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

FORM 8-K/A
(Amendment No. 1)

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

Date of Report (Date of earliest event reported): March 24, 2023 (January 25, 2023)

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

Delaware	001-39421	92-2038755
(State or other jurisdiction of incorporation)	(Commission File Number)	(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

(Former name or former address, if changed since last report)

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

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

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

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

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

Securities registered pursuant to Section 12(b) of the Act

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	**OBIO**	**The Nasdaq Global Market**

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

Emerging growth company ☒

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

INTRODUCTORY NOTE

This Amendment No. 1 on Form 8-K/A ("Amendment No. 1") amends the Current Report on Form 8-K of Orchestra BioMed Holdings, Inc., a Delaware corporation (the "Company"), filed on January 31, 2023 (the "Original Report"), in which the Company reported, among other events, the completion of the Business Combination (as defined in the Original Report) with Health Sciences Acquisitions Corporation 2.

This Amendment No. 1 is being filed to include (A) the audited consolidated financial statements of Orchestra BioMed, Inc., a Delaware corporation ("Orchestra"), at December 31, 2022 and 2021 and for the years then ended and the related notes, (B) the Management's Discussion and Analysis of Financial Condition and Results of Operations of Orchestra as of December 31, 2022 and for the years ended December 31, 2022 and 2021 and (C) the unaudited pro forma condensed combined financial information as of and for the year ended December 31, 2022.

This Amendment No. 1 does not amend any other item of the Original Report (except as otherwise expressly stated herein) or purport to provide an update or a discussion of any developments at the Company or its subsidiaries subsequent to the filing date of the Original Report, except as otherwise expressly stated herein.

The information previously reported in or filed with the Original Report is hereby incorporated by reference to this Amendment No. 1. Terms used but not defined herein shall have the meanings ascribed thereto in the Original Report. The information provided herein relates to Orchestra prior to the consummation of the Business Combination unless otherwise specifically indicated (*e.g.*, with respect to subsequent events disclosures, forward-looking statements, or potential future risk factors) or the context otherwise requires.

Item 2.02. Results of Operations and Financial Condition.

The financial statements set forth under paragraph (a)(1) of Item 9.01 of this Current Report on Form 8-K are incorporated herein by reference.

The information in this Item 2.02 is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(a) Financial statements of businesses acquired.

(1) The consolidated financial statements of Orchestra at December 31, 2022 and 2021, and for the years then ended, and the related notes thereto, are attached as Exhibit 99.1 and are incorporated herein by reference.

(2) The Management's Discussion and Analysis of Financial Condition and Results of Operations of Orchestra as of December 31, 2022 and for the years ended December 31, 2022 and 2021 is attached as Exhibit 99.2 and is incorporated herein by reference.

(b) Pro forma financial information.

The unaudited pro forma condensed combined financial information as of December 31, 2022 and for the year ended December 31, 2022 is attached hereto as Exhibit 99.3 and is incorporated herein by reference.

(d) Exhibits.

Exhibit Number	Description
99.1+	Audited consolidated financial statements of Orchestra and the accompanying notes as of December 31, 2022 and for the years ended December 31, 2022 and 2021.
99.2+	Management's Discussion and Analysis of Financial Condition and Results of Operations of Orchestra as of December 31, 2022 and for the years ended December 31, 2022 and 2021.
99.3+	Unaudited pro forma condensed combined financial information and the accompanying notes as of and for the year ended December 31, 2022.
104+	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

\+ Filed herewith.

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 hereunto duly authorized.

ORCHESTRA BIOMED HOLDINGS, INC.

By: /s/ David P. Hochman
Name: David P. Hochman
Title: Chief Executive Officer

Date: March 24, 2023

Exhibit 99.1

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Financial Statements for Orchestra Biomed, Inc. (accounting predecessor to Orchestra Biomed Holdings, Inc):

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Orchestra BioMed, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Orchestra BioMed, Inc. (the Company) as of December 31, 2021 and 2022 the related consolidated statements of operations and comprehensive loss, stockholders' deficit and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2020.

Philadelphia, Pennsylvania

March 24, 2023

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

	December 31,	
	2021	**2022**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 9,938	$ 19,784
Marketable securities	—	63,915
Strategic investments, current portion	958	86
Accounts receivable, net	121	96
Inventory	68	276
Prepaid expenses and other current assets	234	533
Total current assets	11,319	84,690
Property and equipment, net	1,120	1,489
Right-of-use assets	—	2,187
Strategic investments, less current portion	398	2,495
Deposits and other assets	690	4,711
TOTAL ASSETS	$ 13,527	$ 95,572
LIABILITIES, REDEEMABLE PREFERRED STOCK, AND STOCKHOLDERS' DEFICIT		
CURRENT LIABILITIES:		
Accounts payable	$ 2,029	$ 3,968
Accrued expenses and other liabilities	2,034	5,376
Operating lease liability – current	—	697
Warrant liability	635	2,089
Deferred revenue, current portion	5,542	6,436
Loan payable, current portion	2,000	—
Total current liabilities	12,240	18,566
Deferred revenue, less current portion	16,859	13,103
Loan payable, less current portion	3,673	9,490
Operating lease liability, less current portion	—	1,683
Other long-term liabilities	535	196
TOTAL LIABILITIES	33,307	43,038

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

ORCHESTRA BIOMED, INC.
Consolidated Balance Sheets — (Continued)
(in thousands, except share and per share data)

	December 31,	
	2021	**2022**
REDEEMABLE PREFERRED STOCK		
Series A Preferred Stock, $0.0001 par value, 20,000,000 shares authorized of which 5,346,570 are issued and outstanding at December 31, 2021 and 2022; aggregate liquidation preference of $53,466 at December 31, 2022	51,452	51,452
Series D-1 Preferred Stock, $0.0001 par value, 6,100,000 shares authorized of which 0 are issued and outstanding at December 31, 2021 and 5,864,940 are issued and outstanding at December 31, 2022; aggregate liquidation preference of $27,272 at December 31, 2022	—	27,272
Series D-2 Preferred Stock, $0.0001 par value, 25,000,000 shares authorized of which 0 are issued and outstanding at December 31, 2021 and 18,836,115 shares of Series D-2 are issued and outstanding at December 31, 2022; aggregate liquidation preference of $87,588 at December 31, 2022	—	87,199
STOCKHOLDERS' DEFICIT		
Preferred Stock, $0.0001 par value, 75,000,000 shares authorized of which 3,364,992 shares of Series B are issued and outstanding at December 31, 2021 and 2022; 2,281,562 shares of Series B-1 are issued and outstanding at December 31, 2021 and 2022; and 1,082,852 and 0 shares of Series C are issued and outstanding at December 31, 2021 and 2022, respectively; aggregate liquidation preference of $67,873 at December 31, 2022	—	—
Common Stock, $0.0001 par value, 100,000,000 shares authorized of which 2,185,297 and 2,522,214 are issued and outstanding at December 31, 2021 and 2022, respectively	—	—
Additional paid-in capital	94,894	86,353
Accumulated other comprehensive loss	—	(8)
Accumulated deficit	(166,126)	(199,734)
TOTAL STOCKHOLDERS' DEFICIT	(71,232)	(113,389)
TOTAL LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT	$ 13,527	$ 95,572

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

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

	Years Ended December 31,	
	2021	**2022**
Revenue:		
Partnership revenue	$ (1,475)	$ 2,862
Product revenue	693	671
Total revenue	(782)	3,533
Expenses:		
Cost of product revenues	199	211
Research and development	12,890	21,945
Selling, general and administrative	7,928	14,034
Total expenses	21,017	36,190
Loss from operations	(21,799)	(32,657)
Other income (expense):		
Interest (expense) income, net	(927)	50
Gain (loss) on fair value adjustment of warrant liability	699	(1,350)
Loss on debt extinguishment	—	(682)
(Loss) gain on fair value of strategic investments	(987)	1,031
Total other expense	(1,215)	(951)
Net loss	$ (23,014)	$ (33,608)
Deemed distribution to preferred stockholders	—	(2,010)
Net loss attributable to common shareholders	$ (23,014)	$ (35,618)
Net loss per share attributable to common stockholders		
Basic and diluted	$ (10.90)	$ (14.60)
Weighted-average shares used in computing net loss per share, basic and diluted	2,111,161	2,439,450
Comprehensive loss		
Net loss	$ (23,014)	$ (33,608)
Unrealized gain (loss) on marketable securities	2	(8)
Comprehensive loss	$ (23,012)	$ (33,616)

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

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

	Preferred Stock											
	Series B		Series B-1		Series C		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance – January 1, 2021	3,364,992	$ —	2,281,562	$ —	1,082,852	$ —	2,056,497	$ —	$ 94,572	$ (2)	$ (143,112)	$ (48,542)
Unrealized gain on marketable securities	—	—	—	—	—	—	—	—	—	2	—	2
Stock-based compensation	—	—	—	—	—	—	—	—	302	—	—	302
Restricted stock vesting	—	—	—	—	—	—	119,800	—	—	—	—	—
Exercise of stock options	—	—	—	—	—	—	1,500	—	3	—	—	3
Exercise of warrants	—	—	—	—	—	—	7,500	—	17	—	—	17
Net loss	—	—	—	—	—	—	—	—	—	—	(23,014)	(23,014)
Balance – December 31, 2021	3,364,992	$ —	2,281,562	$ —	1,082,852	$ —	2,185,297	$ —	$ 94,894	$ —	$ (166,126)	$ (71,232)

	Preferred Stock											
	Series B		Series B-1		Series C		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance – January 1, 2022	3,364,992	$ —	2,281,562	$ —	1,082,852	$ —	2,185,297	$ —	$ 94,894	$ —	$ (166,126)	$ (71,232)
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	(8)	—	(8)
Stock-based compensation	—	—	—	—	—	—	—	—	3,375	—	—	3,375
Restricted stock vesting	—	—	—	—	—	—	99,529	—	—	—	—	—
Exercise of stock options	—	—	—	—	—	—	59,888	—	121	—	—	121
Exercise of warrants	—	—	—	—	—	—	157,500	—	79	—	—	79
Shares issued pursuant to consulting agreement	—	—	—	—	—	—	20,000	—	38	—	—	38
Deemed distribution to Series D-1 preferred stockholders due to modification	—	—	—	—	—	—	—	—	(2,010)	—	—	(2,010)
Shares converted to Series D-2 as a result of follow-on offering (Note 8)	—	—	—	—	(1,082,852)	—	—	—	(10,828)	—	—	(10,828)
Issuance of warrants pursuant to debt financing	—	—	—	—	—	—	—	—	178	—	—	178
Other	—	—	—	—	—	—	—	—	506	—	—	506
Net loss	—	—	—	—	—	—	—	—	—	—	(33,608)	(33,608)
Balance – December 31, 2022	3,364,992	$ —	2,281,562	$ —	—	$ —	2,522,214	$ —	$ 86,353	$ (8)	$ (199,734)	$ (113,389)

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

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

	Years Ended December 31,	
	2021	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (23,014)	$ (33,608)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	181	222
Shares issued as compensation for consulting services	—	38
Stock-based compensation	302	3,375
Deferred rent	(33)	—
(Gain) loss on fair value adjustment of warrant liability	(699)	1,350
Loss (gain) on fair value of strategic investments	987	(1,031)
Loss on debt extinguishment	—	682
Non-cash lease expense	—	571
Accretion and interest related to marketable securities	—	(600)
Amortization of deferred financing fees	217	163
Changes in operating assets and liabilities:		
Accounts receivable	47	25
Inventory	1	(208)
Prepaid expenses and other assets	29	(439)
Accounts payable, accrued expenses and other liabilities	1,078	3,352
Operating lease liabilities – current and non-current	—	(319)
Deferred revenue	1,475	(2,862)
Net cash used in operating activities	(19,429)	(29,289)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of property and equipment	(274)	(591)
Purchases of related party convertible notes	(213)	—
Purchases of marketable securities	—	(63,323)
Sales of marketable securities	13,504	—
Purchases of strategic investments	—	(208)
Net cash provided by (used in) investing activities	13,017	(64,122)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Repayment of debt financing, inclusive of debt extinguishment costs	(4,000)	(6,446)
Proceeds from Avenue term loan	—	10,000
Proceeds from exercise of warrants	4	79
Warrant repurchases	—	(10)
Proceeds from exercise of stock options	3	121
Proceeds from Series D-1 Financing	—	27,276
Proceeds from Series D-2 Financing	—	82,554
Deferred financing, offering and merger costs	—	(10,317)
Net cash (used in) provided by financing activities	(3,993)	103,257
Net (decrease) increase in cash and cash equivalents	(10,405)	9,846
Cash and cash equivalents, beginning of the period	20,343	9,938
Cash and cash equivalents, end of the period	$ 9,938	$ 19,784

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

ORCHESTRA BIOMED, INC.
Consolidated Statements of Cash Flows — (Continued)
(in thousands, except share and per share data)

Supplemental Disclosures of Cash Flow Information

	Years Ended December 31,	
	2021	**2022**
Cash paid during the year for:		
Interest	$ 389	$ 1,371
Non-cash financing activities:		
Deferred offering and merger costs in accounts payable and accrued expenses	100	1,646
Warrants issued pursuant to Series D-2 Preferred Stock	—	620
Warrants issued pursuant to debt financing	—	178
Conversion of Series C Preferred Stock to Series D-2 Preferred Stock	—	10,828

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

1. Organization and Basis of Presentation

Orchestra BioMed, Inc. ("Orchestra" or the "Company") is a biomedical innovation company seeking to provide high-impact solutions for large unmet needs in procedure-based medicine. 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 business model seeks to adapt the strategic partnering tactics widely used by the biopharmaceutical industry to the medical device market. The Company's goal is to accelerate and improve the likelihood of the Company's product candidates reaching patients and providers worldwide by sharing the risks and rewards of developing and commercializing these product candidates with established companies. The Company's flagship product candidates are Virtue Sirolimus AngioInfusion Balloon ("Virtue SAB") for the treatment of artery disease, the leading cause of mortality worldwide, and BackBeat Cardiac Neuromodulation Therapy ("BackBeat CNT") for the treatment of hypertension, a significant risk factor for death worldwide. The Company has additional product candidates in its pipeline and plans to thoughtfully expand its product pipeline in the future through acquisitions, strategic collaborations, licensing and organic development.

Orchestra was incorporated in Delaware in January 2017 and was formed to acquire operating and other assets as well as to raise capital conducted through private placements. In May 2018, Orchestra concurrently completed its formation mergers (the "Formation Mergers") with Caliber Therapeutics, Inc. ("Caliber"), a Delaware corporation, BackBeat Medical, Inc. ("BackBeat"), a Delaware Corporation, and FreeHold Surgical, Inc. ("FreeHold"), a Delaware corporation. Collectively, Orchestra, Caliber, BackBeat and FreeHold are referred to herein as Orchestra, or the "Company."

Caliber

Caliber 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, the Company entered into a distribution agreement with Terumo Medical Corporation ("Terumo") for global development and commercialization of Virtue SAB (the "Terumo Agreement") (Note 3).

BackBeat

BackBeat was incorporated in Delaware in January 2010 and began development of its lead product BackBeat CNT that same year. BackBeat CNT is a patented implantable cardiac stimulation-based treatment for hypertension that is designed to immediately, substantially and persistently lower blood pressure while simultaneously modulating autonomic nervous system responses that normally drive and maintain blood pressure higher. BackBeat is currently in a pre-revenue stage of operations. Refer to Note 4 for details regarding the Exclusive License and Collaboration Agreement, dated as of June 30, 2022, by and among, Orchestra, BackBeat Medical, LLC and Medtronic, Inc. (an affiliate of Medtronic plc) (the "Medtronic Agreement").

FreeHold

FreeHold 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. The Company generated revenue of approximately $693,000 and $671,000 during the years ended December 31, 2021 and 2022, respectively related to this legacy FreeHold Surgical, Inc. technology.

Business Combination Transaction

On January 26, 2023, the Company consummated the previously-announced transactions contemplated by the Agreement and Plan of Merger Agreement, 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, and Orchestra (the "Business Combination"). See Note 15 for additional information.

Basis of Presentation and Liquidity

The accompanying consolidated financial statements herein have been prepared by the Company in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

The Company has a limited operating history and the sales and income potential of its businesses and markets are unproven. As of December 31, 2022, the Company had an accumulated deficit of $199.7 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 biotechnology 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 December 31, 2022, as well as the proceeds received from the consummation of the Business Combination in January 2023 (Note 15), 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

Use of Estimates

The preparation of the 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 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 3).

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' deficit 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 a publicly-held company and related party (Motus GI) and preferred shares and convertible notes of a privately-held company and related party (Vivasure). 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 December 31, 2021 and 2022, the carrying value of the investments in Vivasure was $398,000 and $2.5 million, respectively.

