UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2023

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from___ to___
Commission file number: 001-40355

Treace Medical Concepts, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**47-1052611**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

100 Palmetto Park Place
Ponte Vedra, Florida 32081
(Address of principal executive offices, including zip code)

(904) 373-5940
(Registrant's telephone number, including area code)

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, $0.001 par value	TMCI	The Nasdaq Global Select Market

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

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

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

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

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

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

As of November 3, 2023, 61,675,861 shares of the registrant's common stock, $0.001 par value per share, were outstanding.

TREACE MEDICAL CONCEPTS, INC.

FORM 10-Q FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2023

Table of Contents

Part I: Financial Information

Part II: Other Information

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

As used in this Quarterly Report on Form 10-Q ("Quarterly Report"), unless expressly indicated or the context otherwise requires, references to "Treace Medical Concepts," "we," "us," "our," or "the Company," refer to Treace Medical Concepts, Inc. This Quarterly Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as codified in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act") concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology.

These forward-looking statements include, but are not limited to, statements about:

- the expected use of our products by physicians;
- the expected growth of our business and our organization;
- our expected uses of our existing cash, cash equivalents and marketable securities and the sufficiency of such resources to fund our planned operations;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to retain and recruit key personnel, including the continued development of a sales and marketing infrastructure;
- our ability to obtain an adequate supply of materials and components for our products from our third-party suppliers, some of which are single-source suppliers;
- our plans and expected timeline related to our products, or developing or acquiring new products, to address additional indications or otherwise;
- our ability to manufacture sufficient quantities of our products with sufficient quality;
- our ability to obtain and maintain intellectual property protection for our products;
- our ability to identify and develop new and planned products and/or acquire new products;
- our ability to realize the anticipated benefits of the acquisition of MIOS Marketing, LLC d/b/a RedPoint Medical 3D ("RPM-3D") assets as rapidly or to the extent anticipated, if at all;
- our ability to obtain, maintain and expand regulatory clearances for our products and any new products we develop or acquire;
- our ability to expand our business into current and new geographic markets;
- our compliance with Nasdaq requirements and government laws, rules and regulations;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our need for, or ability to obtain, additional financing;
- the impact of inflationary pressures, higher interest rates, recent instability in the banking sector, and general economic conditions on our business;
- the impact of geopolitical tensions and international conflicts on the economy and our business;
- developments and projections relating to our competitors or our industry;
- our plans to conduct further clinical studies;
- the impact of failures, defaults or instability of financial institutions where we have cash accounts; and
- the effect of the COVID-19 pandemic or another infectious disease outbreak and its impact or potential impact on our business.

We believe that it is important to communicate our future expectations to our investors. However, there may be events in the future that we are not able to accurately predict or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. These forward-looking statements are based on management's current expectations, estimates, forecasts and projections about our business and the industry in which we operate, and management's beliefs and assumptions and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Quarterly Report may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those set forth in our Annual Report on Form 10-K under "Part I, Item 1A-Risk Factors", in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 in the section titled "Part II, Item 1A-Risk Factors," and in the section titled "Risk Factors" included elsewhere in this Quarterly Report. Potential investors are urged to consider these factors carefully in evaluating the forward-looking statements.

These forward-looking statements speak only as of the date of this Quarterly Report. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Quarterly Report to conform these statements to actual results or to changes in our expectations.

You should read this Quarterly Report and the documents that we reference in this Quarterly Report and have filed with the Securities and Exchange Commission ("SEC") as exhibits to this Quarterly Report with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited).

TREACE MEDICAL CONCEPTS, INC.
Condensed Balance Sheets
(in thousands, except share and per share amounts)
(unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 7,278	$ 19,473
Marketable securities, short-term	114,885	61,779
Accounts receivable, net of allowance for doubtful accounts of $639 and $735 as of September 30, 2023 and December 31, 2022, respectively	24,996	29,196
Inventories	29,312	19,330
Prepaid expenses and other current assets	10,671	3,624
Total current assets	187,142	133,402
Property and equipment, net	21,536	15,338
Intangible assets, net of accumulated amortization of $238 and $0 as of September 30, 2023 and December 31, 2022, respectively	9,262	—
Goodwill	12,815	—
Operating lease right-of-use assets	9,459	10,138
Other non-current assets	146	146
Total assets	$ 240,360	$ 159,024
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 8,680	$ 8,668
Accrued liabilities	8,936	6,216
Accrued commissions	5,278	7,356
Accrued compensation	5,070	7,666
Other liabilities	5,190	339
Total current liabilities	33,154	30,245
Long-term debt, net of discount of $1,066 and $1,289 as of September 30, 2023 and December 31, 2022, respectively	52,934	52,711
Operating lease liabilities, net of current portion	16,375	15,539
Other long-term liabilities	37	—
Total liabilities	102,500	98,495
Commitments and contingencies (Note 8)		
Stockholders' equity		
Preferred stock, $0.001 par value, 5,000,000 shares authorized as of September 30, 2023 and December 31, 2022; 0 shares issued and outstanding as of September 30, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value, 300,000,000 shares authorized; 61,606,926 issued and outstanding as of September 30, 2023; 300,000,000 shares authorized; 55,628,208 issued and outstanding as of December 31, 2022	62	55
Additional paid-in capital	265,912	145,221
Accumulated deficit	(127,966)	(84,720)
Accumulated other comprehensive (loss) income	(148)	(27)
Total stockholders' equity	137,860	60,529
Total liabilities and stockholders' equity	$ 240,360	$ 159,024

