—	—	20,187,850	2	252,275	(8)	(199,734)	52,535
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	$ 310,459	$ (35)	$ (210,674)	$ 99,753

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)

	Three Months Ended March 31,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (13,463)	$ (10,940)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	74	71
Stock-based compensation	2,588	1,489
Loss on fair value adjustment of warrant liability	—	294
Loss (gain) on fair value of strategic investments	45	(14)
Accretion and interest related to marketable securities	(589)	(1,056)
Non-cash lease expense	54	155
Amortization of deferred financing fees	—	36
Other	11	—
Changes in operating assets and liabilities:		
Accounts receivable	32	20
Inventory	31	44
Prepaid expenses and other assets	(60)	(1,497)
Accounts payable, accrued expenses and other liabilities	(1,277)	(1,795)
Operating lease liabilities – current and non-current	(63)	(169)
Deferred revenue	(497)	(1,019)
Net cash used in operating activities	(13,114)	(14,381)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(8)	(35)
Sales of marketable securities	29,605	—
Purchases of marketable securities	(23,736)	(43,494)
Net cash provided by (used in) investing activities	5,861	(43,529)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of warrants	—	1
Proceeds from exercise of stock options	18	10
Effect of merger, net of transaction costs (Note 3)	—	56,810
Net cash provided by financing activities	18	56,821
Net decrease in cash and cash equivalents	(7,235)	(1,089)
Cash and cash equivalents, beginning of the period	30,559	19,784
Cash and cash equivalents, end of the period	$ 23,324	$ 18,695
Supplemental Disclosures of Cash Flow Information		
Cash paid during the three months ended March 31:		
Interest	$ —	$ 351
Non-cash investing activities:		
Increase in accounts payable, accrued expenses and other liabilities related to fixed assets	$ 107	$ —

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"), also known as Atrioventricular Interval Modulation Therapy ("AVIM therapy"), 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 AVIM therapy that same year. AVIM therapy 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, 2023 has been derived from the audited financial statements at that date. Operating results and cash flows for the three months ended March 31, 2024 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2024 or any other future period. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") have been omitted in accordance with the rules and regulations for interim reporting of the SEC. These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements included in our report for the year ended December 31, 2023 together with the related notes thereto, included in the Company's Annual Report on Form 10-K filed with the SEC on March 27, 2024.

The Company has a limited operating history and the sales and income potential of its businesses and markets are unproven. As of March 31, 2024, the Company had an accumulated deficit of $ 262.3 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 March 31, 2024, 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 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 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 March 31, 2024 and December 31, 2023, 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. 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 March 31, 2024 and December 31, 2023, an allowance for doubtful accounts was no t 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 March 31, 2024 and December 31, 2023, an impairment charge as a result of obsolete inventory was no t 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. 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 no t 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 to support 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), 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 March 31, 2024 and December 31, 2023, the Company recorded a full valuation allowance on its deferred tax assets.

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

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, 2023, there were no deferred transaction costs because upon the close of the Business Combination, they 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 months ended March 31, 2024, the Company made $ 87,000 in contributions under this safe harbor 401(k) Plan. During the three months ended March 31, 2023, the Company made $ 113,000 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 December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* (ASU 2023-09), which requires additional income tax disclosures in the annual consolidated financial statements. The amendments in ASU 2023-09 are intended to enhance the transparency and decision usefulness of income tax disclosures. For public entities, ASU 2023-09 is effective for annual periods beginning after December 15, 2024, with early adoption permitted. As an emerging growth company that has not opted out of the extended transition period for complying with new or revised financial accounting standards, the amendments in ASU 2023-09 are effective for the Company for fiscal years beginning after December 15, 2025, with early adoption permitted.

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, in each case, subject to the holder's continued employment or service with the Company or one of its subsidiaries through such date. As of the issuance date of these financial statements, 90,000 Officer and Director Warrants have been forfeited as a result of the departures of an executive officer and a director of the Company. 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 statements of 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. 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 three $ 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 $ 20 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 the Terumo 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 and Terumo restructure the Terumo Agreement in a manner that provides the Company with a satisfactory amount of additional capital, whether from milestone payments or other financial arrangements. In addition, in light of the recent FDA approval of Boston Scientific Corporation's AGENT™ paclitaxel-coated balloon for the treatment of coronary ISR, we and Terumo are reviewing the design for the Virtue ISR-US pivotal study and considering alternative clinical study designs with input from our clinical steering committee for Virtue SAB. 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 to support 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 March 31, 2024 and December 31, 2023, 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 three months ended March 31, 2024 and 2023:

Deferred Revenue – December 31, 2023 (in thousands)	$	17,433
Revenue recognized		(497)
Deferred Revenue – March 31, 2024	$	16,936
Deferred Revenue – December 31, 2022	$	19,539
Revenue recognized		(1,019)
Deferred Revenue – March 31, 2023	$	18,520

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 March 31, 2024. The Company expects to recognize approximately $ 3.1 million of its deferred revenue during the next twelve months and recognize the remaining approximately $ 13.9 million through the remainder of the performance period, which is currently estimated to be completed in 2029 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 March 31, 2024 and 2023, the expenses incurred related to the Terumo Agreement were approximately $ 2.9 million and $ 3.8 million, respectively. The estimated total costs associated with the Terumo Agreement through completion increased by approximately 1.2 % as of March 31, 2024, as compared to the estimates as of December 31, 2023, and decreased by approximately 0.7 % as of March 31, 2023, as compared to the estimates as of December 31, 2022. 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 $ 153,000 for the three months ended March 31, 2024 and an increase of partnership revenue of $ 81,000 for the three months ended March 31, 2023, 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 March 31, 2024 and 2023 was de minimis.

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 March 31, 2024, 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 AVIM therapy for the treatment of 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 AVIM therapy 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 AVIM therapy 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 AVIM therapy-enabled pacing systems globally following receipt of regulatory approval. Medtronic would be entirely responsible for global commercialization following receipt of regulatory approvals, including manufacturing, sales, marketing and distribution costs.

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

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

The Company assessed whether the 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 months ended March 31, 2024 and 2023, the Company incurred approximately $ 1.2 million and $ 1.3 million, respectively, of research and development costs related to these reimbursements pursuant to the Medtronic Agreement, of which $ 1.9 million is included within accounts payable and accrued expenses in the Company's March 31, 2024 condensed consolidated balance sheet.

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 March 31, 2024, 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:

	March 31, 2024			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets				
Money market fund (included in cash and cash equivalents)	$ 5,996	$ —	$ —	$ 5,996
Investment in Motus GI (see Note 7)	23	—	—	23
Marketable securities (Corporate and Government debt securities)	—	51,691	—	51,691
Total assets	$ 6,019	$ 51,691	$ —	$ 57,710

	December 31, 2023			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets				
Money market fund (included in cash and cash equivalents)	$ 27,592	$ —	$ —	$ 27,592
Investment in Motus GI (see Note 7)	68	—	—	68
Marketable securities (Corporate and Government debt securities)	—	56,968	—	56,968
Total assets	$ 27,660	$ 56,968	$ —	$ 84,628

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	**$ —**

7. Marketable Securities and Strategic Investments

Marketable Securities

The following is a summary of the Company's marketable securities as of March 31, 2024 and December 31, 2023:

	March 31, 2024			
(in thousands)	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Corporate debt securities	$ 26,511	$ 10	$ (13)	$ 26,508
Government debt securities	25,187	—	(4)	25,183
Total	**$ 51,698**	**$ 10**	**$ (17)**	**$ 51,691**

	December 31, 2023			
(in thousands)	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Corporate debt securities	$ 8,655	$ —	$ (8)	$ 8,647
Government debt securities	48,323	7	(9)	48,321
Total	**$ 56,978**	**$ 7**	**$ (17)**	**$ 56,968**

The Company believes it is more likely than not that its marketable securities in an unrealized loss position will be held until maturity or the recovery of the cost basis of the investment. To date, the Company has not recorded any allowance for credit losses on its investment securities. The Company determined that the unrealized losses were not attributed to credit risk but were primarily driven by the broader change in interest rates. As of March 31, 2024, $ 17.4 million of the Company's marketable securities had maturities of 12 to 36 months while the remaining marketable securities had maturities of less than 12 months.