Fair Value of Financial Instruments

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

The carrying value of the Company's cash and cash equivalents, accounts receivable, prepaid expense, accounts payable and accrued expenses approximate fair value because of the short-term maturity of these financial instruments. In addition, the Company records its investment in Motus GI, marketable securities, and warrant liabilities at fair value. In addition, at December 31, 2022, the Company believed the carrying value of debt approximates fair value as the interest rates were reflective of the rate the Company could obtain on debt with similar terms and conditions. See Note 5 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 December 31, 2021 and 2022, an allowance for doubtful accounts was not deemed necessary.

Inventory

Inventory is stated at the lower of standard cost (which approximates actual cost on a first-in, first-out basis) and net realizable value. Net realizable value represents the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The Company analyzes its inventory levels and writes down inventory that has become obsolete or has a cost basis in excess of its expected net realizable value or inventory quantities in excess of expected requirements. Excess requirements are determined based on comparison of existing inventories to forecasted sales, with consideration given to inventory shelf life. Expired inventory is disposed of, and the related costs are recognized in cost of goods sold. As of December 31, 2021 and 2022, an impairment charge as a result of obsolete inventory was not deemed necessary.

Research and Development Prepayments, Accruals and Related Expenses

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

Property and Equipment

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

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

Leases

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, *Leases (Topic 842) ("ASC 842")*, which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. On January 1, 2022, the Company adopted the new lease standard using the optional transition method under which comparative financial information will not be restated and the Company will continue to apply the provisions of the previous lease standard in its annual disclosures for the comparative periods. In addition, the new lease standard provides a number of optional practical expedients in transition. The Company elected the package of practical expedients. As such, the Company did not have to reassess whether expired or existing contracts are or contain a lease and did not have to reassess the lease classifications or reassess the initial direct costs associated with expired or existing leases.

The new lease standard also provides practical expedients for an entity's ongoing accounting. The Company elected the short-term lease recognition exemption under which the Company will not recognize right-of-use ("ROU") assets or lease liabilities for leases that are less than one year in duration. The Company elected the practical expedient to not separate lease and non-lease components for certain classes of assets (facilities).

Upon adoption on January 1, 2022, the Company recognized ROU assets of $2.6 million and lease liabilities of $2.9 million. The adoption of the new lease standard did not impact the Company's condensed consolidated statement of operations and comprehensive loss or its condensed consolidated statement of cash flows. The effect of the transition adjustment along with balances before, and after adoption is outlined below:

	Deferred lease liability	ROU Assets	Lease Liabilities
Balance – December 31, 2021	$ 241	$ —	$ —
ASC 842 Transition adjustment	(241)	2,612	2,853
Balance – January 1, 2022	$ —	$ 2,612	$ 2,853

The Company determines if an arrangement is a lease at inception. For the Company's operating leases, the ROU asset represents the Company's right to use an underlying asset for the lease term and operating lease liabilities represent an obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. Since all the lease agreements do not provide an implicit rate, the Company estimated an incremental borrowing rate in determining the present value of the lease payments. Operating lease expense is recognized on a straight-line basis over the lease term, subject to any changes in the lease or expectations regarding the terms. Variable lease costs such as operating costs and property taxes are expensed as incurred.

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 which the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset. The Company has not identified any such impairment losses to date.

Warrants

The Company evaluates its warrants to determine if the contracts qualify as liabilities in accordance with ASC 480-10, *Distinguishing Liabilities from Equity* and ASC 815, *Derivatives and Hedging*. 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 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 judgements 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 related to the Terumo Agreement as further described in Note 3. In future periods, Partnership revenues may also include revenues related to the Medtronic Agreement as discussed in Note 4.

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

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

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

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

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

The Company has determined that intellectual property licensed to Terumo and the research and development services to be provided through the premarket approval by the 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 do 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 10). 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 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 Attributable to Common Stockholders

Basic and diluted net loss attributable to common stockholders is calculated by dividing net loss attributable to common stockholders 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 attributable to common stockholders is the same as diluted net loss attributable to common stockholders since the effects of potentially dilutive securities are antidilutive. Potentially dilutive securities include all outstanding warrants, stock options, restricted stock and convertible preferred stock. 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 December 31, 2021 and 2022, the Company has recorded a full valuation allowance on its deferred tax assets.

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

Deferred Offering and Merger Costs

Offering and merger costs, consisting of legal, accounting, printer and filing fees, are deferred and will be offset against proceeds received when the financing events are completed. In the event the offering or merger is terminated, all deferred costs will be expensed. As of December 31, 2022, the Company has capitalized $4.0 million of deferred merger costs related to the Business Combination discussed in Note 15, which are included in deposits and other assets on the accompanying balance sheet. As of December 31, 2021, the Company capitalized $100,000 of deferred offering costs related to the Series D equity offerings, which was offset against the Series D-1 proceeds received in March of 2022.

Defined Contribution Plan

The Company has a defined contribution 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. The Company does not make matching employee contributions.

Comprehensive Loss

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

Segment Reporting

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

New Accounting Standards

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. During 2018 and 2019, the FASB also issued subsequent amendments to the initial guidance (collectively, "Topic 326"). Topic 326 requires organizations to measure all expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. Topic 326 will be effective for the Company on January 1, 2023. The Company is evaluating the impact that this standard will have on its consolidated financial statements.

In June 2022, the FASB issued ASU No. 2022-03 — *Fair Value Measurement (ASC 820): Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions*, which clarifies that a contractual restriction on the sale of an equity security is not considered part of the unit of account of the equity security and, therefore, is not considered in measuring fair value. The Company adopted ASU 2022-03 in the second quarter of 2022, and the adoption did not have a material impact on the consolidated financial statements.

3. Terumo Agreement

In June 2019, the Company entered into the Terumo Agreement, pursuant to which Terumo secured global commercialization rights for Virtue SAB in coronary and peripheral vascular indications (the "Terumo Indications"). Under this agreement, the Company 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 Series B-1 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%. As of the issuance date of these financial statements, the target achievement date for two $5 million milestone payments has already passed. In addition, due to delays in Orchestra'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, Orchestra is unlikely to be able to complete the remaining time-based milestones by the specified target achievement dates to earn the remaining $25 million in time-based milestone payments pursuant to the Terumo Agreement. However, in June 2022, Orchestra and Terumo signed a letter agreement whereby the parties agreed to negotiate in good faith over 12 months mutually agreeable adjustments to certain target achievement dates to reflect the regulatory and pandemic-related delays. There is no assurance as to the outcome of these negotiations with respect to any potential modifications to the milestone target achievement dates. Pursuant to the terms of the Terumo Agreement, the Company licensed intellectual property rights to Terumo and the Company shall be primarily responsible for completing the development of the product in the United States through premarket approval by the FDA for the in-stent restenosis ("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, the Company 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 the Company'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 December 31, 2021 and 2022, as the achievement of such milestone payments are uncertain and highly susceptible to factors outside of the Company's control. The Company plans to re-evaluate the transaction price at each reporting period and as uncertain events are resolved or other changes in circumstances occur. In addition, the arrangement also includes sales-based royalties on product sales by Terumo subsequent to commercialization ranging from 10 — 15%, none of which have been recognized to date.

The Company recorded the $30 million upfront payment received from Terumo in 2019 within deferred revenue. The following table presents the changes in the Company's deferred revenue balance from the Terumo Agreement during the years ended December 31, 2021 and 2022:

Deferred Revenue – January 1, 2021 (in thousands)	$	20,926
Revenue reduction		1,475
Deferred Revenue – December 31, 2021	$	22,401
Revenue recognized		(2,862)
Deferred Revenue – December 31, 2022	$	19,539

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 December 31, 2022. The Company expects to recognize approximately $6.4 million of its deferred revenue during the next twelve months and recognize the remaining approximately $13.1 million through the remainder of the performance period, which is estimated through 2026.

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 years ended December 31, 2021 and 2022, the expenses incurred related to the Terumo Agreement were approximately $9.9 million and $14.3 million, respectively. The estimated total costs associated with the Terumo Agreement through completion increased by approximately 85% as of December 31, 2021 as compared to the estimates as of December 31, 2020, and increased by approximately 10% as of December 31, 2022, as compared to the estimates as of December 31, 2021. The increase in the estimated costs relates to an extension of the estimated performance period by twelve months, due in part by delays resulting from the COVID-19 pandemic, as well as 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, that caused the Company to amend its original project plan. 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 reduction of partnership revenues of $6.5 million and $1.0 million for the years ended December 31, 2021 and 2022, respectively, as compared to the amounts that would have been recorded based on the previous estimates. The impact of these changes in estimates on the net loss per share attributable to common stockholders, basic and diluted, was an increase of $3.06 and $0.43 for the years ended December 31, 2021 and 2022, respectively.

Orchestra will also manufacture, or have manufactured, SirolimusEFR and have 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 December 31, 2022, 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.

4. Medtronic Agreement

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

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

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

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

The Company assessed whether the Medtronic Agreement fell within the scope of ASC 808 and concluded that the Medtronic Agreement fell 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 Orchestra. The Company will record such expenses as research and development expenses as incurred. During the year ended December 31, 2022, the Company incurred approximately $1.7 million of research and development costs related to these reimbursements to the Medtronic Agreement, all of which is included within accounts payable and accrued expenses in the December 31, 2022 consolidated balance sheet.

Concurrently with the close of the Medtronic Agreement, Orchestra also received a $40 million investment from Medtronic in connection with the 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 December 31, 2022, there have been no amounts recognized as revenue under the Medtronic Agreement.

5. 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:

	December 31, 2021			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets				
Investment in Motus GI (see Note 6)	$ 958	$ —	$ —	$ 958
Total assets	$ 958	$ —	$ —	$ 958
Liabilities:				
Warrant liability (see Note 9)	$ —	$ —	$ 635	$ 635
Total liabilities	$ —	$ —	$ 635	$ 635

	December 31, 2022			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets				
Investment in Motus GI (see Note 6)	$ 86	$ —	$ —	$ 86
Marketable securities (Corporate and Government debt securities)	—	63,915	—	63,915
Total assets	$ 86	$ 63,915	$ —	$ 64,001
Liabilities:				
Warrant liability (see Note 9)	$ —	$ —	$ 2,089	$ 2,089
Total liabilities	$ —	$ —	$ 2,089	$ 2,089

The Company's warrant liability is measured at fair value on a recurring basis using unobservable inputs and are classified as Level 3 inputs, and any change in fair value is recognized as change in fair value of warrant liability in the consolidated statements of operations and comprehensive loss. Refer to Note 9 for the valuation technique and assumptions used in estimating the fair value of the warrants.

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.

6. Marketable Securities and Strategic Investments

Marketable Securities

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

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

As of December 31, 2021, there were no marketable securities held. For the years ended December 31, 2021 and 2022, the Company did not recognize any realized gains or losses on its marketable securities.

Strategic Investments

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

Aggregate losses of $1.0 million and $0.9 million during the years ended December 31, 2021 and 2022, respectively, were recorded to adjust the strategic investments in equity securities of Motus GI to its fair value of $1.0 million at December 31, 2021 and $86,000 at December 31, 2022, which is classified as strategic investments within current assets on the accompanying consolidated balance sheet.

The Company's long term strategic investments as of December 31, 2022 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 year ended December 31, 2021 related to these investments.

In May 2022, Vivasure announced a Series D private placement, in which it received a material investment from a new strategic investor. As a result, the Company'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.

7. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consists of the following:

	December 31,	
(in thousands)	**2021**	**2022**
Equipment	$ 1,207	$ 1,712
Office furniture	305	364
Leasehold improvements	177	191
Construction in progress	16	—
Property and equipment, gross	1,705	2,267
Less accumulated depreciation and amortization	(585)	(778)
Total Property and equipment, net	$ 1,120	$ 1,489

Depreciation and amortization expense was $181,000 and $222,000 for the years ended December 31, 2021 and 2022, respectively.

Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
(in thousands)	**2021**	**2022**
Accrued compensation	$ 1,319	$ 2,480
Deferred offering and merger costs	100	—
Deferred lease liability	45	—
Clinical trial accruals	39	1,003
Other accrued expenses	531	1,893
Total accrued expenses	$ 2,034	$ 5,376

8. Preferred Stock

As of December 31, 2022, the Company is authorized to issue 75,000,000 shares of $0.0001 par value preferred stock with such designations, rights and preferences as may be determined by the Board of Directors. Of the authorized preferred stock, 20,000,000 shares have been designated as Series A Preferred Stock, 4,200,000 shares have been designated as Series B Preferred Stock, 2,800,000 shares have been designated as Series B-1 Preferred Stock, 15,000,000 shares have been designated as Series C Preferred Stock, 6,100,000 shares have been designated as Series D-1 Preferred Stock, and 25,000,000 shares have been designated as Series D-2 Preferred Stock.

The activity for the Series A Preferred Stock, Series D-1 Preferred Stock and Series D-2 Preferred Stock reported in mezzanine equity on the balance sheets of the Company is shown:

	Series A		Series D-1		Series D-2	
(in thousands, except share data)	**Shares**	**Amount**	**Shares**	**Amount**	**Shares**	**Amount**
Balance at December 31, 2021	5,346,570	$ 51,452	—	—	—	—
Shares issued in a private placement	—	—	2,424,573	$ 25,262	17,753,263	$ 76,371
Extinguishment of Series D-1 Preferred Stock	—	—	(2,424,573)	—	—	—
Shares issued as a result of Series D-1 modification	—	—	5,864,940	2,010	—	—
Conversion of Series C to Series D-2 at closing of follow-on offering	—	—	—	—	1,082,852	$ 10,828
Balance at December 31, 2022	5,346,570	$ 51,452	5,864,940	$ 27,272	18,836,115	$ 87,199

The price per share for conversion into common shares for the Series A, Series B, and Series C Preferred Stock is $10.00, subject in the case of the Series A Preferred Stock to standard anti-dilution adjustments until the second quarter of 2022. The price per share for conversion for Series B-1 Preferred Stock is $15.00. The Series B, Series B-1 and Series C Preferred Stock do not have an anti-dilution adjustment. The price per share for conversion for Series D-1 and Series D-2 Preferred Stock is $4.65, and the Series D-1 and Series D-2 Preferred Stock do not have anti-dilution adjustment provisions.

In January 2022, the Company initiated a Series D Preferred Stock financing comprised of Series D-1 and Series D-2 Preferred Stock. In March 2022, the Company closed on the Series D-1 Preferred Stock over two closings and issued 2,424,573 shares of Series D-1 Preferred Stock, receiving gross proceeds of approximately $27.3 million. Each share of Series D-1 Preferred Stock is convertible into 1.1 shares of common stock. In connection with the Series D-1 Preferred Stock financing, the Company incurred approximately $2.0 million in offering costs.

In June 2022, the Company closed the Series D-2 Preferred Stock financing and modified certain provisions of the Series A Preferred Stock, Series B Preferred Stock, Series B-1 Preferred Stock, and Series D-1 Preferred Stock. The Company issued 17,753,263 shares of Series D-2 Preferred Stock, receiving gross proceeds of approximately $82.6 million inclusive of a $40 million investment from Covidien Group S.à.r.l., an affiliate of Medtronic plc. In connection with the Series D-2 Preferred Stock financing, the Company incurred $6.2 million of offering costs.

To evaluate whether the changes to the terms of the preferred stock should be accounted for as a modification or extinguishment, the Company follows the qualitative approach, in which amendments to preferred shares are analyzed based on the expected economics as well as the business purpose of the amendment. In June 2022, the Company agreed to reduce the price of the Series D-1 Preferred Stock to $4.65 per share, which the Company determined represented an extinguishment for accounting purposes of the original 2,424,573 shares and the issuance of 5,864,940 shares issued to the Series D-1 holders, given the significance of the changes as a result of the amendment. Upon extinguishment and subsequent reissuance of the Series D-1 Preferred Stock, the difference between the prior carrying value and the fair value of $4.65 per share at the date of extinguishment was recorded as a deemed distribution to preferred stockholders in the amount of $2.0 million. The conversion ratio of Series D-1 Preferred Stock to common stock of the Company remained 1.1 to 1. In addition, the Company amended the liquidation preference of the Series D-1 Preferred Stock to establish a participating preferred feature for the Series D-1 Preferred Stock. The other amendments to the Series B Preferred Stock Certificate of Designations, and the Series B-1 Preferred Stock Certificate of Designations, together with the holders of the Series A Preferred Stock waiving their anti-dilution protection, were not deemed to be significant and were therefore accounted for as modifications. As a result of these amendments, all of the series of Preferred Stock automatically converted to common stock upon the closing of the Business Combination.