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

TREACE MEDICAL CONCEPTS, INC.
Condensed Statement of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue	$ 40,758	$ 33,055	$ 124,906	$ 92,069
Cost of goods sold	7,998	6,090	$ 23,712	$ 16,511
Gross profit	32,760	26,965	101,194	75,558
Operating expenses				
Sales and marketing	33,542	25,568	100,970	74,477
Research and development	4,350	3,799	11,288	9,835
General and administrative	12,686	8,916	33,582	22,593
Total operating expenses	50,578	38,283	145,840	106,905
Loss from operations	(17,818)	(11,318)	(44,646)	(31,347)
Interest income	1,570	420	5,017	560
Interest expense	(1,296)	(1,190)	(3,863)	(3,087)
Debt extinguishment loss	—	—	—	(4,483)
Other income, net	23	(45)	246	(46)
Other non-operating income (expense), net	297	(815)	1,400	(7,056)
Net loss	$ (17,521)	$ (12,133)	$ (43,246)	$ (38,403)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	71	—	(121)	—
Comprehensive loss	$ (17,450)	$ (12,133)	$ (43,367)	$ (38,403)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.28)	$ (0.22)	$ (0.71)	$ (0.70)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	61,562,494	55,429,211	60,566,655	55,190,587

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

TREACE MEDICAL CONCEPTS, INC.
Condensed Statement of Stockholders' Equity
(in thousands, except share amounts)
(unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2022	55,628,208	$ 55	$ 145,221	$ (84,720)	$ (27)	$ 60,529
Issuance of common stock upon exercise of stock options	125,890	—	352	—	—	352
Issuance of common stock for vesting of restricted stock units	50,415	—	—	—	—	—
Share-based compensation expense	—	—	2,692	—	—	2,692
Issuance of common stock from public offering, net of issuance costs and underwriting discount of $7.5 million	5,476,190	6	107,521	—	—	107,527
Net loss	—	—	—	(13,454)	—	(13,454)
Unrealized loss on available-for-sale marketable securities	—	—	—	—	(29)	(29)
Balances at March 31, 2023	61,280,703	$ 61	$ 255,786	$ (98,174)	$ (56)	$ 157,617
Issuance of common stock upon exercise of stock options	205,244	1	1,179	—	—	1,180
Issuance of common stock for vesting of restricted stock units	42,462	—	—	—	—	—
Share-based compensation expense	—	—	3,596	—	—	3,596
Net loss	—	—	—	(12,271)	—	(12,271)
Unrealized loss on available-for-sale marketable securities	—	—	—	—	(163)	(163)
Balances at June 30, 2023	61,528,409	$ 62	$ 260,561	$ (110,445)	$ (219)	$ 149,959
Issuance of common stock upon exercise of stock options	46,001	—	159	—	—	159
Issuance of common stock for vesting of restricted stock units	32,516	—	—	—	—	—
Share-based compensation expense	—	—	5,192	—	—	5,192
Net loss	—	—	—	(17,521)	—	(17,521)
Unrealized loss on available-for-sale marketable securities	—	—	—	—	71	71
Balances at September 30, 2023	61,606,926	$ 62	$ 265,912	$ (127,966)	$ (148)	$ 137,860
Balances at December 31, 2021	54,181,082	$ 45	$ 134,933	$ (41,905)	$ —	$ 93,073
Issuance of common stock upon exercise of stock options	1,097,860	1	1,371	—	—	1,372
Share-based compensation expense	—	—	1,409	—	—	1,409
Net loss	—	—	—	(9,036)	—	(9,036)
Balances at March 31, 2022	55,278,942	$ 46	$ 137,713	$ (50,941)	$ —	$ 86,818
Issuance of common stock upon exercise of stock options	112,367	—	165	—	—	165
Share-based compensation expense	—	—	1,963	—	—	1,963
Net loss	—	—	—	(17,234)	—	(17,234)
Balances at June 30, 2022	55,391,309	$ 46	$ 139,841	$ (68,175)	$ —	$ 71,712
Issuance of common stock upon exercise of stock options	107,933	—	353	—	—	353
Share-based compensation expense	—	—	2,269	—	—	2,269
Net loss	—	—	—	(12,133)	—	(12,133)
Balances at September 30, 2022	55,499,242	$ 46	$ 142,463	$ (80,308)	$ —	$ 62,201