For the three months ended March 31, 2024 and 2023, the Company did no t 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 losses of $ 45,000 and gains of $ 14,000 during the three months ended March 31, 2024 and 2023, respectively, were recorded to adjust the strategic investments in equity securities of Motus GI to its fair value of $ 23,000 at March 31, 2024 and $ 68,000 at December 31, 2023, 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 March 31, 2024 represent investments made in Vivasure in 2020, 2021 and 2022 that were originally recorded at cost. There were no observable price changes or impairments identified during the three months ended March 31, 2024 or three months ended March 31, 2023 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)	March 31, 2024	December 31, 2023
Equipment	$ 1,778	$ 1,777
Office furniture	437	343
Leasehold improvements	164	203
Property and equipment, gross	2,379	2,323
Less accumulated depreciation and amortization	(1,070)	(1,044)
Total Property and equipment, net	**$ 1,309**	**$ 1,279**

Depreciation and amortization expense was $ 74,000 and $ 71,000 for the three months ended March 31, 2024 and 2023, respectively.

Accrued Expenses

Accrued expenses consist of the following:

(in thousands)	March 31, 2024	December 31, 2023
Accrued compensation	$ 994	$ 2,661
Clinical trial accruals	1,532	1,409
Other accrued expenses	1,000	1,079
Total accrued expenses	**$ 3,526**	**$ 5,149**

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 March 31, 2024, 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, in each case, subject to the holder's continued employment or service with the Company or one of its subsidiaries through such date. As of the issuance date of these financial statements, 90,000 Officer and Director Warrants have been forfeited as a result of the departures of an executive officer and a director of the Company.

Avenue Warrants

On October 6, 2023, the Company issued equity-classified warrants (the "Avenue 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 to Avenue Venture Opportunities Fund, L.P. ("Avenue I") and Avenue Venture Opportunities Fund II, L.P. ("Avenue II," and, collectively with Avenue I, "Avenue"). The warrants were issued to settle certain fees related to the termination and repayment of the loan and security agreement with Avenue (the "2022 Loan and Security Agreement"). As of October 6, 2023, the Company valued the Avenue Warrants using the Black-Scholes option-pricing model and determined the fair value at $ 66,000 . The key inputs to the valuation model included the annualized volatility of 42.0 % and a risk-free rate of 4.98 %.

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
Expected volatility	44 – 49 %
Risk-free interest rate	3.60 – 4.80 %
Remaining term in years	0.35 – 5.00
Exercise price of common warrants	$ 1.08 – $ 30.11
Common stock price	$ 10.63
Expected dividend yield	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)	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 December 31, 2023	—	$ —

Private Warrants, Avenue Warrants and Assumed Legacy Orchestra Warrants

The following table summarizes outstanding warrants to purchase shares of Company Common Stock as of March 31, 2024 and December 31, 2023:

	Number of Shares			
	March 31, 2024	December 31, 2023	Exercise Price	Term
Equity-classified Warrants				
Legacy Orchestra Warrants	507,841	507,841	$ 1.08 – $ 30.11	0.10 – 8.75
Avenue Warrants (Note 14)	27,707	27,707	$ 7.67	2.50
Private Warrants Held by Sponsor	750,000	750,000	$ 11.50	4.32 – 4.57
Private Warrants Held by Employees (Note 11)	660,000	660,000	$ 11.50	4.32
Total Outstanding	1,945,548	1,945,548		

11. Stock-Based Compensation

As of March 31, 2024, 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 March 31, 2024, approximately 2,890,000 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 March 31,	
(in thousands)	**2024**	**2023**
Research and development	$ 509	$ 485
Selling, general and administrative	481	738
Total stock-based compensation	$ 990	$ 1,223

As of March 31, 2024, there was approximately $ 5.7 million of unrecognized stock-based compensation expense associated with the stock options noted above that is expected to be recognized over a weighted average period of approximately 2.0 years.

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

(in thousands)	Three Months Ended March 31, 2024	2023
Research and development	$ 347	$ —
Selling, general and administrative	987	50
Total stock-based compensation	$ 1,334	$ 50

As of March 31, 2024, there was approximately $ 9.0 million of unrecognized restricted stock-based compensation expense associated with the restricted stock noted above that is expected to be recognized over a weighted average period of approximately 2.0 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 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 year ended December 31, 2023, 90,000 of Officer and Director Warrants were forfeited resulting in 660,000 Officer and Director Warrants remaining outstanding at December 31, 2023. There were no forfeitures of Officer and Director Warrants during the three months ended March 31, 2024.

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

(in thousands)	Three Months Ended March 31, 2024	2023
Research and development	$ 120	$ 86
Selling, general and administrative	144	130
Total stock-based compensation	$ 264	$ 216

As of March 31, 2024, there was approximately $ 1.9 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 1.8 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, 2024	4,438,868	$ 7.72	7.70	$ 8,186
Granted	61,258	6.06	—	—
Exercised	(7,585)	4.39	—	—
Forfeited/canceled	(2,789)	10.00	—	—
Outstanding March 31, 2024	4,489,752	$ 7.70	7.33	$ 1,375
Exercisable at March 31, 2024	2,910,607	$ 7.31	6.50	$ 1,265

The weighted average grant-date fair value of stock options granted during the three months ended March 31, 2024 and 2023 was $ 3.97 and $ 4.99 per share, respectively.

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

	Restricted Stock Awards/Units Outstanding	Weighted Average Grant Date Fair Value
Outstanding January 1, 2024	1,701,208	$ 7.39
Granted	10,000	5.00
Vested	(13,100)	12.65
Forfeited/canceled	—	—
Outstanding March 31, 2024	1,698,108	$ 7.39

No performance-based stock awards were granted in the three months ended March 31, 2024.

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:

	Three Months Ended March 31,	
	2024	2023
Expected term (in years)	5.89	6.00
Expected volatility	71 %	50 %
Risk-free interest rate	4.17 %	3.60 %
Expected dividend yield	0 %	0 %
Fair value of common stock	$ 6.06	$ 9.63

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

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

Expected Volatility — The Company consummated the Business Combination on January 26, 2023 and lacks sufficient company-specific historical and implied volatility information. Therefore, it derives expected stock volatility using a weighted average blend of historical volatility of comparable peer public companies and its own historical volatility, over a period equivalent to the expected term of the stock-based awards.

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. In November 2022, the Company entered into an amendment for this lease which increased the office space square footage to approximately 7,800 and amended the expiration to April 2028. Monthly fees will be between $ 28,000 and $ 40,000 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 three months ended March 31, 2024:

Cash paid for amounts included in the present value of operating lease liabilities was $ 228,000 during the three months ended March 31, 2024 compared to $ 205,000 during the three months ended March 31, 2023.

As of March 31, 2024:	
Weighted average remaining lease term – operating leases, in years	3.54
Weighted average discount rate – operating leases	9.21 %

Operating Leases

Rent/lease expense for office and lab space was approximately $ 219,000 and $ 209,000 , respectively, for the three months ended March 31, 2024 and 2023. The table below shows the future minimum rental payments, exclusive of taxes, insurance, and other costs, under the leases as of March 31, 2024:

Year ending December 31:	**Operating Leases (in thousands)**
2024 (remaining nine months)	$ 509
2025	339
2026	464
2027	476
2028	159
Thereafter	—
Total future minimum lease payments	$ 1,947
Imputed interest	(323)
Total liability	$ 1,624

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 December 31, 2023 and the three months ended March 31, 2024:

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 resulting in a gain of $ 349,000 (Note 7).

14. Debt Financing

In June 2022, Legacy Orchestra entered into the 2022 Loan and Security Agreement. 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 was available at closing of the Legacy Orchestra Series D-2 Preferred Stock financing which was not drawn. Additionally, the Company may have had access to a third tranche of $ 30 million subject to certain financing milestones. The term loan was scheduled to mature on June 1, 2026. In addition, the lender had 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 could 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 the Avenue 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 was 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 were being amortized to interest expense over the term of the facility.

The term loan accrued interest at a floating per annum rate equal to the Wall Street Journal prime rate plus 6.45 %. The repayment terms of the loan included 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 was a final payment equal to 4.25 % of the initial commitment amount of $ 20 million, which was 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 2019 Loan and Security Agreement 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 March 31, 2023 was approximately $ 351,000 while there was no interest expense for the three months ended March 31, 2024.

On October 6, 2023, the Company terminated and repaid the 2022 Loan and Security Agreement in an aggregate amount of $ 10.9 million (the “Payoff Amount”), which resulted in a loss on extinguishment of approximately $ 1.2 million. The Payoff Amount includes $ 10 million of principal and approximately $ 849,000 of net interest, prepayment fees, and legal fees. The Company issued warrants to purchase 27,707 shares of Company Common Stock at an exercise price of $ 7.67 in lieu of a cash payment of approximately $ 212,500 of the Payoff Amount. The Company valued the Avenue Warrants using the Black-Scholes option-pricing model and determined the fair value at $ 66,000 .