The Series D Preferred Stock offering qualified as a Follow-on Offering as contemplated by the Series B Preferred Stock Certificate of Designations, the Series B-1 Certificate of Designations, the Series C Certificate of Designations and certain warrant agreements. As such, each holder of Series B Preferred Stock and Series B-1 Preferred Stock that invested 100% of its original investment in the Series B Preferred Stock or B-1 Preferred Stock in the Series D Preferred Stock offering received an adjustment to the conversion ratio on each share of their Series B Preferred Stock and/or Series B-1 Preferred Stock, such that each share is now convertible into two shares of common stock.

Additionally, all Series C Preferred Stock converted to Series D-2 Preferred Stock on a 1 to 1 basis upon the closing of the Series D-2 Preferred Stock financing and was accounted for by reducing additional paid-in-capital by the original carrying value of the Series C Preferred Stock. The Company issued an additional 344,011 Series B/B-1 common stock warrants to individuals affiliated with the placement agent. These additional warrants were recorded at fair value as a reduction to the proceeds received from the Series D-2 Preferred Stock financing.

The Company recorded its convertible preferred stock at fair value on the dates of issuance, net of issuance costs.

As of December 31, 2021, the Company classified its Series B Preferred Stock, Series B-1 Preferred Stock, and Series C Preferred Stock in stockholders' deficit. As of December 31, 2022, the Company classified its Series B Preferred Stock and Series B-1 Preferred Stock in stockholders' deficit. As of December 31, 2021, the Company classified its Series A Preferred Stock outside of stockholders' deficit in temporary equity. As of December 31, 2022, the Company classified its Series A, Series D-1 and Series D-2 Preferred Stock outside of stockholders' deficit in temporary equity. In the event of certain "Deemed Liquidation Events" (as defined below) that are not solely within the control of the Company, the shares of the Series A, Series D-1 and Series D-2 Preferred Stock would become redeemable at the option of the holders and therefore are classified as temporary equity. As of December 31, 2021, the Company did not adjust the carrying value of the Series A Preferred Stock, and as of December 31, 2022, the Company did not adjust the carrying values of the Series A, Series D-1 or Series D-2 Preferred Stock, to the deemed liquidation values of such shares since a Deemed Liquidation Event was not considered probable at the consolidated balance sheet dates. Subsequent adjustments to increase or decrease the carrying values to the ultimate liquidation values will be made if, and when, it becomes probable that such a Deemed Liquidation Event will occur.

		December 31,	
	Shares	2021	2022
(in thousands, except share data)	Designated	Liquidation Preference	
Series A	20,000,000	$ 53,466	$ 53,466
Series B	4,200,000	33,650	33,650
Series B-1	2,800,000	34,223	34,223
Series C	15,000,000	10,828	—
Series D-1	6,100,000	—	27,272
Series D-2	25,000,000	—	87,588
Total	73,100,000	$ 132,167	$ 236,199

The holders of the Preferred Stock have the following rights, privileges and preferences:

Optional Conversion Rights — Series A

Each share of Series A Preferred Stock is convertible at the option of the holder into the number of shares of common stock determined by dividing the original issue price by the applicable conversion price. The original issue price per share and the initial conversion price per share is $10.00. As of December 31, 2022, Series A Preferred Stock will convert on a one-for-one basis into common stock. The original issue price and conversion price per share for the Series A Preferred Stock shall be adjusted for certain recapitalizations, splits, combinations, stock dividends or as set forth in the Company's amended and restated certificate of incorporation. At December 31, 2021 and 2022, none of the Series A Preferred Stock had been converted into common stock.

Automatic Conversion Rights

Each outstanding share of Series A Preferred Stock, Series B Preferred Stock, Series B-1 Preferred Stock, Series D-1 Preferred Stock and Series D-2 Preferred Stock shall automatically be converted into shares of common stock at the then effective conversion rate for such shares upon the closing of the sale of shares of common stock in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended (the "Securities Act") resulting in at least $16 million of gross proceeds to the Company.

Both the Series B Preferred Stock and the Series B-1 Preferred Stock (collectively, the "Series B/B-1 Preferred Stock") share an innovative conversion feature. In the event of a follow-on offering of at least $8 million, excluding amounts invested attributable to holders exercising their preemptive rights, a holder of Series B/B-1 Preferred Stock is entitled to an adjustment to their conversion ratio to a 1:2 basis (i.e., one share of Series B Preferred Stock or Series B-1 Preferred Stock will be convertible into two shares of common stock) if such investor invests at least 100% of its original investment in the initial offerings of Series B Preferred Stock or Series B-1 Preferred Stock in the follow-on offering (the "Conversion Rate Adjustment"). If a holder of Series B/B-1 Preferred Stock invest less than 100% of its original investment in a follow-on offering, there is no adjustment to the holder's conversion ratio. Notwithstanding the foregoing, persons that received equal amounts of Series B Preferred Stock and Series C Preferred Stock in the Formation Mergers in exchange for convertible bridge notes of Caliber, BackBeat and/or FreeHold will receive the Conversion Rate Adjustment with respect to those shares of Series B Preferred Stock received in the Formation Mergers without having to invest in such follow-on offering upon the conversion of their corresponding shares of Series C Preferred Stock into the securities sold in such follow-on offering. As a result of the Series D-2 Preferred Stock offering in June 2022, certain holders of Series B Preferred Stock who hold the Conversion Rate Adjustment right are entitled to an additional 2,586,546 common shares upon a future conversion, and certain holders of Series B-1 Preferred Stock who hold the Conversion Rate Adjustment right are entitled to an additional 1,682,783 common shares upon a future conversion. In addition, since the Series D-2 Preferred Stock offering qualified as a follow-on offering, the Series C Preferred Stock converted to Series D-2 Preferred Stock, which was recorded to mezzanine equity upon the date of conversion.

Series B Preferred Stock, Series B-1 Preferred Stock, Series D-1 Preferred Stock and Series D-2 Preferred Stock shall automatically be converted into shares of common stock at the then effective conversion rate for such shares upon the earlier of (i) the closing of the sale of shares of common stock to the public in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act, resulting in at least $16,000,000 of gross proceeds to the Company, (a "Qualified IPO") (ii) immediately prior to the consummation of a business combination transaction involving the Company and/or any direct or indirect parent company thereof and a publicly traded U.S. domestic special purpose acquisition company or other similar U.S. domestic corporation that is a "blank check" company under applicable U.S. securities laws and formed for the purpose of effecting such a transaction (such transaction, an "Initial Business Combination"), which such Initial Business Combination has been approved by the Board of Directors of the Company, or (iii) immediately prior to the consummation of a business combination transaction involving the Company and/or any direct or indirect parent company thereof with any public company listed on a U.S. securities exchange which such transaction would not qualify as a Deemed Liquidation Event under, and as defined in, the Certificate of Incorporation (such transaction, a "Standard Public Merger"), which such Standard Public Merger is approved by the Board of Directors of the Company. Each outstanding share of Series A Preferred Stock shall automatically be converted into shares of common stock at the then effective conversion rate for such shares upon the earlier of (x) a Qualified IPO and (y) the date and time, or the occurrence of an event (a "Series A Mandatory Conversion Event"), specified by vote or written consent of the holders of at least a majority of the then outstanding shares of Series A Preferred Stock (the "Series A Majority Vote"). Holders of Series A Preferred Stock in sufficient number to satisfy the Series A Majority Vote entered into support agreements obligating them to consent to and approve the Business Combination, such that the Business Combination would be a Series A Mandatory Conversion Event and all shares of Series A Preferred Stock would convert into shares of common stock immediately prior to the closing of the Business Combination. The Series D-1 Preferred Stock converts on a 1:1.1 basis (i.e., one share of Series D-1 Preferred Stock will be convertible into 1.1 shares of common stock).

Series A Preferred Stock and Series D-2 Preferred Stock convert on a 1:1 basis (i.e., one share of Series A Preferred Stock or Series D-2 Preferred Stock, as applicable, will be convertible into one share of common stock). Certain shares of Series B Preferred Stock and Series B-1 Preferred Stock convert on a 1:1 basis and certain others convert on a 1:2 basis (i.e., one share of Series B Preferred Stock or Series B-1 Preferred Stock, as applicable, will convert into two shares of common stock).

Liquidation Rights

In the event of any liquidation, dissolution or winding-up of the Company, the holders of the Series B Preferred Stock, Series B-1 Preferred Stock, Series D-1 Preferred Stock and Series D-2 Preferred Stock are entitled to liquidation preferences, on a pari passu basis and before any payment shall be made to the holders of Series A Preferred Stock or common stock, in an amount (on a per share basis) equal to, in the case of the Series B Preferred Stock the stated value of $10.00 per share, in the case of the Series B-1 Preferred Stock the stated value of $15.00 per share, in the case of the Series D-1 Preferred Stock the stated value of $4.65 per share, and in the case of the Series D-2 Preferred Stock the stated value of $4.65 per share (each series subject to adjustments for stock splits, stock dividends, combinations or other recapitalizations). Additionally, the holders of the Series A Preferred Stock are entitled to receive a distribution before any payment shall be made to the holders of common stock in an amount equal to the original issue price of $10.00 per share, as adjusted, plus any dividends declared but unpaid thereon. After the payment or setting aside for payment to the holders of the Series A Preferred Stock, Series B Preferred Stock, Series B-1 Preferred Stock, Series D-1 Preferred Stock, and Series D-2 Preferred Stock, then any remaining assets would be distributed among all holders of preferred stock and common stock on a pro-rata basis based on the number of shares held by each holder, treating for this purpose all preferred stock as if it had been converted to common stock immediately prior to such liquidation, dissolution or winding-up.

If the assets of the Company available for distribution to holders of Series B Preferred Stock, Series B-1 Preferred Stock, Series D-1 Preferred Stock and Series D-2 Preferred Stock are insufficient to permit payment in full to such holders of the sums which such holders are entitled to receive in such case, then all of the assets available for distribution to holders of the Series B Preferred Stock, Series B-1 Preferred Stock, Series D-1 Preferred Stock, and Series D-2 Preferred Stock shall be distributed among and paid to such holders ratably in proportion to the amounts that would have been payable to such holders if sufficient assets existed to allow payment in full. If the assets of the Company available for distribution to holders of Series B Preferred Stock, Series B-1 Preferred Stock, Series D-1 Preferred Stock and Series D-2 Preferred Stock are sufficient to permit payment in full to such holders of the sums which such holders are entitled to receive in such case, any remaining assets available for distribution shall be distributed to holders of Series A Preferred Stock next until paid in full. If the assets of the Company available for distribution to holders of Series A Preferred Stock are insufficient to permit payment in full to such holders of the sums which such holders are entitled to receive, then all of the assets available for distribution to holders of the Series A Preferred Stock shall be distributed among and paid to such holders ratably in proportion to the amounts that would have been payable to such holders if sufficient assets existed to allow payment in full. If the assets of the Company available for distribution to holders of Series A Preferred Stock are sufficient to permit payment in full to such holders of the sums which such holders are entitled to receive in such case, then any remaining assets available for distribution would be distributed among the holders of all shares of preferred stock and common stock on a pro-rata basis based on the number of shares held by each holder, treating for this purpose all such preferred stock as if it had been converted to common stock immediately prior to such liquidation, dissolution or winding-up.

A Deemed Liquidation Event is defined as including (i) a merger or consolidation in which the Company or a subsidiary of the Company is a party and the Company issues shares of its capital stock pursuant to such merger or consolidation, except any such transaction involving the Company or a subsidiary in which the shares of capital stock of the Company outstanding immediately prior to such transaction continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such transaction, at least a majority, by voting power, of the capital stock of the surviving or resulting entity, or if the surviving or resulting entity is a wholly owned subsidiary of another corporation immediately following such transaction, the parent corporation of such surviving corporation; or (ii) a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company or any of its subsidiaries taken as a whole, or the sale or disposition of one or more subsidiaries of the Company if substantially all of the assets of the Company and its subsidiaries are held by such subsidiary, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the Company.

Dividend Rights

The Company shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Company (other than dividends on the shares of common stock payable in shares of common stock) unless the holders of the Series A Preferred Stock then outstanding shall first receive a dividend on each outstanding share of Series A Preferred Stock in an amount as set forth in the amended and restated certificate of incorporation. The holders of Series B Preferred Stock, B-1 Preferred Stock, Series D-1 Preferred Stock and Series D-2 Preferred Stock are not entitled to receive dividends. No dividends have been declared to date.

Voting Rights

The holders of Preferred Stock are entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote. Each preferred stockholder is entitled to the number of votes equal to the number of shares of common stock into which each preferred share is convertible at the time of such vote.

As long as any shares of Preferred Stock are outstanding, the Company may not take any of the actions specified in the protective provision section of the amended and restated certificate of incorporation without the written consent or affirmative vote of the holders of at least fifty percent (50%) of the then outstanding shares of Preferred Stock.

In addition, as long as any shares of any particular series of Preferred Stock are issued and outstanding, the Company may not, without the written consent or affirmative vote of holders of a majority of the then outstanding shares of such series, amend, alter or repeal any provision of the applicable Certificate of Designations for such preferred stock series.

9. Warrants

The Company evaluates its outstanding warrants to determine if the instruments qualify for equity or liability classification. To date, the majority of the Company's warrants are required to be accounted for as liabilities, and therefore, the fair value of the warrant liability is marked-to-market at each balance sheet date, with the change in fair value recorded in the statements of operations and comprehensive loss within other income (expense). Upon conversion or exercise of a warrant classified as a liability, the instrument is marked to fair value at the conversion date and then that fair value is reclassified to equity.

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 Orchestra's warrant liability are as follows:

	December 31,	
	2021	**2022**
Expected volatility	44 – 55%	45 – 47%
Risk-free interest rate	0.27 – 1.11%	4.00 – 4.30%
Remaining term in years	1.41 – 7.94	0.14 – 5.07
Exercise price of common warrants	$0.50 – $14.00	$0.50 – $14.00
Exercise price of preferred warrants	$9.00 – $15.00	—
Common stock price	$1.56	$4.52
Preferred stock price	$2.50 – $3.42	—
Expected dividend yield	0%	0%

The Company's warrant liability activity rollforward is as follows:

(in thousands, except share data)	Preferred Warrants	Common Warrants	Amount
Balance December 31, 2020	445,155	2,564,838	$ 1,347
Exercise of warrants	—	(7,500)	(13)
Change in the fair value of warrants	—	—	(699)
Balance December 31, 2021	445,155	2,557,338	$ 635
Reclassification of warrant liability upon exercise	—	(157,500)	(171)
Forfeiture of warrants	—	(10,000)	(38)
Issuance of warrants related to preferred stock financing	—	344,011	620
Amendment of existing warrants	(445,155)	445,155	810
Other	—	(325,081)	(345)
Change in the fair value of warrants	—	—	578
Balance December 31, 2022	—	2,853,923	$ 2,089

In June 2022, concurrent with the close of the Series D-2 Preferred Stock financing, the Company amended the terms of certain existing warrant agreements, which included modifying the underlying shares of the warrants from preferred warrants to common warrants and reducing the strike prices. Such amendments resulted in $0.8 million of additional expense for the year ended December 31, 2022.

As of December 31, 2022, the Company has 537,635 warrants classified within equity with strike prices ranging from $0.62 — $1.89 and remaining terms in years of 6.94 — 9.50. The equity classified warrants were recorded within additional paid-in capital at the time of issuance at fair value and are not subject to subsequent remeasurement.

10. Stock-Based Compensation

Stock-based Compensation — Orchestra BioMed 2018 Stock Incentive Plan

As of December 31, 2022, all stock-based awards were outstanding under a single equity incentive plan, the Orchestra BioMed, Inc. 2018 Stock Incentive Plan (the "Plan"). Under the Plan, up to 5.2 million shares of the Company's common stock may be issued pursuant to awards granted in the form of nonqualified stock options, restricted and unrestricted stock awards, and other stock-based awards. Employees, consultants, and directors are eligible for awards granted under the 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 of directors. Vesting generally occurs over a period of not greater than three years.

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

	Year ended December 31,	
(in thousands)	**2021**	**2022**
Research and development	$ 83	$ 398
Selling, general and administrative	88	2,704
Total stock-based compensation	$ 171	$ 3,102

As of December 31, 2022, there was approximately $7.2 million of unrecognized stock-based compensation expense associated with the stock options noted above that is expected to be recognized over a weighted average period of three years.

Total restricted stock-based compensation was as follows:

	Year ended December 31,	
(in thousands)	**2021**	**2022**
Research and development	$ —	$ —
Selling, general and administrative	131	273
Total stock-based compensation	$ 131	$ 273

As of December 31, 2022, there was approximately $408,000 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 3 years.