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

TREACE MEDICAL CONCEPTS, INC.
Condensed Statements of Cash Flows
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (43,246)	$ (38,403)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization expense	3,583	1,216
(Recovery) provision for allowance for doubtful accounts	79	(38)
Share-based compensation expense	11,480	5,641
Non-cash lease expense	1,868	2,010
Amortization of debt issuance costs	223	169
Recovery of inventory obsolescence	—	(206)
Gain on fair value adjustment to derivative liability	—	(173)
Debt extinguishment loss	—	4,483
Accretion (amortization) of discount (premium) on marketable securities, net	(1,031)	—
Other, net	164	25
Net changes in operating assets and liabilities, net of acquisitions:		
Accounts Receivable	4,121	58
Inventory	(9,915)	(6,027)
Prepaid expenses and other assets	(1,028)	(1,058)
Other non-current assets	—	(146)
Other liabilities	497	3,112
Accounts payable	12	3,825
Accrued liabilities	(1,954)	222
Other, net	40	—
Net cash used in operating activities	(35,107)	(25,290)
Cash flows from investing activities		
Purchases of available-for-sale marketable securities	(140,075)	—
Sales and maturities of available-for-sale marketable securities	82,979	—
Purchases of property and equipment	(9,210)	(12,506)
Acquisition, net of cash acquired	(20,000)	—
Net cash used in investing activities	(86,306)	(12,506)
Cash flows from financing activities		
Proceeds from interest bearing term debt	—	49,651
Proceeds from interest bearing revolving debt	—	3,850
Debt issuance costs	—	(989)
Repayment of term loan	—	(33,893)
Proceeds from issuance of common stock from public offering, net of issuance costs and underwriting discount of $7.5 million	107,527	—
Proceeds from exercise of employee stock options	1,691	1,890
Net cash provided by financing activities	109,218	20,509
Net decrease in cash and cash equivalents	(12,195)	(17,287)
Cash and cash equivalents at beginning of period	19,473	105,833
Cash and cash equivalents at end of period	$ 7,278	$ 88,546
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 3,863	$ 3,087
Operating lease right-of-use assets obtained in exchange for new lease liabilities	$ —	$ 15,300
Operating lease right-of-use asset and lease liability adjustment due to lease incentive	$ (22)	$ —
Noncash investing activities:		
Unrealized losses on marketable securities	$ 121	$ —
Unsettled marketable security purchase and payable to broker	$ (1,100)	$ —
Unsettled matured marketable security and receivable from broker	$ 6,000	$ —

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

1. Formation and Business of the Company

The Company

Treace Medical Concepts, LLC was formed on July 29, 2013, as a Florida limited liability company. Effective July 1, 2014, the entity converted to a Delaware corporation and changed its name to Treace Medical Concepts, Inc. (the "Company"). The Company is a medical technology company with the goal of advancing the standard of care for the surgical management of bunion and related midfoot deformities. The Company received 510(k) clearance for the Lapiplasty® System in March 2015 and began selling its surgical medical devices in September 2015. The Company has pioneered the proprietary Lapiplasty 3D Bunion Correction System – a combination of instruments, implants and surgical methods designed to surgically correct all three planes of the bunion deformity and secure the unstable joint, addressing the root cause of the bunion. In addition, the Company offers other advanced instrumentation and implants for use in the Lapiplasty Procedure or other ancillary procedures performed in high frequency with bunion surgery. The Company operates from its corporate headquarters located in Ponte Vedra, Florida.