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 months ended March 31, 2024 and March 31, 2023, as their effect is anti-dilutive:

	Three Months Ended March 31,	
	2024	2023
Stock options	4,489,752	3,944,635
Company common stock warrants	1,945,548	2,925,936
Unvested restricted stock awards	1,698,108	118,511
Conversion option	—	416,667
Forfeitable shares	500,000	1,000,000
Earnout consideration	4,000,000	8,000,000
Total	12,633,408	16,405,749

16. Subsequent Events

None.

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

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

The following discussion should be read together with "Special Note Regarding Forward-Looking Statements" and the Company's unaudited condensed consolidated financial statements, together with the related notes thereto, included elsewhere in this Quarterly Report on Form 10-Q (the "Consolidated Financial Statements"), and the Company's audited consolidated financial statements, together with the related notes thereto, included in the Company's Annual Report on Form 10-K filed with the SEC on March 27, 2024.

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"), also known as Atrioventricular Interval Modulation Therapy ("AVIM therapy"), 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 AVIM therapy 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 our distribution agreement with Terumo (the "Terumo Agreement"), 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 March 31, 2024. We have incurred net losses each year since inception. Our net losses were $13.5 million and $10.9 million for the three months ended March 31, 2024 and 2023, respectively. We expect to continue to incur significant losses for the foreseeable future. As of March 31, 2024, we had an accumulated deficit of $262.3 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 April 30, 2023, we announced that our AVIM therapy global intellectual property estate reached 110 issued patents. The patent estate covering atrioventricular interval modulation AVIM therapy includes 37 issued U.S. patents and 73 patents outside the U.S. that collectively comprise over 1,800 claims related to the treatment of hypertension. We own additional issued patents related to Cardiac Neuromodulation Therapy™ ("CNT") for other clinical indications and expect further patents to be granted related to AVIM therapy and CNT in the future.

Registration Statement

Due to the significant number of redemptions of HSAC2's ordinary shares in connection with the Business Combination, there was a significantly lower number of HSAC2 ordinary shares that converted into shares of Company Common Stock in connection with the Business Combination. Pursuant to the Amended and Restated Registration Rights Agreement we entered into in connection with the closing of the Business Combination and certain warrant agreements, the Company has filed a registration statement (the "Registration Statement") that registers, among other things, the resale of an aggregate of 18,586,201 shares of Company Common Stock, which constitutes approximately 52% of the outstanding Company Common Stock as of May 1, 2024. Additionally, some of the shares of the Company Common Stock being registered for resale were originally purchased by selling stockholders pursuant to investments in Legacy Orchestra or HSAC2 at prices considerably below the current market price of the Company Common Stock. These selling stockholders may realize a positive rate of return on the sale of their shares of Company Common Stock covered by the Registration Statement and therefore will have an incentive to sell their shares. Public shareholders may not experience a similar rate of return on shares of Company Common Stock they purchased. This discrepancy in purchase prices may have an impact on the market perception of the Company Common Stock's value and could increase the volatility of the market price of the Company Common Stock or result in a significant decline in the public trading price of the Company Common Stock. The registration of these shares of Company Common Stock for resale creates the possibility of a significant increase in the supply of the Company Common Stock in the market. The increased supply, coupled with the potential disparity in purchase prices, may lead to heightened selling pressure, which could negatively affect the public trading price of our Common Stock.

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 three $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 $20 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, we have been negotiating with Terumo for mutually agreeable adjustments to the Terumo 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 and Terumo restructure the Terumo Agreement in a manner that provides us with a satisfactory amount of additional capital, whether from milestone payments or other financial arrangements. In addition, in light of the recent FDA approval of Boston Scientific Corporation's AGENT™ paclitaxel-coated balloon for the treatment of coronary ISR, we and Terumo are reviewing the design of the Virtue ISR-US pivotal study and considering alternative clinical study designs with input from our clinical steering committee for Virtue SAB. If negotiations are not completed to our 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 $13.1 million in cumulative partnership revenues from 2019 through March 31, 2024. There were no other proceeds received pursuant to the Terumo Agreement from 2019 through March 31, 2024.

In June 2022, Legacy Orchestra entered into the Medtronic Agreement for the development and commercialization of AVIM therapy 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 March 31, 2024, 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%. On October 6, 2023, the 2022 Loan and Security Agreement was repaid in full and terminated. Refer to Note 14 to our 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 $10.0 million under the 2019 Loan and Security Agreement which was repaid in connection with entering into the 2022 Loan and Security Agreement.

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 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.”

Loss on Debt Extinguishment

The loss on debt extinguishment represents charges incurred as a result of the payoff of each of the 2019 Loan and Security Agreement and the 2022 Loan and Security Agreement.

(Loss) Gain on Fair Value of Strategic Investments

The (loss) gain 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 royalty certificates previously issued to the Company and other holders 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 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 Three Months Ended March 31, 2024 and 2023

The following table presents our statement of operations data for the three months ended March 31, 2024 and 2023, and the dollar and percentage change between the two periods (in thousands):

	Three Months Ended March 31,			
	2024	2023	Change $	Change %
Revenue:				
Partnership revenue	$ 497	$ 1,019	$ (522)	(51)%
Product revenue	123	145	(22)	(15)%
Total revenue	620	1,164	(544)	(47)%
Expenses:				
Cost of product revenues	34	44	(10)	(23)%
Research and development	9,112	8,254	858	10 %
Selling, general and administrative	5,897	4,411	1,486	34 %
Total expenses	15,043	12,709	2,334	18 %
Loss from operations	(14,423)	(11,545)	(2,878)	(25)%
Other income (expense):				
Interest income, net	1,016	885	131	15 %
Loss on fair value adjustment of warrant liability	—	(294)	294	100 %
(Loss) gain on fair value of strategic investments	(45)	14	(59)	(421)%
Other expense	(11)	—	(11)	NM *
Total other income	960	605	355	59 %
Net loss	$ (13,463)	$ (10,940)	$ (2,523)	(23)%

Partnership Revenue

Partnership revenue decreased by $522,000, or approximately 51%, to $497,000 in the three months ended March 31, 2024 from $1.0 million for the three months ended March 31, 2023. 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 March 31, 2024 and 2023, the expenses incurred related to the Terumo Agreement were approximately $2.9 million and $3.8 million, respectively. The estimated total costs associated with the Terumo Agreement through completion increased by approximately 1.2% as of March 31, 2024 as compared to the estimates as of December 31, 2023, and decreased by approximately 0.7% as of March 31, 2023, as compared to the estimates as of December 31, 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 $22,000, or approximately 15%, to $123,000 in the three months ended March 31, 2024 from $145,000 for the three months ended March 31, 2023.

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 $10,000, or approximately 23%, to $34,000 in the three months ended March 31, 2024 from $44,000 for the three months ended March 31, 2023. The decrease was primarily due to decreased sales 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 March 31, 2024 and 2023 (in thousands):

	Three Months Ended March 31,	
	2024	2023
Personnel and consulting costs	$ 4,706	$ 4,220
Non-clinical development costs	1,971	2,730
Clinical development costs	2,435	1,304
Total research and development expenses	$ 9,112	$ 8,254

Research and development expenses increased by $858,000, or approximately 10%, to $9.1 million for the three months ended March 31, 2024 from $8.3 million for the three months ended March 31, 2023. This is primarily due to an increase in support of ongoing work to advance the BACKBEAT pivotal study and to advance Virtue SAB into a planned pivotal study and included an increase in personnel related expenses of $82,000 due to increased headcount and associated expenses, along with increased stock-based compensation of $405,000, a decrease of $760,000 in non-clinical development costs, and an increase of $1.1 million in research and development program costs, supplies, and testing.

The total research and development expenses summarized above include $2.8 million for the three months ended March 31, 2024 and $3.8 million for the three months ended March 31, 2023 related to the Terumo Agreement. The decrease of $1.0 million is due to decreased expense activity related to the Terumo Agreement during the 2024 period.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $1.5 million, or approximately 34%, to $5.9 million for the three months ended March 31, 2024, from $4.4 million of expense for the three months ended March 31, 2023. The increase primarily resulted from an increase in stock-based compensation of $694,000 and an increase of $536,000 of accounting, finance, legal, investor relations and public relations expenses incurred in connection with the overall growth of the business and being a public company.

Interest Income, Net

Interest income, net, increased by $131,000 to $1.0 million of income for the three months ended March 31, 2024, from $885,000 of income for the three months ended March 31, 2023. The net interest income in the 2024 period consisted primarily of interest earned from marketable securities while 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.