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

	Shares Underlying Options	Weighted Average Exercise Price	Weighted Average Remaining Term (years)	Aggregate Intrinsic Value (thousands)
Outstanding at January 1, 2022	2,899,923	2.08	7.13	—
Granted	5,070,552	4.34	—	—
Exercised	(59,888)	2.01	—	—
Forfeited/canceled	(42,139)	2.17	—	—
Outstanding December 31, 2022	7,868,448	3.51	8.35	$ 8,277
Exercisable at December 31, 2022	3,884,072	2.69	6.72	$ 6,815

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

	Restricted Stock Outstanding	Weighted Average Remaining Term (years)	Aggregate Intrinsic Value (thousands)
Outstanding January 1, 2022	47,111	7.60	—
Granted	393,465	9.15	—
Vested	(99,529)	—	—
Forfeited/canceled	—	—	—
Outstanding December 31, 2022	341,047	9.14	$ 980

During the year ended December 31, 2022, the Company granted 393,465 restricted stock awards (“RSAs”) at a weighted-average grant date fair value of $1.68 while 99,529 RSAs vested at a weighted-average grant date fair value of $1.45.

Determination of 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:

	Year ended December 31,	
	2021	2022
Expected term (in years)	6.00	6.00
Expected volatility	60%	50%
Risk-free interest rate	0.99%	3.01%
Expected dividend yield	0%	0%
Fair value of common stock	$ 2.19	$ 4.52

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

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

Expected Volatility — The expected volatility was derived from the historical stock volatilities of comparable peer public companies within the Company's industry that are considered to be comparable to the Company's business over a period equivalent to the expected term of the stock-based awards since there has been no trading history of the common stock.

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

Expected Dividend Yield — The expected dividend yield is zero as the Company has not paid nor does it anticipate paying any dividends on its common stock in the foreseeable future.

Fair Value of Common Stock — As the Company's 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.

11. Leases

Office Lease

In August 2019, the Company entered into an addendum to the original December 2009 lease agreement for 8,052 square feet of office space in New Hope, PA. The lease will expire in September 2024. Monthly fees will be between $9,000 and $19,000 for the period from commencement through termination.

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

In January 2020, the Company 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 termination.

In May 2022, the Company 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 year ended December 31, 2022:

An initial right-of-use asset of $2.6 million was recognized as an asset and operating lease liabilities of $2.9 million was recognized as a liability upon the adoption of the new lease standard. Cash paid for amounts included in the present value of operating lease liabilities was $702,000 during the year ended December 31, 2022.

As of December 31, 2022:	
Weighted average remaining lease term – operating leases, in years	4.06
Weighted average discount rate – operating leases	6.25%

Operating Leases

Rent/lease expense for office and lab space was approximately $697,000 and $735,000 for the years ended December 31, 2021 and 2022 respectively. The table below shows the future minimum rental payments, exclusive of taxes, insurance and other costs, under the leases as of December 31, 2022:

Year ending December 31:	Operating Leases (in thousands)
2023	$ 823
2024	727
2025	352
2026	352
2027	352
Thereafter	88
Total future minimum lease payments	$ 2,694
Imputed interest	(314)
Total liability	$ 2,380

12. Income Taxes

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company's deferred tax assets relate primarily to its net operating loss carryforwards and other balance sheet basis differences. In accordance with ASC 740, *Income Taxes*, the Company recorded a valuation allowance to fully offset the gross deferred tax asset, because it is not more likely than not that the Company will realize future benefits associated with these deferred tax assets at December 31, 2021 and 2022.

The change in the valuation allowance for the years ended December 31, 2021 and 2022 was an increase of $7.2 million and $8.8 million, respectively.

In general, the U.S. Federal and state income tax returns remain open to examination by taxing authorities for tax years beginning in 2018 to present. However, if the Company claims net operating loss ("NOL") carryforwards from years prior to 2018 against future taxable income, the tax returns pertaining to those losses may be examined by the taxing authorities.

The components of the deferred tax assets are as follows:

	December 31,	
(in thousands)	2021	2022
Deferred tax assets		
Net operating loss carryovers – Federal	$ 19,936	$ 22,798
Net operating loss carryovers – State	5,640	4,811
Unrealized loss on equity securities	2,415	2,913
Research and development credits	2,300	3,149
Loss on impairment of strategic investments	1,449	1,177
Research and experimental costs	—	4,973
Other	552	1,478
Lease liability	—	629
Deferred revenue	5,353	5,166
Total deferred tax assets	37,645	47,094
Less: valuation allowance	(37,630)	(46,457)
Total deferred tax assets	15	637
Deferred tax liabilities		
Right-of-use asset	—	(578)
Depreciation and amortization	(15)	(59)
Total deferred tax liabilities	(15)	(637)
Total net deferred tax asset	$ —	$ —

Reconciliation of the statutory federal income tax to the Company's effective tax is as follows:

	December 31,	
	2021	2022
Income tax benefit at federal statutory rate	21.0%	21.0%
State and local income tax (net of Federal benefit)	7.2%	4.8%
Permanent items	0.6%	(0.9)%
Research and development credits	1.9%	3.1%
Research and development, uncertain tax positions	(0.4)%	(0.6)%
Change in valuation allowance	(31.2)%	(26.2)%
Effect of rate changes	—%	(1.2)%
True-ups	0.9%	—%
Other	—%	—%
Effective tax rate	—%	—%

The Company had approximately $108.6 million and $88.0 million of gross NOL carryforwards (Federal and state, respectively) and approximately $3.1 million of Federal research and development tax credits, respectively, as of December 31, 2022, after applying Section 382 and Section 383 limitations. The federal net operating losses for years ending on or before December 31, 2017 start to expire from 2027 to 2037. The federal net operating losses generated after the year ended December 31, 2017 have an indefinite carryforward period, subject to 80% taxable income limitation on an annual basis. Certain state net operating losses start to expire in 2027, and certain states have an indefinite carryforward period. The federal research and development ("R&D") tax credit starts to expire from 2028 to 2042.

The NOL carryforwards and R&D tax credits are available to reduce future taxable income. However, Sections 382 and 383 of the Internal Revenue Code, and similar state regulations, contain provisions that may limit the NOL carryforwards and R&D tax credits available to be used to offset income in any given year upon the occurrence of certain events, including changes in the ownership interests of significant stockholders. In the event of a cumulative change in the ownership interest of significant stockholders in excess of 50% over a three-year period, the amount of the NOL carryforwards and R&D tax credits that the Company may utilize in any one year may be limited. In 2019, the Company completed Section 382 and Section 383 studies. As a result of these studies, the federal net operating loss and federal R&D tax credit carryforwards were reduced to reflect the amounts that are estimated to not be limited under the provisions of Sections 382 and 383. In 2019, the Company performed an analysis of the impact of ownership changes on state net operating loss carryforwards and provisional amounts were recorded within the income tax provision.

The Tax Cuts and Jobs Act resulted in significant changes to the treatment of research and experimental expenditures under Section 174. For tax years beginning after December 31, 2021, taxpayers are required to capitalize and amortize these expenditures that are paid or incurred in connection with their trade or business. Specifically, costs for U.S.-based research and experimental activities must be amortized over five years and costs for foreign research and experimental activities must be amortized over 15 years—both using a midyear convention. During the year ended December 31, 2022, the Company recorded a deferred tax asset of $5.0 million for such costs.

In assessing the realizability of the net deferred tax asset, the Company considers all relevant positive and negative evidence in determining whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the net operating loss carryforwards. Management believes it is more likely than not that the Company's deferred income tax assets will not be realized. As such, the Company has provided a 100% valuation allowance on its net deferred tax assets as of December 31, 2021 and 2022.

Following is a reconciliation of beginning and ending balances of total amounts of gross unrecognized tax benefits:

	December 31,	
(in thousands)	**2021**	**2022**
Unrecognized tax benefits		
Unrecognized tax benefits at the beginning of the period	$ 481	$ 572
Additions due to current year activity	111	203
Other reductions	(20)	—
Unrecognized tax benefits at the end of the period	$ 572	$ 775

The total liabilities associated with the unrecognized tax benefits that, if recognized, would impact the Company's effective tax rate were $572,000 and $775,000 at December 31, 2021 and 2022, respectively. It is not anticipated that the balance of unrecognized tax benefits at December 31, 2022 will change significantly over the next twelve months. The balance of unrecognized tax benefits as reflected in the table above are recorded on the balance sheet as a reduction to the related deferred tax asset in accordance with ASU 2013-11.

The Company's policy is to recognize interest accrued and, if applicable penalties related to unrecognized tax benefits in income tax expense for all periods presented. No interest or penalties were recognized during 2021 or 2022.

On December 27, 2020, the Consolidated Appropriations Act 2021 (the "Appropriations Act") was enacted in response to the COVID-19 pandemic. The Appropriations Act, among other things, temporarily extends through December 31, 2025, certain expiring tax provisions. Additionally, the Appropriations Act enacts new provisions and extends certain provisions originated within the Coronavirus Aid, Relief, and Economic Security Act, enacted on March 27, 2020. The accounting is now complete. On March 11, 2021, the American Rescue Plan ("ARP") was signed into law. Management has evaluated the impact of the law and does not expect the ARP would result in any tax or cash benefits.

On August 16, 2022, the Inflation Reduction Act of 2022 ("IRA") was signed into law. The IRA made several changes to the U.S. tax code effective after December 31, 2022, including, but not limited to, a 15% minimum tax on large corporations with average annual financial statement income of more than $1 billion for a three tax-year period and a 1% excise tax on public company stock buybacks, which will be accounted for in treasury stock. We do not expect these changes to have a material impact on our provision for income taxes or financial statements.

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 and executive officers during 2021 and 2022:

Vivasure Investments

In December 2020 and 2021, and April 2022, the Company 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 6).

14. Debt Financing

In December 2019, the Company entered into a Loan and Security Agreement with Silicon Valley Bank (the "2019 Loan and Security Agreement"). The terms of the 2019 Loan and Security Agreement include a term loan of $20 million available in two tranches. The first $10 million tranche is available to the Company with interest-only monthly payments during a 12-month draw period from December 2019 through December 31, 2020. On December 31, 2020, the Company borrowed the first $10 million tranche of the 2019 Loan and Security Agreement.

Pursuant to the terms of the 2019 Loan and Security Agreement, the Company issued Silicon Valley Bank a warrant that, to the extent the Company draws on the 2019 Loan and Security Agreement, will be exercisable for a number of shares of common stock equal to 2% of the amount drawn under the 2019 Loan and Security Agreement divided by the exercise price of $0.62 per share. As a result of the draw in December of 2020, the Company issued 322,581 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 is being amortized to interest expense over the term of the credit facility.

The term loan accrues 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 is a final payment equal to 8.25% of the original aggregate principal amount which will be accrued over the term of the loan using the effective-interest method.

The term loan is secured by all of the Company's assets, excluding intellectual property and certain other assets. The loan contains customary affirmative and restrictive covenants, including the Company's ability to enter into fundamental transactions, incur additional indebtedness, grant liens, pay any dividend or make any distributions to its holders, make investments, merge or consolidate with any other person or engage in transactions with the Company's affiliates, but does not include any financial covenants.

In June 2022, the Company entered into a Loan and Security Agreement with Avenue Venture Opportunities Fund I and II (the "2022 Loan and Security Agreement"). The terms of the 2022 Loan and Security Agreement include a term loan of up to $20 million available in two tranches with the first tranche of $10 million that was drawn at closing in June of 2022, and a second tranche of $10 million available at closing of the Series D-2 that has not yet been drawn. Additionally, the Company may have access to a third tranche of $30 million subject to certain financing milestones. The term loan matures on June 1, 2026. In addition, the lender has the right, at their discretion, but not the obligation, to convert any portion of the outstanding principal amount of the loans up to $5 million into shares of the Company's common stock at a price per share equal to $5.58 (the "Conversion Option"), subject to adjustment; provided, however, the Conversion Option shall not be exercised by lender during the six (6) month period after completion of a Qualified SPAC (as defined in the 2022 Loan and Security Agreement). Concurrent with the closing of the 2022 Loan and Security Agreement, the Company terminated and repaid their existing 2019 Loan and Security Agreement, which resulted in a loss on extinguishment of $682,000.

Pursuant to the terms of the 2022 Loan and Security Agreement, the Company issued Avenue Venture Opportunities Fund I and II warrants that will be exercisable for 215,054 shares of common stock, and the estimated fair value of the warrants of $178,000 was recorded as debt discount on the date of issuance and is being amortized to interest expense over the term of the Loan and Security Agreement. In addition, other financing costs totaling $405,000 were also recorded as debt discount and is being amortized to interest expense over the term of the facility.

The term loan accrues interest at a floating per annum rate equal to the Wall Street Journal prime rate plus 6.45%. The rate in effect at December 31, 2022 was 13.45%. Total interest expenses recorded on the facility during the year ended December 31, 2022 was approximately $711,000. The repayment terms of the loan include monthly payments over a 4-year period, consisting of an initial 2 year interest-only period, followed by 24 monthly principal payments of $417,000 plus interest. In addition, there is a final payment equal to 4.25% of the initial commitment amount of $20 million, which will be accrued over the term of the loan using the effective-interest method.

	Principal Payments (in thousands)
Period ending December 31:	
2023	$ —
2024	2,500
2025	5,000
2026	2,500
Total	$ 10,000

The term loan is secured by all of the Company's assets, excluding intellectual property and certain other assets. The loan contains customary affirmative and restrictive covenants, including the Company's ability to enter into fundamental transactions, incur additional indebtedness, grant liens, pay any dividend or make any distributions to its holders, make investments, merge or consolidate with any other person or engage in transactions with the Company's affiliates, but does not include any financial covenants.

15. Subsequent Events

The Company has evaluated subsequent events through March 24, 2023, the date on which these consolidated financial statements were issued.

Business Combination closing of HSAQ2 and Orchestra

On January 26, 2023 (the "Closing Date"), the Company consummated the previously-announced Business Combination (the "Closing"). In connection with the Business Combination, HSAC2 changed its jurisdiction of incorporation from the Cayman Islands to the State of Delaware and changed its name to "Orchestra BioMed Holdings, Inc." ("New Orchestra"). On the Closing Date, Merger Sub merged with and into Orchestra with Orchestra being the surviving corporation and a wholly owned subsidiary of New Orchestra. The Company refers to HSAC2 common stock, after giving effect to the Business Combination, as "New Orchestra Common Stock."

Upon the Closing, based on a ratio (the "Exchange Ratio") of 0.465 shares of HSAC2 Common Stock for each whole share of Orchestra common stock, par value $0.0001 per share (the "Orchestra Common Stock"), 20,191,338 shares of New Orchestra Common Stock were issued to Orchestra stockholders (exclusive of the additional shares subject to earnout discussed below in this paragraph) and 5,523,834 shares of New Orchestra Common Stock were reserved for issuance pursuant to the Orchestra stock options and warrants converted into New Orchestra stock options and warrants in the Merger. In addition, upon the Closing, all of the Company's outstanding preferred stock automatically converted New Orchestra Common Stock.

In connection with the Business Combination, HSAC 2 Holdings, LLC (the "Sponsor") agreed that 25% or 1,000,000 shares of its New Orchestra Common Stock will be forfeited to New Orchestra 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 New Orchestra 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 New Orchestra 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 "IPO") agreed to subject (i) the 4,000,000 shares of New Orchestra Common Stock issued to HSAC2's initial shareholders prior to the IPO (the "Insider Shares") and (ii) the 450,000 shares of New Orchestra Common Stock purchased in a private placement simultaneously with the 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 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 New Orchestra Common Stock to eleven specified employees and directors of Orchestra. These new warrants have substantially similar terms to the forfeited Private Warrants, except that they will become exercisable between 24 and 36 months after the Closing.

In connection with the Business Combination, existing 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 New Orchestra Common Stock in the aggregate ("Earnout Consideration"). Approximately 91% of Orchestra stockholders elected to participate in the Earnout. Each Earnout Participant agreed to extend their applicable lock-up period from 6 months to 12 months, 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 (as defined below) 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.

Prior to the Business Combination, HSAC2's public shares were listed on The Nasdaq Capital Market under the symbol "HSAQ." On January 27, 2023, the New Orchestra Common Stock began trading on The Nasdaq Global Market under the symbol "OBIO."

The Business Combination will be accounted for as a reverse recapitalization in accordance with U.S. GAAP. Under this method of accounting, New Orchestra, which is the legal acquirer, will be treated as the "acquired" company for financial reporting purposes, and Orchestra will be treated as the accounting acquirer. This determination is primarily based the fact that immediately following the Business Combination, Orchestra's stockholders held a majority of the voting power of New Orchestra, Orchestra's board of directors became the board of directors of New Orchestra, and Orchestra's senior management comprised all of the senior management of New Orchestra. Accordingly, for accounting purposes, the Business Combination is treated as the equivalent of a capital transaction in which Orchestra is issuing stock for the net assets of New Orchestra. The net assets of New Orchestra will be stated at historical cost, with no goodwill or other intangible assets recorded. Operations prior to the Business Combination will be those of Orchestra.