Initial Public Offering and Follow-on Offering

On April 27, 2021, the Company completed its initial public offering ("IPO"). The Company received net proceeds of $107.6 million from the IPO. On February 10, 2023, the Company completed a follow-on public offering of 5,476,190 shares of its common stock, which included the exercise in full of the underwriters' option to purchase additional shares, at a price to the public of $21.00 per share. The February 2023 offering resulted in net proceeds of $107.5 million after deducting underwriting discounts and commissions of $6.9 million and offering expenses payable by the Company of $0.6 million.

Liquidity and Capital Resources

The Company has incurred operating losses to date and has an accumulated deficit of $128.0 million as of September 30, 2023. During the nine months ended September 30, 2023 and 2022, the Company used $35.1 million and $25.3 million of cash in its operating activities, respectively. As of September 30, 2023, the Company had cash and cash equivalents of $7.3 million and marketable securities available-for-sale of $114.9 million.

Management believes that the Company’s existing cash, cash equivalents, and marketable securities will allow the Company to continue its planned operations for at least the next 12 months from the date of the issuance of these interim condensed financial statements.

2. Summary of Significant Accounting Policies

The Company prepared the unaudited interim condensed financial statements included in this report in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and the rules and regulations of the Securities and Exchange Commission related to quarterly reports on Form 10-Q.

Basis of Presentation

The condensed financial statements have been prepared on the same basis as the Company’s annual financial statements included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on March 8, 2023, with the exception of the reclassification as discussed below. The unaudited condensed financial statements included herein reflect all adjustments, including normal recurring adjustments, which are, in the opinion of management, necessary for a fair presentation of the financial position, results of operations and cash flows for the periods presented. The results of operations for the nine months ended September 30, 2023 are not necessarily indicative of the results that may be expected for future quarters or for the fiscal year ending December 31, 2023.

An adjustment has been made to the Statement of Operations for the three months and nine months ended September 30, 2022 for $0.5 million and $1.3 million, respectively to reclassify surgical instrument expense from cost of goods sold to sales and marketing expense, to conform with the current year's presentation. This reclassification had no effect on the Company's net loss.

Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

Use of Estimates

The preparation of condensed financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed financial statements and the reported amounts of revenues and expenses during the reporting periods. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Significant estimates and assumptions include valuation of goodwill and intangible assets, contingent earn-out liabilities, reserves and write-downs related to accounts receivable, inventories, the recoverability of long-term assets, stock-based compensation, deferred tax assets and related valuation allowances and impact of contingencies. The Company had no accrued contingent liabilities as of September 30, 2023 and December 31, 2022.

Business Combinations

The Company allocates the purchase consideration to the identifiable assets and liabilities acquired, including intangible assets at fair value on the date of the acquisition. The excess of the fair value of the purchase consideration over the fair value of the identifiable assets and liabilities, if any, is recorded as goodwill. During the measurement period, which is up to one year from the acquisition date, the Company may adjust initial amounts that were recognized at the acquisition date to reflect new information obtained about facts and circumstances that existed as of the acquisition date.

Determining the fair value of assets acquired and liabilities assumed requires significant judgment, including the selection of valuation methodologies that may include the income approach, the cost approach, or the market approach. Significant assumptions used in those methodologies include the timing and amounts of cash flow projections, including revenue growth rates, obsolescence rates, margins, royalty rates, counterparty risk rates, and other discount rates.

Intangibles

Definite-life intangible assets are assessed for impairment upon triggering events that indicate that the carrying value of an asset may not be recoverable. Recoverability is measured by a comparison of the carrying amount to future net undiscounted cash flows expected to be generated by the associated asset. If the asset's carrying value is determined to not be recoverable, the impairment to be recognized is measured by the amount by which the carrying amount exceeds the fair market value of the intangible assets.

Goodwill

Goodwill represents the excess of the purchase price as compared to the fair value of net assets acquired and liabilities assumed. Goodwill is not amortized but is tested for impairment annually or when indications of impairment exist. The Company can elect to qualitatively assess goodwill for impairment if it is more likely than not that the fair value of a reporting unit exceeds its carrying value.

Impairment exists when the carrying amount, including goodwill, of the reporting unit exceeds its fair value, resulting in an impairment charge for this excess (not to exceed the carrying amount of the goodwill). The Company's annual impairment testing date is July 1. The impairment, if determined, is recorded within operating expenses in the Condensed Statement of Operations and Comprehensive Loss in the period the determination is made. There were no impairments recorded during the periods presented.

Contingent Consideration

Business combinations may include contingent consideration as part of the purchase price under which the Company will make future payments to the seller upon the achievement of certain milestones. The fair value of the contingent consideration is estimated as of the acquisition date at the present value of the expected contingent payments and is subsequently remeasured at each balance sheet date. The scenario-based model was used and relies on multiple outcomes to estimate the likelihood of future payout of the contingent consideration. The resulting earnout payout is then probability-weighted and discounted at an appropriate risk adjusted rate in order to arrive at the present value of the expected payment.