Loss on Fair Value Adjustment of Warrant Liability

The loss on fair value adjustment of warrant liability was $294,000 for the three months ended March 31, 2023 and was the result of the final valuation of our outstanding warrants when they had become equity classified and no longer subject to market adjustment upon the close of the Business Combination. There were no additional charges for the adjustment of fair value for warrant liability after the three months ended March 31, 2023.

(Loss) Gain on Fair Value of Strategic Investments

The (loss) gain on fair value of strategic investments was a loss of $45,000 for the three months ended March 31, 2024, as compared to a gain of $14,000 for the three months ended March 31, 2023. The amounts recognized for the three months ended March 31, 2024 and 2023 related to the change in fair value in our common stock holdings of Motus GI.

Liquidity and Capital Resources

From inception through March 31, 2024, we have incurred significant operating losses and negative cash flows from our operations. Our net losses were $13.5 million and $10.9 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, we had an accumulated deficit of $262.3 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 under the Terumo Agreement through March 31, 2024. We had $23.3 million in cash and cash equivalents at March 31, 2024, which consisted primarily of bank deposits and money market funds. We also had $51.7 million of short-term marketable securities at March 31, 2024, which consisted primarily of our investments in corporate and government debt securities.

In addition, the exercise price of our warrants, in certain circumstances, may be higher than the prevailing market price of the Company Common Stock and the cash proceeds to us associated with the exercise of our warrants are contingent upon the price of the Company Common Stock. The value of the Company Common Stock may fluctuate and may not exceed the exercise price of the warrants at any given time. As of the date of this Quarterly Report on Form 10-Q, a significant portion of our warrants are “out of the money,” meaning the exercise price is higher than the market price of the Company Common Stock. Holders of such “out of the money” warrants are not likely to exercise such warrants. As a result, we may not receive any proceeds from the exercise of such warrants. There can be no assurance that such warrants will be in the money prior to their respective expiration dates, and therefore, we may not receive any cash proceeds from the exercise of such warrants to fund our operations.

As a result, we have neither included nor intend to include any potential cash proceeds from the exercise of our warrants in our short-term or long-term liquidity projections. We will continue to evaluate the probability of warrant exercise over the life of our warrants and the merit of including potential cash proceeds from the exercise in our liquidity projections. We do not expect to rely on the exercise of our warrants to fund our operations.

Funding Requirements

We continue to prioritize planned spending on our BackBeat CNT (AVIM therapy) program and the execution of our BACKBEAT pivotal study, for which we announced the commencement of enrollment on January 8, 2024. As previously disclosed, we have also reduced our 2024 planned spending 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 (1) consider the clinical study design implications of the recent FDA approval of BSC’s AGENT paclitaxel DCB for the treatment of coronary ISR; and (2) restructure our partnership agreement with Terumo in a manner that provides us with a satisfactory amount of additional capital, whether from equity investment, milestone payments or other financial arrangements, which additional capital we may not receive. With regard to our AVIM therapy 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 are dependent on many factors, including the cost and pace of execution of clinical studies and research and development activities, the strength of results from clinical studies and other research, development and

manufacturing efforts, 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.

As noted above, the sale of Company Common Stock pursuant to the Registration Statement may result in a decline in the value of our common stock, which may make it more difficult and more dilutive to the existing holders of our common stock to raise funds from the sale of our equity securities.

Cash Flows

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

	Three Months Ended March 31,	
	2024	2023
Net cash used in operating activities	$ (13,114)	$ (14,381)
Net cash provided by (used in) investing activities	5,861	(43,529)
Net cash provided by financing activities	18	56,821
Net decrease in cash and cash equivalents	$ (7,235)	$ (1,089)

Comparison of the Three Months Ended March 31, 2024 and 2023

Net Cash Flows from Operating Activities

Net cash used in operating activities for the three months ended March 31, 2024 was $13.1 million and primarily consisted of our net loss of $13.5 million and changes in net operating assets and liabilities of $1.8 million, which was offset by non-cash charges of $2.2 million. Our non-cash charges primarily consisted of stock-based compensation of $2.6 million, offset by $589,000 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 $1.3 million, an increase in prepaid expenses and other assets of $60,000, and a decrease in deferred revenue of $497,000.

Net cash used in operating activities for the three months ended March 31, 2023, was $14.4 million and primarily consisted of our net loss of $10.9 million, and changes in net operating assets and liabilities of $4.4 million, which was offset by non-cash charges of $975,000. Our non-cash charges primarily consisted of a loss on fair value adjustment of warrant liability of $294,000 and stock-based compensation of $1.5 million, offset by $1.0 million related to accretion and interest of marketable securities. The net change in operating assets and liabilities were primarily due to a decrease in accounts payable and accrued expenses of $1.8 million, an increase in prepaid expenses and other assets of $1.5 million, and a decrease in deferred revenue of $1.0 million and various other immaterial changes.

Net Cash Flows from Investing Activities

Net cash provided by investing activities for the three months ended March 31, 2024 was $5.9 million, which primarily consisted of marketable securities purchases of $23.7 million offset by the maturities of marketable securities of $29.6 million.

Net cash used in investing activities for the three months ended March 31, 2023 was $43.5 million, which consisted of the purchase of $43.5 million of marketable securities, and $35,000 of property and equipment.

Net Cash Flows from Financing Activities

Net cash provided by financing activities of $18,000 for the three months ended March 31, 2024 was primarily attributable to exercises of stock options.

Net cash provided by financing activities of $56.8 million for the three months ended March 31, 2023 was attributable to net proceeds from the Business Combination. For additional information, see Note 3 to the Consolidated Financial Statements.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations and commitments as of March 31, 2024 (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease obligations	$ 1,947	$ 594	$ 838	$ 515	$ —
Total	$ 1,947	$ 594	$ 838	$ 515	$ —

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 pursuant to the Terumo Agreement. 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 to support the premarket approval by the FDA for the ISR indication represent a combined performance obligation that is satisfied over time, which is currently estimated to be completed in 2029, 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 three months ended March 31, 2024, 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 $153,000, which resulted in an immaterial effect on net loss per share, basic and diluted. In the three months ended March 31, 2023, the impact of the changes in estimates resulted in an increase of partnership revenues of $81,000, which resulted an immaterial 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 AVIM therapy 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 March 31, 2024, 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 fees 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* — We consummated the Business Combination on January 26, 2023 and lack sufficient company-specific historical and implied volatility information. Therefore, we derived expected stock volatility using a weighted average blend of historical volatility of comparable peer public companies and our own historical volatility, over a period equivalent to the expected term of the stock-based awards.

- *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 March 31, 2024 and 2023, stock-based compensation was $2.6 million and $1.5 million, respectively. As of March 31, 2024, we had approximately $16.6 million of total unrecognized stock-based compensation, which we expect to recognize over a weighted-average period of approximately 2.0 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 March 31, 2024, 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 March 31, 2024.

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 March 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitation on the Effectiveness of Internal Control.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures, or our internal controls, will prevent all 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 2023 10-K, which could adversely affect our business, financial condition, results of operations, liquidity and the trading price of our common stock. There have been no material changes from the risk factors previously disclosed in the 2023 10-K.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Rule 10b5-1 Trading Arrangements

During the three months ended March 31, 2024, 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).
10.1+#	First Amendment of Lease dated as of November 22, 2022, by and between ESRT One Grand Central Place, L.L.C., and Orchestra BioMed, Inc.
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.

\# Certain of the exhibits and schedules to this exhibit have been omitted in accordance with Regulation S-K Item 601. The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.

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: May 13, 2024

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

Exhibit 10.1

FIRST AMENDMENT OF LEASE

THIS FIRST AMENDMENT OF LEASE, made as of the 22 day of November, 2022 (this " Amendment"), by and between ESRT ONE GRAND CENTRAL PLACE, L.L.C., a Delaware limited liability company, having an office c/o ESRT Management, L.L.C., 111 West 33rd Street, New York, New York 10120 (" Landlord"), and ORCHESTRA BIOMED, INC., a Delaware corporation, having an office at One Grand Central Place, 60 East 42nd Street, New York, New York 10165 (" Tenant").