Exhibit 99.2

ORCHESTRA'S MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of the financial condition and results of operations of Orchestra BioMed, Inc. and its consolidated subsidiaries should be read together with Orchestra's audited consolidated financial statements as of and for the years ended December 31, 2022, and 2021, together with the related notes thereto, filed as Exhibit 99.1 to the Current Report on Form 8-K/A (the "Form 8-K/A") with which this Exhibit is filed. In addition to historical financial information, this discussion contains forward-looking statements based upon Orchestra's current expectations that involve risks and uncertainties. Orchestra's actual results could differ materially from such forward-looking statements as a result of various factors, including those set forth under the heading "Risk Factors—Risks Related to Orchestra's Business and New Orchestra Following the Business Combination" in the definitive proxy statement/prospectus of Health Sciences Acquisitions Corporation 2 ("HSAC2") filed with the U.S. Securities and Exchange Commission pursuant to Rule 424(b)(3) on December 16, 2022. HSAC2 is the predecessor of Orchestra BioMed Holdings, Inc. ("New Orchestra"), which become the holding company of Orchestra Biomed upon the closing of the business combination between HSAC2 and Orchestra BioMed (the "Business Combination") on January 26, 2023. All references to years, unless otherwise noted, refer to our fiscal years, which end on December 31. Unless otherwise indicated or the context otherwise requires, references included in this Orchestra's Management's Discussion and Analysis of Financial Condition and Results of Operations section to "Orchestra," "Orchestra's, "we," "its," and "our" refer to Orchestra BioMed, Inc. and its consolidated subsidiaries.

Closing of Business Combination with HSAC2

On January 26, 2023, we closed the Business Combination with HSAC2, which resulted in, among other things, our becoming a wholly owned subsidiary of New Orchestra, and New Orchestra's receipt of gross proceeds of approximately $70.0 million from the Business Combination. On January 27, 2023, New Orchestra's common stock began trading on The Nasdaq Global Market under the symbol "OBIO." For additional information, see Note 15, *Subsequent Events*, to Orchestra's audited consolidated financial statements as of and for the years ended December 31, 2022 and 2021, together with the related notes thereto, filed as Exhibit 99.1 to the Form 8-K/A.

Overview

Orchestra is a biomedical innovation company accelerating high-impact solutions for large unmet needs in procedure-based medicine through risk-reward sharing partnerships with leading medical device companies. Orchestra's partnership-enabled business model focuses on forging strategic collaborations with leading medical device companies to drive successful global commercialization of products it develops. Orchestra is led by a highly accomplished, multidisciplinary management team and a board of directors with extensive experience in all phases of therapeutic device development. Orchestra's business was formed in 2018 by assembling a pipeline of multiple late-stage clinical product candidates originally developed by its founding team. Its flagship product candidates are BackBeat CNT for the treatment of hypertension ("HTN"), a significant risk factor for death worldwide, and Virtue SAB for the treatment of atherosclerotic artery disease, the leading cause of mortality worldwide.

Since inception, Orchestra has devoted the substantial majority of its resources to performing research and development and clinical activities in support of its product development and collaboration efforts. Orchestra has funded its operations primarily through the issuance of convertible preferred stock as well as through proceeds from our distribution agreement (the "Terumo Agreement") with Terumo Medical Corporation ("Terumo"), and borrowings under debt arrangements. Orchestra has raised a cumulative $166.8 million in gross proceeds through the issuance of convertible preferred stock and has received $30.0 million from the Terumo Agreement through December 31, 2022. Orchestra has incurred net losses each year since inception. Orchestra's net losses were $23.0 million and $33.6 million during 2021 and 2022, respectively. Orchestra expects to continue to incur significant losses for the foreseeable future. As of December 31, 2022, Orchestra had an accumulated deficit of $199.7 million.

Orchestra 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. 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.

COVID-19 Impact and Business Update

Outbreaks of contagious disease, including COVID-19, or other adverse public health developments in the U.S. or worldwide could have a material adverse effect on our business, financial condition and results of operations. While many of the direct impacts of the COVID-19 pandemic have eased, the longer-term macroeconomic effects on global supply chains, inflation, labor shortages and wage increases continue to impact many industries. Moreover, with the potential for new strains of existing viruses to emerge, or other pandemics or epidemics, governments and businesses may re-impose aggressive measures to help slow its spread in the future. As the COVID-19 pandemic developed, Orchestra took numerous steps to help ensure the health and safety of its employees.

Orchestra continues to actively monitor the impact of the COVID-19 pandemic on its development programs. To date, Orchestra has experienced some impacts on its development programs due to the pandemic, including delays in receiving products and services from certain of Orchestra's manufacturing and other key vendors as a direct or indirect result of the COVID-19 pandemic, including supply chain issues, and competition for manufacturing capacity from manufacturers of COVID-19 related therapeutics. Orchestra has also experienced challenges related to recruiting, enrolling and treating patients in clinical studies due to patients' concern regarding exposure risk; patients and clinical study staff being exposed to SARS-CoV-2 or contracting COVID-19; reduced staffing at clinical study sites due to the diversion of resources at clinical sites to address the effects of the pandemic; and travel restrictions and shutdowns impacting patients and clinical study staff. While many of these impacts have been resolved, Orchestra continues to monitor its clinical development and supply chain and contingency planning is ongoing with its partners to reduce the possibility and magnitude of interruptions to its development activities or the availability of necessary materials.

The full extent of the impact and effects of COVID-19, and any future pandemics or epidemics, will depend on future developments, including, among other factors, how rapidly variants develop, availability, acceptance and effectiveness of vaccines along with related travel advisories, quarantines and restrictions, the recovery time of the disrupted supply chains and industries, the impact of labor market interruptions, the impact of government interventions, and uncertainty with respect to the duration of the global economic slowdown. Orchestra will continue to actively monitor the situation related to COVID-19 and any future pandemics or epidemics and may take further actions that alter Orchestra's operations, including those that federal, state or local authorities may require, or that Orchestra determines in the best interests of Orchestra's clinical study subjects, employees and other third parties with whom Orchestra does business. While many of the direct impacts of the COVID-19 pandemic have eased, the extent to which the COVID-19 pandemic may affect Orchestra's future business, operations and development timelines and plans, including the resulting impact on Orchestra's expenditures and capital needs, remains uncertain.

Components of Our Results of Operations

Partnership Revenue

To date, Orchestra's partnership revenues relate 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 June 30, 2022, by and among, Orchestra, BackBeat Medical, LLC and Medtronic, Inc. (an affiliate of Medtronic plc) (the "Medtronic Agreement"), discussed in Note 4, Medtronic Agreement, to our consolidated financial statements included in Exhibit 99.1 to the Form 8-K/A.

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*. Under this agreement, Orchestra received an upfront payment of $30.0 million in 2019, may receive 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%.

Under the Terumo Agreement, Orchestra was initially eligible for certain milestone payments in the amount of $65 million from Terumo upon completion of certain minimum enrollments in clinical studies, making certain filings and submissions, and obtaining certain regulatory approvals and certifications. Of these milestone payments, $35 million relate to achieving certain milestones by specified target achievement dates. As of the date of this filing, Orchestra has already passed the target achievement dates for two $5 million milestone payments, in each case, without achieving the related milestones. In addition, due to delays in Orchestra's 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 Orchestra to amend its original project plan, Orchestra is unlikely to be able to complete the remaining time-based milestones by the specified target achievement dates to earn the remaining $25 million in time-based milestone payments pursuant to the Terumo Agreement. Further, Terumo has the right to terminate the agreement, or certain of its obligations thereunder, if certain milestones are not achieved. However, in June 2022, Orchestra and Terumo signed a letter agreement whereby the parties agreed to negotiate in good faith over 12 months mutually agreeable adjustments to certain target achievement dates to reflect the regulatory and pandemic-related delays. There is no assurance as to the outcome of these negotiations with respect to any potential modifications to the milestone target achievement dates. In addition, Orchestra will 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, and Terumo may also request other services from Orchestra from time to time.

Orchestra recorded the $30.0 million upfront payment received in 2019 from Terumo within deferred revenue and is 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 ISR indication, for which Orchestra is primarily responsible. Orchestra has recognized $10.5 million in cumulative partnership revenues from 2019 through December 31, 2022. There were no other proceeds received pursuant to the Terumo Agreement from 2019 through December 31, 2022.

In June 2022, we entered into the Medtronic Agreement for the development and commercialization of BackBeat CNT for the treatment of HTN in patients indicated for a cardiac pacemaker. Orchestra entered into the Medtronic Agreement and has determined that the arrangement is a collaboration within the scope of *ASC 808, Collaborative Arrangements*. In addition, Orchestra concluded that Medtronic, Inc. ("Medtronic"), an affiliate of Medtronic plc, 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 December 31, 2022, 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. Orchestra expects cost of finished goods product revenue to increase in absolute terms as our revenue grows.

Orchestra's 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, or CROs, 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 Orchestra's 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, Orchestra expects research and development expenses to increase in absolute dollars as it continues 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. Orchestra does 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/press relations, non-income taxes, insurance costs, cost of outside consultants and employee recruiting and training costs. Moreover, Orchestra expects to incur additional expenses associated with operating as a public company, including legal, accounting, insurance, exchange listing and SEC compliance and investor relations. Orchestra expects quarterly selling, general and administrative expenses, excluding stock 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 December 2019, Orchestra entered into a Loan and Security Agreement with Silicon Valley Bank for a term loan as described in Note 14, Debt Financing, to our consolidated financial statements included in Exhibit 99.1 to the Form 8-K/A (the "**2019 Loan and Security Agreement**"). This agreement provided Orchestra with capital for development and general corporate purposes. On December 31, 2020, Orchestra borrowed $10 million under the 2019 Loan and Security Agreement.

In June 2022, Orchestra entered into a Loan and Security Agreement with Avenue Venture Opportunities Fund I and II (the "**2022 Loan and Security Agreement**"). As part of the 2022 Loan and Security Agreement, Orchestra paid off the balance of the 2019 Loan and Security Agreement with Silicon Valley Bank. The terms of the 2022 Loan and Security Agreement include a term loan of up to $20 million available in two tranches with the first tranche of $10 million that was drawn at closing in June of 2022, and a second tranche of $10 million available at closing of the Series D-2 that has not yet been drawn. Additionally, Orchestra may have access to a third tranche of $30 million subject to certain financing milestones. The term loan accrues interest at a floating per annum rate equal to the Wall Street Journal prime rate plus 6.45%. The rate in effect at December 31, 2022 was 13.45%. Refer to Note 14, Debt Financing, to our consolidated financial statements included in Exhibit 99.1 to the Form 8-K/A.

Gain (Loss) on Fair Value Adjustment of Warrant Liability

Certain of Orchestra's outstanding warrants contain features that require the warrants to be accounted for as liabilities. The warrants are subject to re-measurement at each balance sheet date with gains and losses reported through Orchestra's consolidated statements of operations and comprehensive loss as gain (loss) on fair value adjustment of warrant liability.

Loss on Debt Extinguishment

As part of the 2022 Loan and Security Agreement, Orchestra paid off the balance of the 2019 Loan and Security Agreement with Silicon Valley Bank. The loss on debt extinguishment represents charges incurred as a result of the payoff of the 2019 Loan and Security Agreement.

Gain (Loss) on Fair Value of Strategic Investments

The gain (loss) on fair value of strategic investments represents a change in the fair value of Orchestra's investment in Motus GI and preferred shares and convertible notes of a privately-held company and related party (Vivasure). 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.

Results of Operations

Comparison of the Years Ended December 31, 2021 and 2022

The following table presents Orchestra's statements of operations for the years ended December 31, 2021 and 2022, and the dollar and percentage change between the two years (in thousands):

	Year Ended December 31,			
	2021	**2022**	**Change $**	**Change %**
Revenue:				
Partnership revenue	$ (1,475)	$ 2,862	$ 4,337	294%
Product revenue	693	671	(22)	(3)%
Total revenue	(782)	3,533	4,315	552%
Expenses:				
Cost of product revenue	199	211	12	6%
Research and development	12,890	21,945	9,055	70%
Selling, general and administrative	7,928	14,034	6,106	77%
Total expenses	21,017	36,190	15,173	72%
Loss from operations	(21,799)	(32,657)	(10,858)	(50)%
Other income (expense):				
Interest (expense) income, net	(927)	50	977	105%
Gain (loss) on fair value adjustment of warrant liability	699	(1,350)	(2,049)	(293)%
Loss on debt extinguishment	—	(682)	(682)	NM(1)
(Loss) gain on fair value of strategic investments	(987)	1,031	2,018	204%
Total other expense	(1,215)	(951)	264	22%
Net loss	$ (23,014)	$ (33,608)	$ (10,594)	(46)%

(1) Amount is not meaningful

Partnership Revenue

Partnership revenue increased by $4.3 million, or 294%, from ($1.5) million in 2021 to $2.9 million in 2022. Partnership revenue relates to the recognition of the combined performance obligation for the license granted to Terumo and the ongoing research and development services over the estimated performance period for the Virtue SAB Coronary ISR indication, using a proportional performance model, based on the costs incurred relative to the total estimated costs of the research and development services. As of each quarterly reporting date, Orchestra 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 years ended December 31, 2021 and 2022, the expenses incurred related to the Terumo Agreement were approximately $9.9 million and $14.3 million, respectively. The estimated total costs associated with the Terumo Agreement through completion increased by approximately 85% as of December 31, 2021 as compared to the estimates as of December 31, 2020, and increased by approximately 10% as of December 31, 2022, as compared to the estimates as of December 31, 2021. The increase in the estimated costs relates to an extension of the estimated performance period by twelve months, due in part to delays resulting from the COVID-19 pandemic, as well as 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, that caused the Company to amend its original project plan. 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. While Orchestra 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.

Product Revenue

Product revenue decreased by $22,000, or 3%, from $693,000 in 2021 to $671,000 in 2022. The decrease was primarily due to a decrease in the purchase volume of FreeHold Duo and Trio intracorporeal organ retractors. There have been no changes to the per unit sale price in either period presented. Product revenue consisted of the sale of FreeHold Duo and Trio intracorporeal organ retractors and revenue is recognized when product is shipped to customers.

Cost of Product Revenue

Cost of product revenue increased by $12,000, or 6%, from $199,000 in 2021 to $211,000 in 2022. The increase was primarily due to increased production costs of FreeHold Duo and Trio intracorporeal organ retractors.

Research and Development Expenses

The following table summarizes Orchestra's research and development expenses for the years ended December 31, 2021 and 2022 (in thousands):

	Years Ended December 31,	
	2021	**2022**
Personnel and consulting costs	$ 6,539	$ 9,442
Research and development program costs, supplies and testing	4,139	9,175
Clinical development costs	742	1,932
Other research and development costs	1,470	1,396
Total research and development expenses	$ 12,890	$ 21,945

Research and development expenses increased by $9.1 million, or 70%, from $12.9 million in 2021 to $21.9 million in 2022. This was primarily due to an increase of $5.0 million in animal study and drug formulation development costs. There was also an increase in personnel related expenses of $2.9 million due to increased headcount and associated expenses.

The total research and development expenses summarized above include $9.1 million in 2021 and $13.9 million in 2022 related to the Terumo Agreement. The increase of $4.8 million is due to increased expense activity related to the Terumo Agreement during the 2022 period.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $6.1 million, or 77%, from $7.9 million in 2021 to $14.0 million in 2022. The increase was primarily due to an increase in headcount which resulted in a $2.1 million increase in salary and medical benefit costs, along with increased stock-based compensation of $2.7 million, increased outside consultant expenses of $499,000 and $464,000 of accounting, finance and legal expenses incurred in connection with the overall growth of the business and in preparation for becoming a public company.

Interest (Expense) Income, Net

Interest (expense) income, net, increased by $977,000, or 105%, from $927,000 of expense in 2021 to $50,000 of income in 2022. The net interest expense in 2021 consisted primarily of interest expense incurred resulting from the December 31, 2020 drawdown of the $10.0 million tranche from the termination of the 2019 Loan and Security Agreement. The net interest income in 2022 consisted primarily of monthly interest incurred resulting from the 2019 Loan and Security Agreement and interest expense incurred resulting from the 2022 Loan and Security Agreement through September 2022 offset by interest earned from marketable securities.

Gain (Loss) on Fair Value Adjustment of Warrant Liability

The gain on fair value adjustment of warrant liability was $699,000 in 2021 as compared to a loss of $1.4 million in 2022. The change year over year is primarily a result of an amendment to the terms of certain existing warrant agreements, which included modifying the underlying shares of the warrants from preferred warrants to common warrants and reducing the strike prices. Such amendments resulted in $810,000 of additional expense for the year ended December 31, 2022. Further, the change in the fair value of our outstanding warrants due to an increase in the fair value of the underlying common and preferred stock resulted in $578,000 of additional expense for year ended December 31, 2022.