The Company reviews the probabilities of achievement of the earnout milestones to determine the impact on the fair value of the contingent consideration on a quarterly basis over the earn-out period. Actual results are compared to the estimates and probabilities of achievement used in its forecasts. The estimated fair value of the contingent consideration liability will increase or decrease, up to the contractual limit, as applicable. Changes in the estimated fair value of the contingent consideration are recorded in operating expenses in the Statement of Operations and Comprehensive Loss and are reflected in the period in which they are identified. Changes in the estimated fair value of the Company's contingent consideration may materially impact or cause volatility in its operating results.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of risk consist principally of cash, cash equivalents, marketable securities and accounts receivable. The Company maintains its cash and cash equivalents balances with established financial institutions and, at times, such balances with any one financial institution may be in excess of the Federal Deposit Insurance Corporation (“FDIC”) insured limits. The Company's available-for-sale securities portfolio primarily consists of U.S. treasury and agency securities, money market funds, commercial paper, Yankee CDs, high credit quality asset-backed securities and corporate debt securities. The Company's investment policy requires its available-for-sale securities to meet certain criteria including investment type, credit ratings, and a maximum portfolio duration of one year. If any of the financial institutions where the Company holds deposits were to fail or be taken over by the FDIC, its access to these accounts could be temporarily unavailable or permanently lost for the amounts in excess of the FDIC insured limits. The Company did not have material cash deposits in excess of the FDIC insured limits at September 30, 2023.

The Company earns revenue from the sale of its products to customers such as hospitals and ambulatory surgery centers. The Company’s accounts receivable is derived from revenue earned from customers. On September 30, 2023 and December 31, 2022, no customer accounted for more than 10% of accounts receivable. For the nine months ended September 30, 2023 and 2022, there were no customers that represented 10% or more of revenue.

3. Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses*. This guidance requires financial instruments measured at amortized cost, and trade accounts receivable to be presented at the net amount expected to be collected. The model requires an entity to estimate credit losses based on historical information, current conditions and reasonable and supportable forecasts of future economic conditions. In November 2019, the FASB issued ASU 2019-10, which provides that this standard is effective for the Company for fiscal years beginning after December 15, 2022, and interim periods within that fiscal year. The Company adopted the new standard as of January 1, 2023. Adoption of the standard did not have a material impact on the Company's financial position, results of operations, or its disclosures.

4. Fair Value Measurements

Assets and liabilities recorded at fair value in the condensed financial statements are categorized based upon the level of judgment associated with the inputs used to measure their fair value. Hierarchical levels which are directly related to the amount of subjectivity associated with the inputs to the valuation of these assets or liabilities are as follows:

Level 1—Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access as of the measurement date.

Level 2—Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities.

Level 3—Unobservable inputs for the asset or liability only used when there is little, if any, market activity for the asset or liability at the measurement date. This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

Assets and Liabilities Measured and Recorded at Fair Value on a Recurring Basis – The following assets and liabilities are measured at fair value on a recurring basis as of September 30, 2023 and December 31, 2022 (in thousands):

	September 30, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents				
Money market funds	$ 2,738	$ —	$ —	$ 2,738
Short-term marketable securities at fair value				
U.S. treasury and government agencies	23,892	20,833	—	44,725
Commercial paper	—	2,846	—	2,846
Corporate debt	—	27,479	—	27,479
Asset-backed securities	—	29,141	—	29,141
Yankee CD	—	10,694	—	10,694
Total assets	$ 26,630	$ 90,993	$ —	$ 117,623
Liabilities:				
Contingent consideration	$ —	$ —	$ 2,901	$ 2,901
Total liabilities	$ —	$ —	$ 2,901	$ 2,901

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents				
Money market funds	$ 13,141	$ —	$ —	$ 13,141
Commercial paper	—	323	—	323
Corporate debt	—	2,197	—	2,197
Yankee CD	—	550	—	550
Short-term marketable securities at fair value				
U.S. treasury and government agencies	12,873	3,570	—	16,443
Corporate debt	—	23,372	—	23,372
Asset-backed securities	—	13,896	—	13,896
Yankee CD	—	8,068	—	8,068
Total assets	$ 26,014	$ 51,976	$ —	$ 77,990

The carrying amounts of the Company's money market funds classified as cash and cash equivalents, accounts receivable, accounts payable, and accrued liabilities, approximate their fair value due to the short-term nature of these assets and liabilities. Based on the borrowing rates currently available to the Company for debt with similar terms and consideration of default and credit risk, the carrying value of the term loan approximates fair value.