W I T N E S S E T H :

WHEREAS, by Agreement of Lease, dated as of November 5, 2019, between Landlord, as landlord, and Tenant, as tenant (the "Original Lease"), as modified by that certain letter agreement, dated as of November 5, 2019, between Landlord and Tenant (the "Letter Agreement", and, together with the Original Lease, collectively, the " Lease"), Landlord does demise and lease unto Tenant, and Tenant does hire and lease from Landlord, a portion of the rentable area located on the twenty-fourth (24th) floor of the building known as One Grand Central Place and by the street address of 60 East 42nd Street, New York, New York 10165 (the " Building"), designated as Suite 2430 and as more particularly described in the Lease (the "Existing Premises"), for a term expiring on April 30, 2028 (the "Fixed Expiration Date") or on such earlier date upon which said term may expire or be terminated pursuant to any conditions of limitation or other provisions of the Lease or pursuant to law; and

WHEREAS, Landlord requested that Tenant relocate from the Existing Premises to the New Premises (defined below) (the "Relocation Request"); and

WHEREAS, because the New Premises are not located on or above the eighteenth (18 th) floor of the Building, Tenant has no obligation, pursuant to Article 43, to comply with the Relocation Request, but Tenant has nonetheless agreed to accommodate Landlord's request on the terms set forth herein; and

WHEREAS, in connection with the Relocation Request, Landlord and Tenant desire that (x) Tenant surrender the Existing Premises to Landlord and Landlord accept the surrender thereof on the terms and conditions more particularly set forth herein, (y) Landlord let unto Tenant and Tenant hire and take from Landlord, a portion of the rentable area located on the fourteenth (14 th) floor of the Building, designated as Suite 1420 and as more particularly shown hatched on the floor plan attached hereto as Exhibit "A" and made a part hereof (the "New Premises"), and (z) Landlord and Tenant otherwise modify the Lease as set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the mutual receipt and legal sufficiency of which are hereby acknowledged, the parties hereto, for themselves, their legal representatives, successors and assigns, hereby agree as follows:

1. Recitals; Definitions. The recitals set forth above are true and correct and by this reference are incorporated herein in their entirety. All capitalized terms used herein shall have the meanings ascribed to them in the Lease, unless otherwise defined herein.

2. Surrender of Existing Premises.

(A) No earlier than the New Premises Commencement Date (as hereinafter defined) and no later than the date which is fourteen (14) days after the New Premises Commencement Date (such date, the "Outside Surrender Date"; and the actual date of surrender in accordance herewith being referred to as the "Surrender Date"), Tenant shall vacate, quit and surrender to Landlord possession of the Existing

Premises, free of all liens, encumbrances, tenancies and occupancies created by, through, or under Tenant, in its then "as is" condition (it being agreed that all of the personal property of Tenant and Persons claiming by, through, or under Tenant, including, without limitation, movable fixtures, movable partitions, furniture, furnishings and decorations (collectively, "Tenant's Property"), but excluding Tenant's telecommunications and computer systems and equipment, shall be removed therefrom by Landlord at Landlord's expense), as if the Surrender Date were the Fixed Expiration Date with respect to the Existing Premises only; it being agreed that, notwithstanding anything contained in the Lease to the contrary, Tenant shall have no obligation to restore the Existing Premises to the condition that existed on the Commencement Date, or to remove any Alterations or any Tenant's Property from the Existing Premises, except Tenant's telecommunications and computer systems and equipment, as set forth in Paragraph 3(C) below. With the intent and purpose that the term of the Lease with respect to the Existing Premises only be wholly merged and extinguished effective as of the Surrender Date, Tenant hereby gives, grants and surrenders all of its right, title and interest in, to and under the Lease with respect to the Existing Premises only to Landlord effective as of the Surrender Date. If possession of the Existing Premises is not surrendered to Landlord on or prior to the Outside Surrender Date, the provisions of Article 12 of the Lease shall be applicable to such holdover by Tenant. Nothing contained in this Paragraph 2(A) shall permit Tenant to retain possession of the Existing Premises beyond the Surrender Date (or sooner termination of the Term of the Lease pursuant to the terms thereof) or limit in any manner Landlord's right to regain possession of the Existing Premises, through summary proceedings or otherwise. The provisions of this Paragraph 2(A) shall survive the surrender of the Existing Premises and the Surrender Date.

(B) Tenant covenants, represents and warrants to Landlord that (i) Tenant is the sole and present tenant under the Lease and Tenant has not assigned, conveyed, encumbered, pledged, sublet or otherwise transferred, in whole or in part, its interest in the Lease or the Existing Premises, nor shall Tenant do any of the foregoing prior to the Surrender Date, (ii) there are no persons or entities claiming by, through, or under Tenant, or who or which may claim under Tenant, any rights with respect to the Existing Premises, nor shall Tenant permit any such claim to arise prior to the Surrender Date, (iii) Tenant has the right, power and authority to execute and deliver this Amendment and to perform Tenant's obligations hereunder, and (iv) this Amendment is a valid and binding obligation of Tenant enforceable against Tenant in accordance with the terms hereof. Landlord covenants, represents and warrants to Tenant that (x) Landlord has the right, power and authority to execute and deliver this Amendment and to perform Landlord's obligations hereunder, and (y) this Amendment is a valid and binding obligation of Landlord enforceable against Landlord in accordance with the terms hereof. The foregoing covenants, representations and warranties shall survive the surrender of the Existing Premises and the Surrender Date.

(C) Subject to the terms of Paragraph 2(A) hereof, any and all provisions of the Lease which impose obligations on Tenant to pay Rental or any other amounts, fees or other costs or reimbursements with respect to the Existing Premises only, shall cease as of the Surrender Date; provided, however, that such payments shall be apportioned as of such date, and the obligation to pay any such amounts shall survive the surrender of the Existing Premises and the Surrender Date. Nothing contained herein shall be deemed to relieve Tenant from Tenant's obligation to pay Rental with respect to the New Premises, including, without limitation, as set forth in Paragraph 4 hereof.

(D) Effective as of Surrender Date, Tenant hereby releases and relieves Landlord and its successors and assigns from and against any and all actions, causes of action, suits, controversies, damages, judgments, claims and demands whatsoever, at law or in equity, of every kind and nature whatsoever arising out of, or in connection with, the Existing Premises or the Lease with respect to the Existing Premises only. Tenant hereby acknowledges and agrees that, to the best of Tenant's knowledge, Landlord is not in default, breach or an event of default in any respect under any terms of the Lease and no facts or circumstances exist that, with the passage of time or giving of notice or both, will or could constitute a default, event of default or breach by Landlord under the Lease.

(E) Landlord, on the Surrender Date, shall accept Tenant's surrender of the Existing Premises and, effective as of the Surrender Date, except as otherwise set forth in this Paragraph 2(E) and in Paragraphs 2(A), 2(B), and 2(C) hereof, hereby releases and relieves Tenant and its respective successors and assigns from and against all actions, causes of action, suits, controversies, damages, judgments, claims, demands, obligations and liabilities whatsoever, at law or in equity, of every kind and nature whatsoever arising out of, or in connection with, the Existing Premises or the Lease with respect to the Existing Premises only. Notwithstanding the foregoing, neither Landlord nor Tenant shall be released from any covenant, representation or warranty contained in this Amendment and the Lease, which by the terms of this Amendment or the Lease is specifically stated to survive the Surrender Date, the surrender of the Existing Premises, or the expiration of the term of the Lease. Other than as expressly set forth in Paragraph 2(C) hereof, and except for any covenant, representation or warranty contained in this Amendment or the Lease, which by the terms of this Amendment or the Lease is specifically stated to survive the Surrender Date, the surrender of the Existing Premises, or the expiration of the term of the Lease, Tenant shall not have any obligations or liabilities whatsoever with respect to the Existing Premises (including, without limitation, for the payment of Fixed Annual Rent, Escalation Rent, Additional Rent, other Rental or other costs, expenses, fees, reimbursements, payments or amounts) from and after the Surrender Date. Landlord hereby acknowledges and agrees that, to the best of Landlord's knowledge, Tenant is not in default, breach or an event of default in any respect under any terms of the Lease and no facts or circumstances exist that, with the passage of time or giving of notice or both, will or could constitute a default, event of default or breach by Tenant under the Lease.

(F) Landlord and Tenant, each upon request of the other party, at any time and from time to time hereafter and without further consideration, shall execute, acknowledge and deliver to the other any instruments or documents, or take such further action, as shall be reasonably requested or as may be necessary to more effectively assure the vacation, quitting and surrender of the Existing Premises and the full benefits intended to be created by this Amendment; provided, however, such instruments or documents shall not increase the obligations or liabilities, or decrease the rights or liabilities, of Tenant or Landlord beyond that provided for in the Lease, as amended hereby.