Loss on Debt Extinguishment

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

(Loss) Gain on Fair Value of Strategic Investments

The loss on fair value of strategic investments was $1.0 million in 2021, as compared to a gain of $1.0 million for 2022. The amount recognized in 2021 related to the change in fair value in our common stock holdings of Motus GI Holdings, Inc. The amount recognized in 2022 relates to a gain on our strategic investment in Vivasure of $1.9 million, partially offset by the change in fair value in our common stock holdings of Motus GI Holdings, Inc. The gain on our strategic investment in Vivasure is attributable to an observable price change for an identical investment due to a new third-party investment. Therefore, the investment is measured at fair value and a gain was recognized.

Liquidity and Capital Resources

From inception through December 31, 2022, Orchestra has incurred significant operating losses and negative cash flows from its operations. Orchestra's net losses were $23.0 million and $33.6 million for the years ended December 31, 2021 and 2022, respectively. As of December 31, 2022, Orchestra had an accumulated deficit of $199.7 million. Orchestra has funded its operations primarily through the issuance of convertible preferred stock as well as through proceeds from the Terumo Agreement, borrowings under debt arrangements and, to a lesser extent, from FreeHold product revenue. Orchestra has raised a cumulative $166.8 million in gross proceeds through the issuance of convertible preferred stock and has received $30.0 million from the Terumo Agreement through December 31, 2022. Orchestra had $19.8 million in cash and cash equivalents at December 31, 2022, which consisted primarily of bank deposits and money market funds. Orchestra also had $63.9 million of short-term marketable securities at December 31, 2022, which consisted primarily of its investments in corporate and government debt securities.

In addition, On January 26, 2023, we closed the Business Combination with HSAC2, which resulted in, among other things, our becoming a wholly owned subsidiary of New Orchestra, and New Orchestra's receipt of gross proceeds of approximately $70.0 million from the Business Combination. On January 27, 2023, New Orchestra's common stock began trading on The Nasdaq Global Market under the symbol "OBIO." For additional information, see Note 15, *Subsequent Events*, to Orchestra's audited consolidated financial statements as of and for the years ended December 31, 2022, and 2021, together with the related notes thereto, filed as Exhibit 99.1 to the Form 8-K/A.

Funding Requirements

Orchestra expects its operating expenses to increase significantly as Orchestra continues to develop and seek regulatory approvals and along with its partners, prepare for potential commercialization of Orchestra's product candidates. Orchestra's research and development spending is expected to increase from historical levels during 2023 as it performs enabling work in preparation for the BackBeat CNT and Virtue SAB pivotal studies, commences enrollment of both planned studies and executes additional planned research and development activities. In addition, Orchestra expects its selling, general and administrative expenses to increase due to increases in headcount along with expenses associated with being a public company. Based on current clinical development and other research and development plans and budget estimates, Orchestra anticipates that its cash and cash equivalents and marketable securities, in combination with the net proceeds received from the consummation of the Business Combination in January 2023, are sufficient to fund its operations into 2026.

The amount and timing of Orchestra's future funding requirements may change from current estimates and will depend 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 for its flagship product candidates and other research, development, manufacturing and commercial activities as well as the potential receipt of revenues under the Medtronic Agreement, the Terumo Agreement and/or future collaborations. Orchestra may seek additional funding through the issuance of new equity, may make drawdowns on its existing or new loan facilities, may receive milestone payments from the Terumo Agreement or through payments from collaborations or partnerships with other companies, and/or may realize cash from the sale of some or all of its strategic holdings, although there are no assurances in this regard.

Cash Flows

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

	Year Ended December 31,	
	2021	**2022**
Net cash used in operating activities	$ (19,429)	$ (29,289)
Net cash provided by (used in) investing activities	13,017	(64,122)
Net cash provided by (used in) financing activities	(3,993)	103,257
Net (decrease) increase in cash and cash equivalents	$ (10,405)	$ 9,846

Comparison of the Years Ended December 31, 2022 and 2021

Net Cash Flows from Operating Activities

Net cash used in operating activities for the year ended December 31, 2022 was $29.3 million and primarily consisted of our net loss of $33.6 million, and changes in net operating assets and liabilities of $450,000, which was offset by non-cash charges of $4.7 million. Our non-cash charges primarily consisted of a loss on fair value adjustment of warrant liability of $1.4 million, loss on debt extinguishment of $682,000, stock-based compensation of $3.4 million, amortization of deferred financing costs of $163,000 and non-cash lease expense of $571,000, offset by a $1.0 million gain on the fair value of investments and $600,000 related to accretion and interest of marketable securities. The net change in operating assets and liabilities were primarily due to a decrease in deferred revenue of $2.9 million, an increase in prepaid expenses and other assets of $439,000, and an increase in inventory of $208,000, offset by an increase in accounts payable, accrued expenses and other liabilities of $3.4 million and various other immaterial changes.

Net cash used in operating activities for the year ended December 31, 2021 was $19.4 million and primarily consisted of our net loss of $23.0 million, which was offset by non-cash charges of $1.0 million and changes in net operating assets and liabilities of $2.6 million. Our non-cash charges primarily consisted of a $1.0 million adjustment in fair value of strategic investments, stock-based compensation of $302,000, and amortization of deferred financing fees of $217,000, partially offset by a gain on fair value adjustment of warrant liability of $699,000. The net change in operating assets and liabilities were primarily due to an increase in deferred revenue of $1.5 million related to the extension of the expected timeline and increasing budgeted costs of the performance obligation from the Terumo Agreement during the year and an increase of $1.1 million in accounts payable and accrued expenses due to timing of vendor payments.

Net Cash Flows from Investing Activities

Net cash used in investing activities for the year ended December 31, 2022, was $64.1 million, which consisted of the purchase of $63.3 million of marketable securities, $591,000 of property and equipment and $208,000 of strategic investments.

Net cash provided by investing activities for the year ended December 31, 2021 was $13.0 million, which primarily consisted of the sale of $13.5 million of marketable securities, partially offset by the purchase of property and equipment for $274,000 and the purchase of unsecured convertible redeemable loan notes and accumulated interest from Vivasure for $213,000.

Net Cash Flows from Financing Activities

Net cash provided by financing activities of $103.3 million for the year ended December 31, 2022 was attributable to gross proceeds from the Series D-1 private equity financing (the "**Series D-1 Financing**"), and the Series D-2 private equity financing (the "**Series D-2 Financing**") totaling $110 million, and proceeds from the 2022 Loan and Security Agreement of $10 million. These proceeds were offset by $10.3 million of deferred financing and offer costs and principal repayment of $6.4 million, inclusive of debt extinguishment costs, from the termination of the 2019 Loan and Security Agreement to Silicon Valley Bank.

Net cash used in financing activities of $4.0 million for the year ended December 31, 2021 was primarily related to the principal repayment of $4.0 million from the 2019 Loan and Security Agreement to Silicon Valley Bank.

Contractual Obligations and Commitments

The following table summarizes Orchestra's contractual obligations and commitments as of December 31, 2022 (in thousands):

	Payments Due by Period				
	Total	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
Operating lease obligations	$ 2,694	$ 823	$ 1,079	$ 704	$ 88
Debt, principal and interest[(1)]	14,328	1,414	9,491	3,423	—
Total	$ 17,022	$ 2,237	$ 10,570	$ 4,127	$ 88

(1) In June 2022, the Company entered into the 2022 Loan and Security Agreement with Avenue Venture Opportunities Fund I and II. As part of the 2022 Loan and Security Agreement, the Company paid off the balance of the 2019 Loan and Security Agreement with Silicon Valley Bank. The 2022 Loan and Security Agreement will mature in June 2026. Refer to Note 14, Debt Financing, to our consolidated financial statements included in Exhibit 99.1 to the Form 8-K/A for additional information.

In addition, Orchestra enters 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

Orchestra's financial statements are prepared in accordance with U.S. GAAP. The preparation of the financial statements in conformity with U.S. GAAP requires Orchestra's 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. Orchestra evaluates its 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. Orchestra bases its estimates on historical experience and on various other assumptions that Orchestra believes 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.

Orchestra believes that the accounting policies described below involve a significant degree of judgment and complexity. Accordingly, Orchestra believes these are the most critical to aid in fully understanding and evaluating its financial condition and results of operations. For further information, see Note 2, *Summary of Significant Accounting Policies*, to Orchestra's audited consolidated financial statements as of and for the years ended December 31, 2022 and 2021, together with the related notes thereto, filed as Exhibit 99.1 to the Form 8-K/A.

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.

Orchestra's 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 judgements 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, Orchestra's partnership revenues relate to the Terumo Agreement described below. In future periods, partnership revenues may also include revenues related to the Medtronic Agreement, discussed in Note 4 in the consolidated financial statements for the years ended December 31, 2021 and 2022.

Orchestra entered into the Terumo Agreement as further described in Note 3 to Orchestra's audited consolidated financial statements as of and for the years ended December 31, 2021 and 2022, together with the related notes thereto, filed as Exhibit 99.1 to the Form 8-K/A. Orchestra 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. Orchestra determined that the Terumo Agreement did not fall within the scope of ASC 808. Orchestra 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 Orchestra's intellectual property, and (ii) research and development services. Orchestra 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, Orchestra 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.

Orchestra 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, Orchestra evaluates the amount of potential payment and the likelihood that the payments will be received. Orchestra 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, Orchestra 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, Orchestra 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, Orchestra will recognize royalty revenue when the related sales occur. To date, Orchestra has not recognized any royalty revenue under the arrangement.

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

In 2021, the Company updated its 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 reduction of partnership revenues of $6.5 million, or a net loss per share, basic and diluted, of $3.06. In 2022, the impact of the changes in estimates resulted in reduction of partnership revenues of $1.0 million, or a net loss per share, basic and diluted, of $0.43.

Orchestra 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 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 Orchestra performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the right to consideration is unconditional.

In June 2022, Orchestra, BackBeat Medical, LLC and Medtronic entered into the Medtronic Agreement for the development and commercialization of BackBeat CNT for the treatment of HTN in patients indicated for a cardiac pacemaker. Orchestra entered into the Medtronic Agreement and has determined that the arrangement is a collaboration within the scope of ASC 808, Collaborative Arrangements. In addition, Orchestra 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 December 31, 2022, there have been no amounts recognized as revenue under the Medtronic Agreement.

Research and Development Prepayments, Accruals and Related Expenses

Orchestra incurs costs of research and development activities conducted by its 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. 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.

Stock-Based Compensation

Orchestra accounts 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 Orchestra's common stock underlying the award as of the grant date, described further below under "Fair value of common stock". 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. Orchestra accounts for forfeitures as they occur.

Due to the absence of an active market for the Company's common stock, the Company 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 the common stock has been determined based upon a variety of factors, including valuations of the Company's common stock performed with the assistance of independent third-party valuation specialists; the Company'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; the Company's business conditions and projections; the Company'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 the Company's common stock as a private company; the prices of the Company'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 the Company's common stock, such as an initial public offering or a sale of the Company 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 common stock at each valuation date. In determining the exercise prices for options granted and fair value of restricted stock, the Company has considered the fair value of the common stock as of the grant date.

In the valuation analysis conducted as of December 31, 2021, which was used for grants in February of 2022, a probability weighted expected return method ("**PWERM**") was utilized, in which the probability of a public company scenario was considered via either an IPO or SPAC transaction. A 10.0% discount for lack of marketability ("**DLOM**") was applied to this scenario based on various put option models in which a key input is the expected time to the IPO or SPAC transaction. A private company scenario was also considered, in which the discounted cash flow method, guideline public company method, and guideline transaction methods were all utilized in determining fair value in the private company scenario. A 30.0% DLOM was applied to the private company scenario using the same put option methodology with a longer expected period. As of December 31, 2021, the valuation analysis resulted in a common stock fair value of $1.56.

In the valuation analysis conducted as of March 31, 2022, related to grants spanning April to June of 2022, a PWERM was utilized, in which the SPAC transaction was considered as a scenario using the expected pricing per share on an as-converted basis. For the quarter ended March 31, 2022, a SPAC transaction was considered with increased likelihood based on the fact that Orchestra had signed a non-binding letter of intent contemplating a business combination with HSAC2. A 13.0% DLOM was applied to the SPAC transaction scenario, which was estimated using put option models. A private company scenario was also considered, in which the discounted cash flow method, guideline public company method, and guideline transaction methods were all utilized in determining fair value in the private company scenario. A 30.0% DLOM was applied to the private company scenario using the same put option methodology. As of March 31, 2022, the valuation analysis resulted in a common stock fair value of $1.89.

In the valuation analysis conducted as of June 30, 2022, related to grants in August of 2022, a PWERM with SPAC transaction and private company scenarios was also utilized. For the quarter ended June 30, 2022, it was imminent that Orchestra would enter into a definitive merger agreement with HSAC2. Therefore, the pricing in the SPAC scenario in this analysis was also updated to reflect the negotiated pricing of that definitive agreement of $4.65 per share, which was subsequently entered into on July 5, 2022. The private company scenario was calculated using a recent financing methodology derived from the completion of the Series D-2 Financing, which was also priced at a $4.65 per share consistent with the implied value given the exchange ratio in the merger agreement and considered an arms' length transaction. Given the definitive merger agreement with HSAC2 and the Series D-2 offering were both priced at $4.65 per share, the Company used this share price when establishing the strike prices of the options awarded in August and October of 2022. However, to estimate the fair value of common stock for stock-based compensation purposes, the Company applied a 30.0% DLOM to the private company scenario, which was estimated using put option models, while no DLOM was applied to the SPAC transaction scenario, given the $4.65 per share price was believed to reflect a marketable value. As of June 30, 2022, the valuation analysis resulted in a common stock fair value of $4.27.

In the valuation analysis conducted as of December 31, 2022, related to grants in fourth quarter of 2022, a PWERM with SPAC transaction and private company scenarios was also utilized. For the quarter ended December 31, 2022, Orchestra had achieved effectiveness related to its definitive merger agreement with HSAC2. Therefore, the pricing in the SPAC scenario in this analysis was also updated to reflect the negotiated pricing of that definitive agreement of $4.65 per share. The private company scenario was calculated using a recent financing methodology derived from the completion of the Series D-2 financing, which was priced at a $4.65 per share. Given the definitive merger agreement with HSAC2 and the Series D-2 offering were both priced at $4.65 per share, the Company used this share price when establishing the strike prices of the options awarded in the fourth quarter of 2022. However, to estimate the fair value of common stock for stock-based compensation purposes, the Company applied a 30.0% DLOM to the private company scenario, which was estimated using put option models, while no DLOM was applied to the SPAC transaction scenario, given the $4.65 per share price was believed to reflect a marketable value. As of December 31, 2022, the valuation analysis resulted in a common stock fair value of $4.52.

The following table summarizes the stock options granted by Orchestra in 2022, under the Orchestra 2018 Plan:

Issue Date	Shares	Strike Price	Fair Market Value per share (Common)	Stock-based Compensation expense through 12/31/2022
April 12, 2022	513,167	$ 1.89	$ 1.89	$ 151,759
April 13, 2022	5,000	$ 1.89	$ 1.89	$ 1,041
April 18, 2022	20,000	$ 1.89	$ 1.89	$ 4,163
May 2, 2022	10,000	$ 1.89	$ 1.89	$ 2,081
June 20, 2022	10,000	$ 1.89	$ 1.89	$ 998
August 18, 2022	4,222,385	$ 4.65	$ 4.27	$ 2,660,971
August 29, 2022	20,000	$ 4.65	$ 4.27	$ 4,565
October 26, 2022	130,000	$ 4.65	$ 4.52	$ 25,392
October 31, 2022	45,000	$ 4.65	$ 4.52	$ 8,807
November 28, 2022	15,000	$ 4.65	$ 4.52	$ 2,901
December 15, 2022	80,000	$ 4.65	$ 4.52	$ 6,718

The following table summarizes the restricted stock granted by Orchestra in 2022, under the Orchestra 2018 Plan:

Issue Date	Shares	Fair Market Value per share (Common)	Stock-based Compensation expense through 12/31/2022
February 3, 2022	251,413	$ 1.56	$ 43,150
April 12, 2022	142,052	$ 1.89	$ 57,369

Orchestra classifies stock-based compensation expense in the statement 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. Orchestra's historical share option exercise information is limited due to a lack of sufficient data points and does not provide a reasonable basis upon which to estimate an expected term. The expected term for option grants is therefore determined using the "simplified" method, as prescribed in the SEC's Staff Accounting Bulletin (SAB) No. 107. The simplified method deems the expected term to be the midpoint between the vesting date and the contractual life of the stock-based awards.