The Company's available-for-sale securities portfolio consists of investments in U.S. treasury and government agency securities, commercial paper, corporate debt securities, asset-backed securities, and Yankee CDs. Yankee CDs are certificates of deposit issued in the United States by a branch of a foreign bank and are denominated in U.S. dollars. The fair value of Level 1 securities is determined on trade prices in active markets for identical assets. The fair value of Level 2 securities is determined using valuation models using inputs that are observable either directly or indirectly, such as quoted prices for similar assets, interest rates, yield curves, credit spreads, default rates, loss severity, broker quotes, as well as other relevant economic measures. The Level 3 contingent consideration was recorded at fair value on the date of the acquisition and thereafter based on the consideration expected to be transferred on the projected payment date estimated as the probability weighted future cash flows, discounted back to the present value. This calculation uses unobservable inputs that reflect the Company's own assumptions as to the ability of the acquired business to meet the targeted benchmarks and the discount rate used in the determination of fair value.

The following table sets forth a summary of the changes in fair value of the Company's Level 3 financial instruments (in thousands):

Fair value as of December 31, 2022	$	-
Contingent consideration from acquisition of RPM-3D		2,814
Change in fair value		87
Fair value as of September 30, 2023	$	2,901

Contingent consideration is included in Other liabilities on the Condensed Balance Sheets. As of September 30, 2023, the entire balance is classified as current due to the timing of the expected payment. The change in fair value for the contingent consideration related to the technology advancements milestone payment is classified as research and development expense within the Condensed Statements of Operations and Comprehensive Loss. We made no cash payments for contingent consideration during the nine months ended September 30, 2023.

There were no assets or liabilities measured at fair value on a nonrecurring basis as of September 30, 2023 and December 31, 2022.

5. Business Combination

On June 12, 2023 (the "closing date"), the Company acquired certain assets of MIOS Marketing, LLC d/b/a RedPoint Medical3D (“RPM-3D”), a medical technology company offering pre-operative planning and patient-specific guides designed to deliver accurate surgical correction of deformities tailored to the patient’s unique foot anatomy. RPM-3D’s 22 patent applications further expand and reinforce the Company's global intellectual property portfolio covering technologies for the correction of bunion and related deformities.

The Company paid $20.0 million in exchange for certain assets used in providing pre-operative planning and patient-specific guides for the surgical correction of foot and ankle deformities. The Company is obligated to make additional payments of up to $10.0 million in cash upon completion of certain milestones as follows: $3.5 million upon completion of certain transition services at 12 months from the closing date, $3.5 million upon completion of certain technological advancement milestones within 12 months of the closing date, and, subject to prior completion of the transition services and the technological advancement milestones, up to $3.0 million upon the issuance of certain patent claims. Payments made for the transition services and patent claims require satisfaction of the milestone, as well as the continued service of key individuals and are expensed over the service period of 12 months following the closing date. The milestone payment for technological advancements does not require continued service and is recorded as contingent consideration at fair value in other liabilities at September 30, 2023.

The following table summarizes the components of the acquisition-date fair value of consideration transferred (in thousands):

Cash	$	20,000
Contingent consideration		2,814
Total	$	22,814

The following table summarizes the preliminary components of the acquisition-date fair value of assets acquired (in thousands):

Prepaid expenses and other current assets	$	19
Inventory		67
Property, plant and equipment		413
Intangible assets		9,500
Total identifiable assets acquired		9,999
Goodwill		12,815
Total assets acquired	$	22,814

Identified intangible assets consist of developed technology. The fair value was determined with the assistance of an external valuation specialist using an income approach, in accordance with ASC Topic 805 - Business Combinations. The developed technology is a finite lived intangible asset with a useful life of ten years that is amortized on straight-line basis. There were no other material intangibles from the RPM-3D acquisition. The intangible amortization for the three months ended September 30, 2023 and 2022 was $0.2 million and $0, respectively. The amortization for the nine months ended September 30, 2023 and 2022 was $0.2 million and $0, respectively.

The purchase consideration was allocated to the identifiable net assets acquired based on estimated fair values at the date of the acquisition. The excess of the fair value of the purchase consideration over the fair value of the identifiable assets and liabilities, if any, was recorded as goodwill. The goodwill is attributable to the expected synergies with the Company's existing operations. The purchase price allocated to goodwill will be deductible for income tax purposes over a 15-year period.