3. New Premises.

(A) From and after the New Premises Commencement Date through and including the Fixed Expiration Date, or such earlier date upon which the term of the Lease, as modified hereby, may expire or be terminated pursuant to any conditions of limitation or other provisions of the Lease or pursuant to law, Landlord hereby leases to Tenant, and Tenant hereby hires from Landlord, the New Premises upon all of the same terms, covenants and conditions set forth in the Lease, except as modified and amended herein. Except as and to the extent otherwise provided herein, from and after the New Premises Commencement Date until the Surrender Date, all references in the Lease to the "Premises" shall be deemed to mean, collectively, the Existing Premises and the New Premises, and, from and after the Surrender Date, all references in the Lease to the "Premises" shall be deemed to mean the New Premises only, for all purposes of the Lease, as amended hereby.

(B) The "New Premises Commencement Date" shall mean the day after the date upon which all of the following have occurred: (i) the New Premises Work (as hereinafter defined) is Substantially Complete, (ii) Landlord shall complete, or be deemed to have completed, the Relocation (as hereinafter defined), and (iii) Landlord shall have tendered to Tenant vacant exclusive possession of the New Premises, which shall be in broom clean condition with all Building systems (including the distribution portions thereof and the A/C Equipment) providing service to the New Premises in good working order.

(C) Landlord, at Landlord's expense, shall physically relocate such of Tenant's movable furniture and other personal property (other than Tenant's telecommunications and computer systems and equipment) as is identified by Tenant for relocation from the Existing Premises to the New Premises (the "Relocation"). Tenant shall assist Landlord, at no out-of-pocket expense to Tenant, with facilitating, cooperating, and coordinating the Relocation. In the event that Landlord is delayed in the completion of the Relocation as a result of Tenant's failure to reasonably cooperate and coordinate with Landlord in the performance of the same or by reason of any other act or wrongful omission of Tenant or any Person acting by, through, or under Tenant, for purposes of determining the New Premises Commencement Date, the Relocation shall be deemed to have been completed on the date that the Relocation would have been completed but for such failure, act, or wrongful omission of Tenant or any Person acting by, through, or under Tenant, as reasonably determined by Landlord. In addition, Tenant, at Tenant's expense, shall remove Tenant's telecommunications and computer systems and equipment from the Existing Premises and re-install such systems in the New Premises, which work shall be coordinated with Landlord so as to be completed no later than the Surrender Date.

(D) Tenant waives any right to rescind this Amendment under Section 223-a of the New York Real Property Law or any successor statute of similar nature and purpose then in force and further waives the right to recover any damages which may result from Landlord's failure for any reason to deliver possession of the New Premises to Tenant by any date certain. The provisions of this Paragraph are intended to constitute an "express provision to the contrary" within the meaning of Section 223-a of the New York Real Property Law. If Tenant takes possession of the New Premises, or otherwise enters therein, for any reason prior to the New Premises Commencement Date, all of the terms, covenants and conditions of the Lease (as amended hereby) shall be applicable to such possession or entry (specifically, including without limitation, the provisions of Article 21 of the Lease); it being expressly understood that Tenant may only do so with Landlord's prior written approval (which may be granted or withheld in Landlord's sole discretion) and that the foregoing shall not be construed to permit Tenant to access or otherwise take possession of the New Premises prior to the New Premises Commencement Date without first obtaining such approval.

(E) Landlord hereby agrees to waive its customary charges in connection with Tenant's after-hours use of the freight elevator service for Tenant's initial move into the New Premises, but not in excess of twenty (20) hours in the aggregate, which freight elevator use shall be scheduled on such days and during such hours (in no less than four (4) hour blocks of time) as are scheduled in advance with, and reasonably approved by, Landlord. Tenant expressly acknowledges and agrees that any portion of such hours allotted to Tenant for free after-hours freight elevator service which are remaining after Tenant's completion of Tenant's initial move to the New Premises shall be deemed forfeited and that in no event shall any such hours be applied to Tenant's use of the freight elevator service in connection with the ordinary conduct of Tenant's business. Notwithstanding anything to the contrary contained herein, Tenant shall not be responsible for any charges for the use of the freight elevators by Landlord in connection with the Relocation and no such use by Landlord shall be offset against the twenty (20) hours of free after-hours use of the freight elevator service described in this Paragraph 3(E).

4. Modification of Lease: New Premises. From and after the New Premises Commencement Date, the Lease with respect to the New Premises only shall be deemed modified and amended as follows:

(A) Fixed Annual Rent. Tenant shall pay Fixed Annual Rent pursuant to Section 2.B of the Lease, which Fixed Annual Rent, with respect to the New Premises only, shall be an amount equal to:

(i) Three Hundred Thirty-Nine Thousand Two Hundred Nine and 64/100 Dollars ($339,209.64) per annum, for the period commencing on the New Premises Rent Commencement Date and

ending on the day immediately preceding the date which is the second (2nd) anniversary of the New Premises Rent Commencement Date, payable in advance, in equal monthly installments of Twenty-Eight Thousand Two Hundred Sixty-Seven and 47/100 Dollars ($28,267.47) per month, at the times and in the manner provided in the Lease; it being understood and agreed, that if no monetary Default has occurred that is then continuing, the Fixed Annual Rent for the period commencing on the New Premises Commencement Date and ending on the day immediately preceding the New Premises Rent Commencement Date shall be abated; it being expressly acknowledged and agreed however, that Tenant shall continue to be responsible for paying all other Rental (specifically including, without limitation, any and all charges for electricity) without any credit, set off, deduction or reduction during the aforesaid period; and

(ii) Four Hundred Seventy-Five Thousand Eight Hundred Sixty-One and 00/100 Dollars ($475,861.00) per annum, for the period commencing on the second (2nd) anniversary of the New Premises Rent Commencement Date and ending on the Fixed Expiration Date, payable in advance, in equal monthly installments of Thirty-Nine Thousand Six Hundred Fifty-Five and 08/100 Dollars ($39,655.08) per month, at the times and in the manner provided in the Lease.

As used herein, the term "New Premises Rent Commencement Date" shall mean the Surrender Date. Should the New Premises Rent Commencement Date or the second (2nd) anniversary of the New Premises Rent Commencement Date occur on any day other than the first day of a calendar month, then the Fixed Annual Rent payable for the calendar month during which such date occurs shall be adjusted appropriately on a per diem basis.

(B) Operating Expense Escalations. From and after the New Premises Commencement Date, Tenant shall continue to pay to Landlord, as Additional Rent with respect to the New Premises, operating expense escalations in accordance with Section 2.C of the Lease, which Section 2.C., with respect to the New Premises only, shall be deemed modified as follows:

(i) The term "Base Expense Year" (as such term is defined in Section 2.C.(ii)(b) of the Lease), for the determination of operating expense escalation with respect to the New Premises only, shall mean the 2023 calendar year.

(ii) The term "Comparative Year" (as such term is defined in Section 2.C.(ii)(d) of the Lease), for the determination of operating expense escalation with respect to the New Premises only, shall mean each calendar year commencing on or after January 1, 2024 during which occurs any part of the Term.

(iii) The term "Tenant's Expense Share" (as such term is defined in Section 2.C.(ii)(h) of the Lease), for the determination of operating expense escalation with respect to the New Premises only, shall mean sixty-two hundredths percent (0.62%).

(iv) Notwithstanding anything contained herein or in the Lease to the contrary, Landlord hereby agrees that Tenant shall have no obligation to make any payments of Escalation Rent pursuant to Section 2.C of the Lease during the period from the New Premises Commencement Date through and including the date immediately preceding the first anniversary of the New Premises Commencement Date.

(C) Tax Escalation. From and after the New Premises Commencement Date, Tenant shall continue to pay to Landlord, as Additional Rent with respect to the New Premises, real estate tax escalations in accordance with Section 2.D of the Lease, as modified, the terms of which shall be deemed further modified as follows:

(i) The term "Base Tax Year" (as such term is defined in Section 2.D.(i)(b) of the Lease), for the determination of real estate tax escalation with respect to the New Premises only, shall mean the second (2nd) half of the Tax Year commencing on July 1, 2022 and ending on June 30, 2023 and the first (1st) half of the Tax Year commencing on July 1, 2023 and ending on June 30, 2024 (i.e., calendar year 2023).

(ii) The term "Comparative Tax Year" (as such term is defined in Section 2.D.(i)(c) of the Lease), for the determination of real estate tax escalation with respect to the New Premises only, shall mean the second (2nd) half of the Tax Year commencing on July 1, 2023 and ending on June 30, 2024 and the first (1st) half of the Tax Year commencing on July 1, 2024 and ending on June 30, 2025 (i.e., calendar year 2024), and each subsequent calendar year thereafter.