- *Expected Volatility* — The expected volatility is derived from the historical stock volatilities of comparable peer public companies within Orchestra's industry that are considered to be comparable to its business over a period equivalent to the expected term of the stock-based awards, since there has been no trading history of Orchestra's common stock.

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

- *Expected Dividend Yield* — The expected dividend yield is zero as Orchestra has not paid, nor do it anticipate paying, any dividends on its common stock in the foreseeable future.

- *Common Stock Valuation* — Given the absence of a public trading market for Orchestra's common stock, Orchestra's board of directors considers numerous subjective and objective factors to determine the best estimate of fair value of Orchestra's common stock underlying the stock options granted to its employees and non-employees. In determining the grant date fair value of its common stock, Orchestra's board considers, 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 completion of the Merger, the Board intends to determine the fair value of the common stock based on the closing price of the common stock on or around the date of grant.

During the years ended December 31, 2021 and 2022, stock-based compensation was $302,000 and $3.4 million, respectively. As of December 31, 2022, Orchestra had approximately $7.4 million of total unrecognized stock-based compensation, which it expects to recognize over a weighted-average period of approximately 3 years.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact Orchestra's financial position and results of operations is disclosed in Note 2 to our 2022 Consolidated Financial Statements. Refer to Note 2, Summary of Significant Accounting Policies, to our consolidated financial statements included in Exhibit 99.1 to the Form 8-K/A.

Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our cash and cash equivalents and marketable securities as of December 31, 2021 and 2022 consisted of $9.9 million and $83.7 million, respectively, in bank deposits, money market funds and corporate and government debt instruments. Such interest-earning instruments carry a degree of interest rate risk. The goals of our investment policy are liquidity and capital preservation; we do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate exposure. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short-term nature of our cash and cash equivalents and marketable securities.

Inflation Risk

Inflation could affect Orchestra by increasing its cost of labor and clinical study costs. Orchestra does not believe that inflation has had a material effect on its business, financial condition, or results of operations during the periods presented.

Exhibit 99.3

UNAUDITED PRO FORMA CONDENSED CONSOLIDATED COMBINED FINANCIAL INFORMATION

This Unaudited Pro Forma Condensed Consolidated Combined Financial Information is included as Exhibit 99.3 to the Current Report on Form 8-K/A (the "Form 8-K/A") filed by Orchestra BioMed Holdings, Inc. (the "Company" or "New Orchestra") with the Securities and Exchange Commission (the "SEC") on March 24, 2023. Defined terms included below have the same meaning as terms defined and included in Company's Current Report on Form 8-K filed with the SEC on January 31, 2023 (the "Original 8-K") to which the Form 8-K/A relates and, if not defined in the Original 8-K, in the final prospectus and definitive proxy statement filed with the SEC pursuant to Rule 424(b)(3) on December 16, 2022 (the "Proxy Statement/Prospectus"). Unless the context otherwise requires, "Orchestra" refers to Orchestra BioMed, Inc. prior to the Closing, and "HSAC2" refers to Health Sciences Acquisitions Corporation 2 prior to the Closing.

The following unaudited pro forma condensed consolidated combined financial information has been prepared in accordance with Article 11 of Regulation S-X as amended by the final rule, Release No. 33-10786 "Amendments to Financial Disclosures about Acquired and Disposed Businesses."

The historical financial information of HSAC2 was derived from the audited financial statements of HSAC2 as of and for the year ended December 31, 2022. The historical financial information of Orchestra was derived from the audited consolidated financial statements of Orchestra as of and for the year ended December 31, 2022. Such unaudited pro forma financial information has been prepared on a basis consistent with the audited financial statements of HSAC2 and Orchestra, respectively, and should be read in conjunction with the audited historical financial statements and related notes. This information should be read together with Orchestra's audited financial statements and related notes included as Exhibit 99.1 to the Form 8-K/A and "*Orchestra's Management's Discussion and Analysis of Financial Condition and Results of Operations*" included as Exhibit 99.3 to the Form 8-K/A and HSAC2's audited financial statements and related notes beginning on page F-1 of HSAC2's Form 10-K for the fiscal year ended December 31, 2022 filed with the SEC on January 25, 2023 (the "HSAC2 2022 Form 10-K") as well as HSAC2's "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" included in Item 7 of the HSAC2 2022 Form 10-K.

The unaudited pro forma condensed consolidated combined balance sheet as of December 31, 2022 combines the historical balance sheet of HSAC2 and the historical consolidated balance sheet of Orchestra on a pro forma basis as if the Business Combination and the related transactions contemplated by the Merger Agreement, summarized below, had been consummated on December 31, 2022. The unaudited pro forma condensed consolidated combined statement of operations for the year ended December 31, 2022 combines the historical statement of operations of HSAC2 and historical consolidated statement of operations of Orchestra for the period on a pro forma basis as if the Business Combination and the transactions contemplated by the Merger Agreement, summarized below, had been consummated on January 1, 2022. There were no pro forma adjustments required to eliminate activities between the companies.

The Business Combination will be accounted for as a reverse recapitalization, with no goodwill or other intangible assets recorded, in accordance with U.S. GAAP. Under this method of accounting, HSAC2 is treated as the "acquired" company for financial reporting purposes. Accordingly, the Business Combination has been treated as the equivalent of Orchestra issuing stock for the net assets of HSAC2, accompanied by a recapitalization. Orchestra has been determined to be the accounting acquirer because Orchestra, as a group, has retained a majority of the outstanding shares of the combined company as of the Closing, Orchestra nominated all seven persons who comprise the New Orchestra Board upon Closing, Orchestra's management manages the combined company and Orchestra's business comprises the ongoing operations of the combined company.

These unaudited pro forma condensed consolidated combined financial statements are for informational purposes only. They do not purport to indicate the results that would have been obtained had the Business Combination and related transactions actually been completed on the assumed date or for the period presented, or which may be realized in the future. The pro forma adjustments are based on the information currently available and the assumptions and estimates underlying the pro forma adjustments are described in the accompanying notes. Actual results may differ materially from the assumptions within the accompanying unaudited pro forma condensed consolidated combined financial information.

Description of the Business Combination

On July 4, 2022, HSAC2 entered into the Merger Agreement, pursuant to which the Business Combination between HSAC2 and Orchestra was effected in two steps. First, before the Closing, HSAC2 effected the Domestication by deregistering in the Cayman Islands and domesticating as a Delaware corporation in accordance with Section 388 of the Delaware General Corporation Law and the Companies Act. Second, at the Closing, the Merger was effected by Merger Sub merging with and into Orchestra, with Orchestra surviving such merger as the surviving entity. Upon consummation of the Business Combination, Orchestra became a wholly owned subsidiary of HSAC2. HSAC2 then changed its name to "Orchestra BioMed Holdings, Inc."

Simultaneously with the execution of the Merger Agreement, HSAC2 and Orchestra entered into the Forward Purchase Agreement with the RTW Funds and Medtronic, pursuant to which each of the Purchasing Parties agreed to purchase $10.0 million of HSAC2 Ordinary Shares, for a total of $20.0 million, less the dollar amount of HSAC2 Ordinary Shares holding redemption rights that the Purchasing Party acquired and held until immediately prior to the Domestication.

Simultaneously with the execution of the Merger Agreement and Forward Purchase Agreements, HSAC2, Orchestra, and the RTW Funds entered into 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 Parent Closing Cash as of immediately prior to the closing of the Merger was less than $60.0 million (which calculation excludes amounts received pursuant to the Medtronic Forward Purchase Agreement or are otherwise held in the Trust Account in respect of Medtronic's Forward Purchase Shares, but is inclusive of amounts received pursuant to the RTW Forward Purchase Agreement and otherwise held in the Trust Account in respect of the RTW Funds' Forward Purchase Shares).

On October 21, 2022, the parties amended the RTW Forward Purchase Agreement and the Backstop Agreement, pursuant to which the RTW Funds agreed that (1) the per share price under each of the RTW Forward Purchase Agreement and the Backstop Agreement will not exceed the redemption price available to HSAC2 shareholders exercising redemption rights at the Meeting, (2) any shares purchased pursuant to the RTW Forward Purchase Agreement or the Backstop Agreement, or otherwise acquired by the RTW Funds outside of the existing redemption offer, will not be voted in favor of approving the Business Combination, and (3) the RTW Funds will waive redemption rights with respect to such purchases in the vote to approve the Business Combination.

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 New Orchestra Common Stock on or before January 30, 2023. Pursuant to the Backstop Agreement, the RTW Funds purchased 1,808,512 HSAC2 Ordinary Shares on January 25, 2023, immediately prior to the Domestication. The Sponsor and the Purchasing Parties have registration rights pursuant to the Amended and Restated Registration Rights Agreement with respect to the New Orchestra Common Stock.

In addition, the Sponsor has agreed that 25% or 1,000,000 shares of its New Orchestra Common Stock received in the Domestication will be forfeited to New Orchestra on the first business day following the fifth anniversary of the Closing unless, (i) as to 500,000 shares, the VWAP of the New Orchestra Common Stock is greater than or equal to $15.00 per share over any 20 Trading Days within any 30-Trading Day period, and (ii) as to the remaining 500,000 shares, the VWAP of the New Orchestra Common Stock is greater than or equal to $20.00 per share over any 20-Trading Days within any 30-Trading Day period. Further, the Sponsor and HSAC2's other initial shareholders prior to its initial public offering have agreed to subject the 4,000,000 shares of New Orchestra Common Stock to be received in the Domestication in exchange for the 4,000,000 HSAC2 Ordinary Shares issued to HSAC2's initial shareholders prior to its initial public offering and 450,000 shares of New Orchestra Common Stock to be received in the Domestication in exchange for 450,000 HSAC2 Ordinary Shares purchased in a private placement simultaneously with the HSAC2 initial public offering, to a lock-up for up to 12 months following the Closing and, subject to the Closing, the Sponsor agreed to forfeit 50% of its 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 such forfeiture and prior to the Closing, HSAC2 issued 750,000 New Warrants to eleven specified employees and directors of Orchestra. These New Warrants have substantially similar terms to the forfeited Private Warrants, except that they will become exercisable between 24 and 36 months after the Closing.

On January 24, 2023, HSAC2 held the Meeting, at which time the HSAC2 shareholders approved, among other matters, the Domestication and the Merger Agreement.

The consideration paid at Closing by HSAC2 to Orchestra security holders was paid in shares of HSAC2 Common Stock subject to the Exchange Ratio.

Orchestra stockholders had the opportunity to elect to participate in an earnout pursuant to which each such Earnout Participant may receive Earnout Consideration of up to 8,000,000 shares of New Orchestra Common Stock in the aggregate. Each Earnout Participant agreed to extend their applicable Lock-up Period from 6 months to 12 months, pursuant to an Earnout Election Agreement and will be entitled to receive the Earnout Consideration as follows:

- Earnout Participants will collectively be entitled to receive 4,000,000 Initial Earnout Shares, in the event that, over any 20 Trading Days within any 30-Trading Day period during the Earnout Period the VWAP of the New Orchestra Common Stock is greater than or equal to $15.00 per share; and

- Earnout Participants will collectively be entitled to receive an additional 4,000,000 Final Earnout Shares, in the event that, during the Earnout Period, over any 20-Trading Days within any 30-Trading Day period during the Earnout Period the VWAP of the New Orchestra Common Stock is greater than or equal to $20.00 per share.

- Upon the first change in control meeting certain conditions that occurs during the Earnout Period, if the corresponding valuation of New Orchestra is equal to or greater than $15.00 per share (taking into consideration the Initial Earnout Shares in determining such calculation), the Initial Milestone Event will be deemed to have occurred and if equal to or greater than $20.00 per share (taking into consideration the issuance of all Earnout Consideration in determining such calculation), the Final Milestone Event will be deemed to have occurred, in each case immediately prior to such change in control.

Orchestra accounts for the Earnout Shares as either equity-classified or liability-classified instruments based on an assessment of the Earnout Shares specific terms and applicable authoritative guidance in ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC 815, *Derivatives and Hedging* ("ASC 815"). Orchestra has preliminarily determined that the Earnout Shares are indexed to New Orchestra's stock and are therefore will be classified within stockholders' equity. The unaudited pro forma condensed combined financial information does not reflect pro forma adjustments related to the recognition of the Earnout Shares as the issuance of the shares would be represented by both an increase and offsetting decrease to additional paid-in capital. The unaudited pro forma condensed combined financial information does not reflect pro forma adjustments on a per share basis for the Earnout Shares because the earnout contingencies have not yet been met and because the earnout shares would be anti-dilutive.

The issuance of such Earnout Shares would dilute the value of all shares of New Orchestra Common Stock outstanding at the time of issuance. Assuming the current capitalization structure, the 4,000,000 Initial Earnout Shares that would become vested upon meeting the $15.00 earnout threshold, would represent approximately 13% of total shares outstanding for the redemption scenarios set forth. Assuming the current capitalization structure, the total 8,000,000 shares representing the Initial Earnout Shares and Final Earnout Shares that would become vested upon meeting the $20.00 earnout threshold, would represent approximately 26% of total shares outstanding for the redemption scenarios set forth.

Each share of Orchestra capital stock, if any, that is owned by HSAC2, Merger Sub, or Orchestra, or any of their subsidiaries (as treasury stock or otherwise) was canceled and extinguished without any conversion or consideration.

At the Effective Time, each issued and outstanding share of Orchestra Common Stock (other than any such shares of Orchestra Common Stock canceled as described above and any dissenting shares) was converted into the right to receive (1) a number of shares of HSAC2 Common Stock at the Exchange Ratio, and (2) shares of Earnout Consideration as, and subject to the contingencies, described above, including entry into an Earnout Election Agreement.

Each share of common stock, par value $0.01 per share, of Merger Sub issued and outstanding immediately prior to the Effective Time was converted into one newly issued share of Orchestra as the surviving corporation in the Merger.

At the Effective Time, each outstanding option to purchase shares of Orchestra Common Stock was converted into an option to purchase, subject to substantially the same terms and conditions as were applicable under such options prior to the Effective Time, shares of New Orchestra Common Stock equal to the number of shares subject to such option prior to the Effective Time multiplied by the Exchange Ratio, at an exercise price per share of New Orchestra Common Stock equal to the exercise price per share of Orchestra Common Stock subject to such option divided by the Exchange Ratio.

Effective immediately prior to the Effective Time, each outstanding warrant to purchase shares of Orchestra capital stock was treated in accordance with the terms of the relevant agreements governing such warrants and converted into New Orchestra warrants. The outstanding warrants to purchase shares of Orchestra capital stock are expected to be equity classified upon the consummation of the Business Combination.

Extension Proposal

On July 1, 2022, HSAC2 filed a proxy statement seeking approval of the Extension Proposal from its shareholders to amend the Company's Existing Charter to: (a) extend from August 6, 2022 to November 6, 2022, the date by which, if the Company has not consummated a merger, amalgamation, share exchange, asset acquisition, share purchase, reorganization or similar business combination involving one or more businesses or entities, the Company must: (i) cease all operations except for the purpose of winding up; (ii) as promptly as reasonably possible but not more than ten business days thereafter, redeem the Public Shares; and (iii) as promptly as reasonably possible following such redemption liquidate and dissolve, subject in each case to its obligations under Cayman Islands law to provide for claims of creditors and in all cases subject to the other requirements of applicable law, and (b) allow the Company, without another shareholder vote, to elect to extend the date to consummate a business combination on a monthly basis for up to three times by an additional one month each time after November 6, 2022, upon five days' advance notice prior to the applicable deadlines, until February 6, 2023 or a total of up to six months after August 6, 2022, unless the closing of the Company's initial business combination shall have occurred.

On November 15, 2022, the Directors of the Company elected to extend the deadline until January 6, 2023 and on December 15, 2022, the Directors of the Company elected to further extend the deadline until February 6, 2023.

The submission of the Extension Proposal to amend HSAC2's Existing Charter entitled holders of Public Shares to redeem their shares for their pro rata portion of the funds held in the trust account established at the time of the HSAC2 initial public offering. In connection with the Extension Meeting, as of July 22, 2022, HSAC2 received requests for redemption from shareholders with respect to 9,237,883 HSAC2 Ordinary Shares.

HSAC2 held the Meeting on January 24, 2023 for the purposes of considering and voting upon, among other things, the Business Combination. The submission of the Business Combination to the shareholders entitled holders of Public Shares to redeem their Public Shares for their pro rata portion of the funds held in the trust account established at the time of the HSAC2 initial public offering. In connection with the Meeting, as of January 24, 2023, HSAC2 received requests for redemption from shareholders with respect to 1,597,888 HSAC2 Ordinary Shares.