There is no supplemental proforma presentation of operating results of the acquisition of the RPM-3D assets due to the immaterial impact on the Company's operations for the three and nine months ended September 30, 2023 and 2022.

No impairment charges were recorded in any of the periods presented.

6. Balance Sheet Components

Cash and Cash Equivalents

The Company's cash and cash equivalents consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Cash	$ 4,540	$ 3,262
Cash equivalents:		
Money market funds	2,738	13,141
Commercial paper	—	323
Corporate debt	—	2,197
Yankee CD	—	550
Total cash and cash equivalents	$ 7,278	$ 19,473

There were no changes to cash pledged to SVB for the nine months ended September 30, 2022. During the nine months ended September 30, 2023, $0.9 million of pledged cash was released by SVB.

Marketable Securities

The Company's available-for-sale marketable securities consisted of the following (in thousands):

	September 30, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable securities - short-term				
U.S. treasury and government agencies	$ 44,811	$ —	$ (86)	$ 44,725
Commercial paper	2,851	—	(5)	2,846
Corporate debt	27,484	18	(23)	27,479
Asset-backed securities	29,188	12	(59)	29,141
Yankee CD	10,699	1	(6)	10,694
Total marketable securities - short-term	$ 115,033	$ 31	$ (179)	$ 114,885

	December 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable securities - short-term				
U.S. treasury and government agencies	$ 16,472	$ 11	$ (40)	$ 16,443
Corporate debt	23,376	31	(35)	23,372
Asset-backed securities	13,892	27	(23)	13,896
Yankee CD	8,066	10	(8)	8,068
Total marketable securities - short-term	$ 61,806	$ 79	$ (106)	$ 61,779

As of September 30, 2023, there were no available-for-sale securities with unrealized losses greater than 12 months. There was not an allowance for credit losses required as of September 30, 2023 and December 31, 2022.

Property and equipment, net

The Company’s property and equipment, net consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Furniture and fixtures, and equipment	$ 2,467	$ 1,577
Construction in progress	649	705
Machinery and equipment	2,392	928
Capitalized surgical equipment	12,867	9,248
Computer equipment	928	571
Leasehold improvements	9,325	6,434
Software	138	138
Total property and equipment	28,766	19,601
Less: accumulated depreciation and amortization	(7,230)	(4,263)
Property and equipment, net	$ 21,536	$ 15,338

Depreciation and amortization expense on property and equipment was $1.4 million and $0.4 million for the three months ended September 30, 2023 and 2022, respectively. Depreciation and amortization expense on property and equipment was $3.4 million and $1.2 million for the nine months ended September 30, 2023 and 2022, respectively.

Accrued liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2023	December 31, 2022
Accrued royalties expense	$ 1,683	$ 2,299
Accrued interest	398	412
Accrued professional services	899	1,727
Accrued compensation expense for RPM-3D earn-out	1,828	—
Other accrued expense	4,128	1,778
Total accrued liabilities	$ 8,936	$ 6,216

Other liabilities

Other liabilities consist of the following (in thousands):

	September 30, 2023	December 31, 2022
Current portion of operating lease liabilities	$ 1,178	$ 339
Contingent consideration	2,901	—
Payable to broker	1,100	—
Other	11	—
Total other liabilities	$ 5,190	$ 339

7. Long-Term Debt

The Company's long-term debt consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Revolving line of credit		
MidCap revolving loan facility	$ 4,000	$ 4,000
Term loans		
MidCap term loan facility	50,000	50,000
Total term and revolving loans	54,000	54,000
Less: debt discount and issuance costs	(1,066)	(1,289)
Total long-term debt, net	$ 52,934	$ 52,711

As of September 30, 2023, future payments of long-term debt were as follows (in thousands):

Fiscal Year	
2023	$ —
2024	—
2025	—
2026	33,333
2027	20,667
Total principal payments	54,000
Less: Unamortized debt discount and debt issuance costs	(1,066)
Total long-term debt, net	$ 52,934

MidCap Loan and Revolving Loan Facility

On April 29, 2022, the Company entered into a five-year $150.0 million loan facility with entities affiliated with MidCap Financial Trust ("MidCap"), providing up to $120.0 million in a term loan facility and a $30.0 million revolving loan facility.

The term loan facility provides for a 60-month term loan up to $120.0 million in borrowing capacity to the Company, over four tranches. At loan closing, the Company drew $50.0 million under tranche one. The remaining tranches provide up to an additional $70.0 million in borrowing capacity in the aggregate, subject to the achievement of certain revenue targets for the third and fourth tranches.