(iii) The term "Tenant's Tax Share" (as such term is defined in Section 2.D.(i)(i) of the Lease), for the determination of real estate tax escalation with respect to the New Premises only, shall mean fifty-nine hundredths percent (0.59%).

(v) Notwithstanding anything contained herein or in the Lease to the contrary, Landlord hereby agrees that Tenant shall have no obligation to make any payments of Escalation Rent pursuant to Section 2.D of the Lease during the period from the New Premises Commencement Date through and including the date immediately preceding the first anniversary of the New Premises Commencement Date.

(D) Rentable Square Feet. For all purposes of the Lease (as amended hereby), the parties agree that the rentable square foot area of the New Premises shall be deemed to be seven thousand eight hundred one (7,801) rentable square feet; accordingly, with respect to the New Premises, all references in the Lease to the term "five thousand one hundred seventy-six (5,176) rentable square feet" shall be deemed deleted and the term "seven thousand eight hundred one (7,801) rentable square feet" substituted in its place and stead.

(E) Electricity - Submetered. Landlord shall furnish electricity to the New Premises on a submetering basis, subject to and in accordance with the provisions of Article 3 of the Lease. Notwithstanding the foregoing, if the submeter or submeters to measure Tenant's KW and KWH in the New Premises has not or have not been not been installed, connected and/or is not or are not yet functioning by the New Premises Commencement Date, Tenant shall pay, for the distribution of electric power and use of Landlord's facilities to provide electrical power to the New Premises, a charge equal to the amount that results from (a) multiplying One and 50/100 Dollars ($1.50) by the number of rentable square feet within the New Premises, (b) dividing such result by 365 and (c) multiplying the result of (b) by the number of days until the date on which the appropriate submeter(s) are installed, connected and functioning; provided, however, that if Landlord is unable to connect the applicable submeter or submeters as a result of the obstruction of, or interference by, Tenant or Persons acting by, through, under, or on behalf of Tenant, and such obstruction or interference continues for five (5) Business Days following notice thereof, then, without limiting Landlord's other remedies under the Lease, the aforesaid amount of One and 50/100 Dollars ($1.50) shall be increased to Three and 25/100 Dollars ($3.25) from the expiration of such five (5) Business Day period until either the submeters are installed, connected, and functioning or such obstruction or interference ceases. Notwithstanding anything to the contrary contained in this Section 4(E) or in Article 3 of the Lease, as of the New Premises Commencement Date, a submeter or submeters measuring Tenant's demand for and consumption of electricity in Suite 1420 shall be installed, connected and functioning, and such submeter(s) shall exclusively measure Tenant's demand for and consumption of electricity in the New Premises.

5. Condition of Premises.

(A) Tenant acknowledges that Landlord has made no representations to Tenant with respect to the condition of the Existing Premises. Notwithstanding anything to the contrary contained in this Amendment, Landlord shall have no obligation to perform any work, provide any work allowance or rent credit, alter, improve, decorate, or otherwise prepare the Existing Premises for Tenant's continued occupancy.

(B) Tenant represents that it has made a thorough inspection of the New Premises and, subject to the provisions of Paragraph 5(C) hereof, agrees to take the New Premises in its "as-is" condition existing on the New Premises Commencement Date. Tenant further acknowledges and agrees that notwithstanding anything to the contrary contained in the Lease, as amended hereby, Landlord has made no representations with respect to the New Premises and Landlord shall have no obligation to perform any work, alter, improve, decorate, or otherwise prepare the New Premises for Tenant's occupancy as a condition to the occurrence of the New Premises Commencement Date (other than Landlord's New Premises Work) or to provide any work allowance or rent credit (other than as expressly set forth in Paragraph 4(A) hereof).

(C) Landlord shall, at its sole cost and expense and without cost to Tenant (subject to the provisions of Paragraph 5.(D) hereof), perform the following work to the New Premises for Tenant's occupancy thereof (collectively, "Landlord's New Premises Work"), all of which shall be performed using materials and finishes consistent with those described in the work letter attached hereto and made a part hereof as Exhibit "C" (the "Work Letter") and otherwise reasonably comparable or superior in design, finish, color, quality and price to the materials and finishes utilized in the Existing Premises (such materials and finishes are hereinafter referred to as the "Building Standard Installations"): (i) modify the layout of the New Premises substantially in accordance with the plan attached hereto and made a part hereof as Exhibit "B" (the "Final Space Plan"), (ii) install three (3) television mounts and power locations (with wall blocking and a television-height outlet in the wall for each); and (iii) install floor trenching to provide power and data connectivity for Tenant's conference room table. Tenant hereby approves the Final Space Plan, the Work Letter, and the use of Building Standard Installations and acknowledges and agrees that the Final Space Plan and the Work Letter are final and Tenant shall not have the right to make any changes thereto from and after the date hereof. Notwithstanding the foregoing, Tenant shall have the right, within ten (10) Business Days following the date on which this Amendment is mutually executed and delivered, to request that Landlord, at Tenant's cost and expense, install additional television mounts within the New Premises during the performance of Landlord's New Premises Work in locations designated by Tenant and approved by Landlord (which approval shall not be unreasonably withheld), and, provided that Tenant timely make such request and pays Landlord the cost thereof (determined in accordance with Landlord's standard bidding procedure) within no more than five (5) Business Days following Landlord's demand therefor, Landlord shall install such additional television mounts in the New Premises during the performance of Landlord's New Premises Work. If any other changes to the Final Space Plan or use of other than Building Standard Installations or any other changes to Landlord's New Premises Work are hereafter requested by Tenant and approved by Landlord, Tenant shall be responsible for reimbursing Landlord, as Additional Rent, for any increased costs incurred by Landlord in connection with Landlord's New Premises Work as a result thereof.

(D)

(i) Notwithstanding anything contained in this Amendment to the contrary, Tenant shall pay for the cost of any and all items of Tenant Extra Work (as hereinafter defined) subject to and in accordance with the provisions of this Paragraph 5.(D). For purposes hereof, the term "Tenant Extra Work" shall mean collectively, (i) any portion of Landlord's New Premises Work that is described in the Work

Letter under the section thereof titled “Tenant Alternate” and/or any other portion of Landlord’s New Premises Work as is appropriately described or denoted on any architectural or engineering plans or drawings derived from the Work Letter or the Final Space Plan (including, without limitation, the “Note” and “Legends” sections of such plans) as “Alternate Pricing”, “Alt. Pricing” or similar language denoting any alternatives to be paid for by Tenant, (ii) any additional television mounts requested by Tenant pursuant to the penultimate sentence of Paragraph 5.(C) hereof, and/or (iii) any other additional installations that exceed the scope of Landlord’s New Premises Work. The cost for performing any Tenant Extra Work shall be determined in accordance with Landlord’s standard bidding procedure. Notwithstanding the foregoing to the contrary, Landlord shall have the right to let the construction contract to the lowest responsible qualified bidder without taking into account the cost of any items of Tenant Extra Work (with the understanding that Landlord shall have the right to exercise Landlord’s reasonable business judgment in selecting the form of contractual arrangement for the construction contract).