The following summarizes the pro forma ownership of New Orchestra Common Stock following the Business Combination:

	Number of Shares	Percentage of Outstanding Shares
Orchestra stockholders[(1)]	13,881,338	45.3%
Medtronic[(2)]	4,992,588	16.3%
HSAC2 Public Shareholders[(3)]	3,141,641	10.3%
Sponsor and related parties[(4)(5)]	8,598,512	28.1%
Pro forma Common Stock at December 31, 2022	**30,614,079**	**100.0%**

(1) Excludes (i) 8,000,000 Earnout Ordinary Shares as the earnout contingencies have not yet been met, (ii) shares issuable in connection with outstanding Orchestra options and warrants, (iii) shares available for issuance pursuant to the 2022 Equity Incentive Plan, (iv) 2,310,000 shares held by certain funds managed by RTW Investments, LP. and (v) shares held by Medtronic.
(2) Includes 4,000,000 shares of Orchestra and 992,588 HSAC2 Ordinary Shares.
(3) Reflects the redemption of 9,237,883 HSAC2 Ordinary Shares in connection with the Extension Amendment and 1,597,888 ordinary shares in connection with the Meeting. Excludes 1,992,588 Public Shares acquired by the RTW Funds and Medtronic pursuant to the Forward Purchase Agreements and 30,000 Ordinary Shares held by officers of HSAC2.
(4) Excludes 1,000,000 HSAC2 Ordinary Shares subject to forfeiture upon the expiration of the Earnout Period, includes 1,000,000 HSAC2 Ordinary Shares purchased pursuant to the Forward Purchase Agreement with RTW Funds.
(5) Excludes 750,000 Private Warrants. If all potential sources of dilution were exercised and converted into HSAC2 Ordinary Shares the Sponsor and related parties would hold approximately 20.7%

UNAUDITED PRO FORMA CONDENSED CONSOLIDATED COMBINED BALANCE SHEET
AS OF DECEMBER 31, 2022
(in thousands, except share and per share data)

	HSAC2 (Historical)	Orchestra (Historical)	Transaction Accounting Adjustments		Pro Forma Combined
ASSETS					
Current assets					
Cash and cash equivalents	$ 175	$ 19,784	$ 51,760	**B**	$ 76,509
			18,085	**C**	
			(2,235)	**D**	
			(5,460)	**E**	
			(5,600)	**F**	
Marketable securities	—	63,915	—		63,915
Strategic investments	—	86	—		86
Accounts receivable, net	—	96	—		96
Inventory	—	276	—		276
Prepaid expenses and other current assets	124	533	—		657
Total current assets	299	84,690	56,550		141,539
Property and equipment, net	—	1,489	—		1,489
Right-of-use assets	—	2,187	—		2,187
Strategic investments, less current portion	—	2,495	—		2,495
Deposits and other assets	—	4,711	(3,981)	**E**	730
Investments held in Trust Account	67,776	—	(51,760)	**B**	—
			(16,016)	**A**	
Total assets	$ 68,075	$ 95,572	$ (15,207)		$ 148,440
LIABILITIES, REDEEMABLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)					
Current liabilities					
Accounts payable	$ 377	$ 3,968	$ (361)	**D**	$ 2,338
			(1,646)	**E**	
Accrued expenses and other liabilities	1,367	5,376	(1,367)	**D**	5,376
Operating lease liability - current	—	697	—		697
Warrant liability	—	2,089	(2,089)	**G**	—
Deferred revenue, current portion	—	6,436	—		6,436
Total current liabilities	1,744	18,566	(5,463)		14,847
Deferred revenue, less current portion	—	13,103	—		13,103
Loan payable, less current portion	—	9,490	—		9,490
Operating lease liability, less current portion	—	1,683	—		1,683
Other long-term liabilities	—	196	—		196
Deferred underwriting commissions	5,600	—	(5,600)	**F**	—
Total liabilities	7,344	43,038	(11,063)		39,319
Ordinary shares subject to possible redemption	67,676	—	(16,016)	**A**	—
			(51,660)	**H**	
Series A preferred stock	—	51,452	(51,452)	**J**	—
Series D-1 preferred stock	—	27,272	(27,272)	**J**	—
Series D-2 preferred stock	—	87,199	(87,199)	**J**	—
Stockholders' equity (deficit)					
Preferred Stock	—	—	—		—
Ordinary stock	—	—	1	**H**	—
			(1)	**I**	
New Orchestra Common Stock	—	—	1	**I**	3
			2	**J**	
Additional paid-in capital	—	86,353	18,085	**C**	309,367
			(7,795)	**E**	
			2,089	**G**	
			51,659	**H**	
			165,921	**J**	
			(6,945)	**K**	
Accumulated other comprehensive loss	—	(8)	—		(8)
Accumulated deficit	(6,945)	(199,734)	(507)	**D**	(200,241)
			6,945	**K**	
Total stockholders' equity (deficit)	(6,945)	(113,389)	229,455		109,121
Total liabilities, preferred stock and stockholders' equity (deficit)	$ 68,075	$ 95,572	$ (15,207)		$ 148,440

UNAUDITED PRO FORMA CONDENSED CONSOLIDATED COMBINED STATEMENT OF OPERATIONS
FOR THE YEAR ENDED DECEMBER 31, 2022
(in thousands, except share and per share data)

	HSAC2 (Historical)	Orchestra (Historical)	Transaction Accounting Adjustments		Pro Forma Combined
Revenue					
Partnership revenue	$ —	$ 2,862	$ —		$2,862
Product revenue	—	671	—		671
Total revenue	—	3,533	—		3,533
Expenses					
Cost of product revenues	—	211	—		211
Research and development	—	21,945	—		21,945
Selling, general and administrative	2,960	14,034	507	**B.1**	18,581
			1,080	**D.1**	
Administrative fee - related party	120	—	—		120
Total expenses	3,080	36,190	1,587		40,857
Operating loss	(3,080)	(32,657)	(1,587)		(37,324)
Other income (expense)					
Interest income from investments held in Trust Account	345	—	(345)	**A.1**	—
Interest income (expense), net	—	50	—		50
Loss on fair value adjustment of warrant liability	—	(1,350)	1,350	**C.1**	—
Loss on debt extinguishment	—	(682)	—		(682)
Gain on fair value of strategic investments	—	1,031	—		1,031
Total other income (expense)	345	(951)	1,005		399
Net loss	$ (2,735)	$ (33,608)	$ (582)		$ (36,925)
Net loss per share (Note 4)					
Weighted average shares outstanding	16,425,826	2,439,450			30,614,079
Basic and diluted net loss per share	$ (0.17)	$ (14.60)			$ (1.21)

NOTES TO UNAUDITED PRO FORMA CONDENSED CONSOLIDATED COMBINED FINANCIAL INFORMATION

Note 1. Basis of Presentation

The Business Combination has been accounted for as a reverse recapitalization, with no goodwill or other intangible assets recorded, in accordance with U.S. GAAP. Under this method of accounting, HSAC2 has been treated as the "accounting acquiree" and Orchestra as the "accounting acquirer" for financial reporting purposes. Accordingly, for accounting purposes, the Business Combination has been treated as the equivalent of Orchestra issuing shares for the net assets of HSAC2, followed by a recapitalization. The net assets of HSAC2 have been stated at historical cost. Operations prior to the Business Combination are those of Orchestra.

The unaudited pro forma condensed consolidated combined balance sheet as of December 31, 2022 gives effect to the Business Combination and related transactions as if they had been completed on December 31, 2022. The unaudited pro forma condensed consolidated combined statement of operations for the year ended December 31, 2022 gives effect to the Business Combination and related transactions as if they had been completed on January 1, 2022. This period is presented on the basis that Orchestra is the acquirer for accounting purposes.

The pro forma adjustments reflecting the consummation of the Business Combination and the related transaction are based on certain currently available information and certain assumptions and methodologies that New Orchestra management believes are reasonable under the circumstances. The unaudited condensed consolidated combined pro forma adjustments, which are described in the accompanying notes, may be revised as additional information becomes available and is evaluated. Therefore, it is likely that the actual adjustments will differ from the pro forma adjustments, and it is possible that the difference may be material. New Orchestra management believes that its assumptions and methodologies provide a reasonable basis for presenting all of the significant effects of the Business Combination and the related transactions based on information available to management at this time and that the pro forma adjustments give appropriate effect to those assumptions and are properly applied in the unaudited pro forma condensed consolidated combined financial information.

The unaudited pro forma condensed consolidated combined financial information does not give effect to any anticipated synergies, operating efficiencies, tax savings, or cost savings that may be associated with the Business Combination. The unaudited pro forma condensed consolidated combined financial information is not necessarily indicative of the future consolidated results of operations or financial position of the post-combination company. They should be read in conjunction with the historical consolidated financial statements and notes thereto of HSAC2 and Orchestra.

Note 2. Accounting Policies and Reclassifications

Upon consummation of the Business Combination, New Orchestra management performed a comprehensive review of the two entities' accounting policies. As a result of the review, management did not identify any differences between the accounting policies of the two entities that would have a material impact on the unaudited pro forma condensed consolidated combined financial information. As a result, the unaudited pro forma condensed consolidated combined financial information does not assume any differences in accounting policies.

As part of the preparation of these unaudited pro forma condensed consolidated combined financial statements, certain reclassifications were made to align HSAC2's financial statement presentation with that of Orchestra.

Preferred Stock Conversion

Immediately prior to the consummation of the Business Combination, each share of Orchestra's pre-merger preferred stock converted into Orchestra common stock. Upon the closing of the Business Combination (after giving effect to the conversion of Orchestra preferred stock into Orchestra common stock), all shares of Orchestra common stock outstanding have been converted into shares of New Orchestra Common Stock.

Accounting for Stock Option Conversion

The Company accounts for stock-based compensation arrangements with employees and non-employee consultants using a fair value method which requires the recognition of compensation expense for costs related to all stock-based payments, including stock options. As of the Effective Time, each Orchestra option that was outstanding prior to the business combination has been converted into an option to purchase shares of New Orchestra Common Stock upon substantially the same terms and conditions as were in effect with respect to such option immediately prior to the Effective Time, subject to specific terms and conditions. As there was no change in the terms of the options or material change in fair value, Orchestra did not recognize any incremental stock compensation expense.

Note 3. Adjustments to Unaudited Pro Forma Condensed Consolidated Combined Financial Information

The unaudited pro forma condensed consolidated combined financial information has been prepared to illustrate the effect of the Business Combination and related transactions and has been prepared for informational purposes only.

The following unaudited pro forma condensed consolidated combined financial information has been prepared in accordance with Article 11 of Regulation S-X as amended by the final rule, Release No. 33-10786 "Amendments to Financial Disclosures about Acquired and Disposed Businesses." Release No. 33-10786 replaces the existing pro forma adjustment criteria with simplified requirements to depict the accounting for the transaction ("Transaction Accounting Adjustments") and present the reasonably estimable synergies and other transaction effects that have occurred or are reasonably expected to occur ("Management's Adjustments"). The pro forma adjustments reflecting the consummation of the Business Combination and related transactions are based on certain currently available information and certain estimates, assumptions and methodologies that management believes are reasonable under the circumstances. The unaudited condensed consolidated combined pro forma adjustments, which are described in the accompanying notes, may be revised as additional information becomes available and is evaluated. New Orchestra has elected not to present Management's Adjustments and will only be presenting Transaction Accounting Adjustments in the unaudited pro forma condensed consolidated combined financial information. There were no pro forma adjustments required to eliminate activities between the companies.

The pro forma condensed combined financial information does not include an income tax adjustment. Upon closing of the Business Combination, it is likely that the combined company will record a valuation allowance against the total U.S. and state deferred tax assets as the recoverability of the tax assets is uncertain. The pro forma combined provision for income taxes does not necessarily reflect the amounts that would have resulted had the combined company filed consolidated income tax returns during the period presented.

The pro forma basic and diluted earnings per share amounts presented in the unaudited pro forma condensed consolidated combined statement of operations are based upon the number of shares of New Orchestra Common Stock outstanding, assuming the Business Combination and related transactions occurred on the beginning of the earliest period presented. The pro forma basic and diluted earnings per share amounts exclude the impact of the Earnout Shares as the earnout contingencies have not yet been met and because the earnout shares would be anti-dilutive.

Adjustments to Unaudited Pro Forma Condensed Consolidated Combined Balance Sheet:

The adjustments included in the unaudited pro forma condensed consolidated combined balance sheet as of December 31, 2022 are as follows:

A. Reflects the redemption payment totaling approximately $16.0 million as a result of the redemption of 1,597,888 HSAC2 Ordinary Shares in connection with the Closing, inclusive of $0.4 million of available interest at January 26, 2023.

B. Reflects the reclassification of marketable securities of $51.8 million held in the trust account to cash and cash equivalents.

C. Reflects the proceeds of 1,808,512 HSAC2 Ordinary Shares purchased by certain funds managed by RTW Investments, LP pursuant to the Backstop Agreement.

D. Represents HSAC2 transaction costs of $2.4 million inclusive of advisory, banking, printing, legal, accounting fees and other professional fees that are expensed as a part of the Business Combination within accumulated deficit. Of the transaction costs, $1.9 million has already been incurred and reflected in the historical financial statements of HSAC2, of which $0.2 million had already been paid.

E. Represents Orchestra transaction costs of $7.8 million inclusive of advisory, banking, legal and other professional fees that were incurred as a part of the Business Combination within additional paid-in capital. Of the transaction costs, $4.0 million had already been incurred pre-merger and reflected in the historical financial statements of Orchestra, of which $2.3 million has already been paid.

F. Reflects the settlement of $5.6 million in deferred underwriting fee payable.

G. Reflects the reclassification of $2.1 million of Orchestra warrant liabilities to equity. The Orchestra warrants are expected to meet the fixed-for-fixed indexation criteria to be equity classified following the consummation of the Business Combination.

H. Reflects the reclassification of $51.7 million of HSAC2 Ordinary Shares subject to possible redemption into permanent equity upon closing of the business combination.

I. Reflects the conversion of 9,614,229 HSAC2 Ordinary Shares into 9,614,229 shares of New Orchestra Common Stock in the Domestication after reflecting the redemption of 10,835,771 HSAC2 Ordinary Shares in connection with the Extension Proposal and the Closing.

J. Reflects the recapitalization of Orchestra's outstanding equity and temporary equity comprised of 35,694,179 shares of preferred stock and 2,518,359 shares of common stock, par value of $0.0001 (aggregate value of $165.9 million) reflected as an increase in additional paid-in capital.

K. Reflects the reclassification of HSAC2's historical accumulated deficit.

Adjustments to Unaudited Pro Forma Condensed Consolidated Combined Statement of Operations

The pro forma adjustments included in the unaudited pro forma condensed consolidated combined statement of operations for the year ended December 31, 2022 is as follows:

A.1 Reflects elimination of investment income on the trust account.

B.1 Reflects transactions costs of $0.6 million as if incurred on January 1, 2022, the date the Business Combination occurred for the purposes of the unaudited pro forma condensed consolidated combined statement of operations. The amount presented is comprised of transaction costs outlined in adjustment (C) that were not yet recognized and expensed in the historical statement of operations as part of the Business Combination.

C.1 Reflects the reclassification of the Orchestra warrant liabilities to equity as of January 1, 2022 and the elimination of changes in the fair value of the warrant liabilities recorded in the statement of operations. The Orchestra warrants are expected to meet the fixed-for-fixed indexation criteria to be equity classified following the consummation of the Business Combination.

D.1 Reflects additional stock compensation expense related to the grant of new warrants to purchase an aggregate of 750,000 shares of New Orchestra Common Stock to specified employees and directors of Orchestra.

Note 4. Net Loss per Share

Net loss per share was calculated using the historical weighted average shares outstanding, and the issuance of additional shares in connection with the Business Combination and the related transactions, assuming the shares were outstanding since January 1, 2022. As the Business Combination and the related transactions are being reflected as if they had occurred at the beginning of the period presented, the calculation of weighted average shares outstanding for basic and diluted net loss per share assumes that the shares issuable relating to the Business Combination and related have been outstanding for the entirety of the period presented.

	Year Ended December 31, 2022 [1]
	(in thousands, except share and per share data)
Pro forma net loss	$ (36,925)
Weighted average shares outstanding - basic and diluted	30,614,079
Net loss per share - basic and diluted	$ (1.21)
Excluded securities:[2]	
Private Warrants	750,000
Orchestra Warrants	2,325,936
Orchestra Options	3,929,298
Sponsor and related parties shares subject to forfeiture on expiration of Earnout	1,000,000
Earnout Shares	8,000,000

(1) Pro forma net loss per share includes the related pro forma adjustments as referred to within the section "*Adjustments to Unaudited Pro Forma Condensed Consolidated Combined Financial Information*."

(2) The potentially dilutive outstanding securities were excluded from the computation of pro forma net loss per share, basic and diluted, because their effect would have been anti-dilutive and/or issuance or vesting of such shares is contingent upon the satisfaction of certain conditions which were not satisfied by the end of the period presented.