(ii) Landlord shall notify Tenant (which notice, notwithstanding anything in the Lease to the contrary, shall be deemed effectively given if sent by email to Silas Newcomb at snewcomb@orchestrabiomed.com) after Landlord’s bidding procedure is completed of the estimated price for each item of Tenant Extra Work. On or prior to the date that is ten (10) business days after Landlord gives Tenant notice of such estimated price (the “Tenant Extra Estimate”), Tenant shall pay Landlord the Tenant Extra Estimate for such Tenant Extra Work (such payment received by Landlord, the “Tenant Extra Work Estimate Payment”; it being understood and agreed that (x) if Tenant fails to pay the Tenant Extra Estimate within the aforesaid ten (10) business day period, or (y) if Tenant notifies Landlord not to perform such item of Tenant Extra Work, then, in either event, (i) Landlord shall have the right (but not the obligation) to substitute a Building Standard Installation for such item of Tenant Extra Work if the same is capable of being so substituted and if Landlord is unable or unwilling to substitute a Building Standard Installation for such item of Tenant Extra Work, then such item shall be excluded from Landlord’s New Premises Work and Landlord shall have no obligation to perform the same, and (ii) Tenant shall reimburse Landlord for any and all soft costs that may have been actually incurred by Landlord in connection with such item(s) of Tenant Extra Work within ten (10) business days following receipt of Landlord’s invoice therefor (including, without limitation, any softs costs incurred for items of Tenant Extra Work which Tenant elected for Landlord not to perform or with respect to which Tenant failed to respond as contemplated herein, as the case may be). In the event that any item of Tenant Extra Work creates a field condition that requires a change to Landlord’s New Premises Work resulting in an increase of the cost of Landlord’s New Premises Work, Landlord shall have the right before proceeding with such change to require Tenant (a) to agree in writing to pay such increase in cost within three (3) business days from the date of Landlord’s request (which request may be verbal) for Tenant’s agreement and (b) to pay such increase within ten (10) business days of Landlord’s invoice therefor, which invoice may be based upon a reasonable estimate thereof. If Tenant shall fail or refuse to so agree to and/or pay for such increase then Landlord shall have the right (but not the obligation) to either refuse to perform such Tenant Extra Work, and continue the performance of Landlord’s New Premises Work without making the changes thereto contemplated by such Tenant Extra Work or to revise the scope of Landlord’s New Premises Work so as not to require a change resulting from a field condition (it being understood that Tenant shall reimburse Landlord for any and all costs (including soft costs) that may have been actually incurred by Landlord in connection with or as a result of such item(s) of Tenant Extra Work within ten (10) business days following receipt of Landlord’s invoice therefor). Landlord shall give to Tenant, within sixty (60) days after the date that Landlord Substantially Completes Landlord’s New Premises Work, a notice that sets forth the actual hard and soft costs incurred by or on behalf of Landlord in performing all items of Tenant Extra Work, if any (the “Actual Tenant Extra Work Cost”) (such notice being referred to herein as the “ Final Cost Notice”). Tenant shall pay to Landlord, within ten (10) business days after the date that Landlord gives the Final Cost Notice to Tenant, an amount equal to the excess (if any) of (I) the Actual Tenant Extra Work Cost, as reflected in the Final Cost Notice, over (II) the Tenant Extra Work Estimate Payment (if any). Landlord shall pay to Tenant, within thirty (30) days after the date that Landlord gives the Final Cost Notice to

Tenant, an amount equal to the excess (if any) (I) the Tenant Extra Work Estimate Payment, over (II) the Actual Tenant Extra Work Cost, as reflected in the Final Cost Notice.

6. Security Deposit. Landlord and Tenant agree that Landlord shall continue to hold the security deposit (pursuant to Article 32 of the Lease) in the amount of Three Hundred Thirty-Six Thousand Four Hundred Forty and 00/100 Dollars ($336,440.00), in the form of an unconditional irrevocable Letter of Credit as security for the performance by Tenant of the terms of the Lease, as modified hereby, in accordance the provisions of Article 32 of the Lease.

7. Change of Location.

(A) Following the New Premises Commencement Date, Landlord shall continue to have the right to relocate Tenant to Substitute Space pursuant to, and in accordance with, the provisions, terms, and conditions of Article 43 of the Lease; provided, however, following the New Premises Commencement Date, Article 43 of the Lease shall be deemed amended to provide that (i) Landlord shall only have the right to exercise its rights under Article 43 one (1) time during the period between the New Premises Commencement Date and the Fixed Expiration Date, and (ii) in no event shall Landlord have the right to relocate Tenant pursuant to Article 43 of the Lease on or by a Relocation Effective Date that is any earlier than the date that is twenty-four (24) months following the New Premises Commencement Date.

(B) Notwithstanding anything in the Lease to the contrary, including, without limitation, Article 43 thereof, the provisions of Article 43 of the Lease shall not be applicable to the relocation from the Existing Premises to the New Premises. Without limiting the generality of the foregoing, except as expressly provided in this Amendment, Landlord shall have no obligation to reimburse Tenant for the costs incurred by Tenant in physically relocating from the Existing Premises to the New Premises, removing Tenant's telecommunications and computer systems from the Existing Premises and reinstalling such systems in the New Premises, or replacing any business stationary or business cards utilized by Tenant which lists the Existing Premises as Tenant's address.

8. Brokerage.

(A) Tenant represents and warrants to Landlord that it has not dealt with any broker, finder or like agent in connection with this Amendment. Tenant does hereby indemnify and hold Landlord harmless of and from any and all loss, costs, damage or expense (including, without limitation, attorneys' fees and disbursements) incurred by Landlord by reason of any claim of or liability to any broker, finder or like agent who shall claim to have dealt with Tenant in connection herewith.

(B) Landlord represents and warrants to Tenant that it has not dealt with any broker, finder or like agent in connection with this Amendment, other than Newmark & Company Real Estate, Inc. ("Landlord's Agent"). Landlord does hereby indemnify and hold Tenant harmless of and from any and all loss, costs, damage or expense (including, without limitation, attorneys' fees and disbursements) incurred by Tenant by reason of any claim of or liability to any broker, finder or like agent, including Landlord's Agent, who shall claim to have dealt with Landlord in connection herewith.

(C) The provisions of this Paragraph 8 shall survive the expiration or termination of the Lease, as amended by this Amendment.

9. Design Guidelines. The current Design Guidelines are annexed to this Amendment as Exhibit "D" and made a part hereof and are hereby deemed substituted for the Design Guidelines attached to the Lease as Exhibit C, and Tenant hereby acknowledges and agrees that any Alterations made after the

date hereof shall be performed in accordance with the Design Guidelines attached hereto, as the same may be amended from time to time.

10. Authorization. Tenant represents and warrants to Landlord that its execution and delivery of this Amendment has been duly authorized and that the person executing this Amendment on behalf of Tenant has been duly authorized to do so, and that no other action or approval is required with respect to this transaction. Landlord represents and warrants to Tenant that its execution and delivery of this Amendment has been duly authorized and that the person executing this Amendment on behalf of Landlord has been duly authorized to do so, and that no other action or approval is required with respect to this transaction.

11. Full Force and Effect of Lease. Except as modified by this Amendment, the Lease and all covenants, agreements, terms and conditions thereof shall remain in full force and effect and are hereby in all respects ratified and confirmed.

12. Entire Agreement. The Lease, as amended by this Amendment, constitutes the entire understanding between the parties hereto with respect to the Premises thereunder and may not be changed orally but only by an agreement in writing signed by the party against whom enforcement of any waiver, change, modification or discharge is sought. In the event of any conflict between the terms and provisions of the Lease and the terms and provisions of this Amendment, the terms and provisions of this Amendment shall control.

13. Enforceability. This Amendment shall not be binding upon or enforceable against either Landlord or Tenant unless, and until, Landlord and Tenant, each in its sole discretion, shall have executed and unconditionally delivered to the other an executed counterpart of this Amendment.

14. Invalidity. If any of the provisions of the Lease, as amended hereby, or the application thereof to any person or circumstance, shall, to any extent, be invalid or unenforceable, the remainder of the Lease, as amended hereby, or the application of such provision or provisions to persons or circumstances other than those as to whom or which it is held invalid or unenforceable shall not be affected thereby, and every provision of the Lease, as amended hereby, shall be valid and enforceable to the fullest extent permitted by law.

15. Binding Effect. The covenants, agreements, terms and conditions contained in this Amendment shall bind and inure to the benefit of the parties hereto and their respective successors, and (except as otherwise provided in the Lease, as hereby supplemented) their respective assigns.

16. Captions. The captions herein are inserted only for convenience and are in no way to be construed as a part of this Amendment or as a limitation of the scope of any provision of this Amendment.

17. Counterparts. This Amendment may be executed in one or more counterparts each of which when taken together shall constitute but one original. Execution of this Amendment, or any counterpart thereof, by means of an electronic signature shall be legally binding and shall have the same full force and effect as if this Amendment, or any such counterpart thereof, had been executed manually. Delivery of an executed counterpart of this Amendment by electronic transmission in a Portable Document Format ("PDF") or other digital format acceptable to Landlord shall be equally effective as manual delivery of an executed counterpart of this Amendment, and each such counterpart, whether delivered manually, or by PDF or such other digital format shall be deemed an original.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties hereto have executed this Amendment of Lease as of the date first above written.

LANDLORD:

ESRT ONE GRAND CENTRAL PLACE, L.L.C.

By: ESRT One Grand Central Place Parent, L.L.C., as its sole member

By: ESRT One Grand Central Place G-Parent, L.L.C., as its sole member

By: Empire State Realty OP, L.P., as its sole member

By: Empire State Realty Trust, Inc., as its general partner

By: /s/ Ryan O. Kass
Name: Ryan O. Kass
Title: Authorized Signatory

TENANT:

ORCHESTRA BIOMED, INC.

By: /s/ David Hochman
Name: David Hochman
Title: CEO

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: May 13, 2024

/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: May 13, 2024

/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 March 31, 2024 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: May 13, 2024

/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 March 31, 2024 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: May 13, 2024

/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.