The revolving loan facility provides up to $30.0 million in borrowing capacity to the Company based on the borrowing base. The borrowing base is calculated based on certain accounts receivable and inventory assets. On September 30, 2023, the borrowing base allows a total of $21.3 million available to the Company under the revolving loan facility. The balance drawn as of September 30, 2023 is $4.0 million under the revolving loan facility. The Company may request an increase in the revolving loan facility up to $20.0 million for a total commitment of up to $50.0 million. The Company is required to either (i) maintain a minimum drawn balance under the revolving loan facility or (ii) pay a minimum balance fee that is equal to the amount of the minimum balance deficit multiplied by the applicable interest rate during the period. If the outstanding balance under the revolving loan facility exceeds the lesser of (i) 50% of the revolving borrowing capacity or (ii) 50% of the borrowing base, or the Company is in default, MidCap will apply funds collected from the Company's lockbox account to reduce the outstanding balance of the revolving loan facility (“Lockbox Deductions”). As of September 30, 2023, the Company's borrowing level has not activated the Lockbox Deductions, nor is it expected to for the next 12 months; therefore, the Company has determined that the revolving loan balance is long-term debt.

The loans bear interest at an annual rate based on a 30-day forward looking secured overnight financing rate plus 0.10% (subject to a floor of 1.0% and a cap of 3.0% for both loan agreements) plus (i) 6.0% under the term loan agreement and (ii) 4.0% under the revolving loan facility. Interest is payable monthly in arrears on the first day of each month and on the maturity of the loan agreements. The term loan agreement and the revolving loan facility are accruing interest as of September 30, 2023 at the capped interest rates of 9% and 7%, respectively. The Company is obligated to pay interest only for the first 48 months and straight-line amortization for the remaining 12 months, subject to the Company’s election to extend the initial interest-only period by 12 months to 60 months total if the Company’s trailing twelve-month revenue is at or above certain levels. If the term loan is repaid before the maturity date or the revolving loan facility is terminated before the end of its term, the prepayment fees are 3.0% of the amount repaid in the first year, 2.0% in the second year and 1.0% in the third year and thereafter, and a final payment fee of 3.0% of the amount borrowed is due under the term loan. The revolving loan facility prepayment fees are based on the revolving loan commitment amount.

The loans are secured by substantially all of the Company’s assets, including intellectual property. The loan agreements and other ancillary documents contain customary representations and warranties and affirmative and negative covenants. Under the loan agreements, the Company is not required to meet any minimum level of revenue if liquidity (defined as unrestricted cash plus undrawn availability under the revolving loan agreement) is greater than the outstanding balance under the term loan. If liquidity falls below such outstanding balance, then the Company is subject to a minimum trailing twelve-month revenue covenant. The Company is not subject to this covenant on September 30, 2023.

8. Commitments and Contingencies

License and Royalty Commitments

As of September 30, 2023 and December 31, 2022, the Company has royalty agreements with certain members of its surgeon advisory board. The Company recognized royalty expense under these agreements of $1.5 million and $1.6 million for the three months ended September 30, 2023 and 2022, respectively, and $4.7 million and $4.3 million for the nine months ended September 30, 2023 and 2022, respectively. For the three months ended September 30, 2023 and 2022, the aggregate royalty rates were 3.8% and 4.8%, respectively. For the nine months ended September 30, 2023 and 2022, the aggregate royalty rates were 3.8% and 4.7%, respectively.

Contingencies

From time to time, the Company may be a party to various litigation claims in the normal course of business. Legal fees and other costs associated with such actions are expensed as incurred. The Company assesses, in conjunction with legal counsel, the need to record a liability for litigation and contingencies. Accrual estimates are recorded when and if it is determinable that such a liability for litigation and contingencies are both probable and reasonably estimable. There were no accrued contingent liabilities as of September 30, 2023 and December 31, 2022.

9. Stockholders' Equity

Stock Options

During the nine months ended September 30, 2023 and 2022, the Company granted stock options to employees to purchase an aggregate of 877,910 and 1,237,675 shares of the Company's common stock, respectively. The weighted-average grant-date fair value of the employee stock options granted during the nine months ended September 30, 2023 and 2022 was $10.42 and $7.32 per share, respectively.

Restricted Stock Units

During the nine months ended September 30, 2023 and 2022, the Company granted 870,326 and 499,244 restricted stock units ("RSUs"), respectively. The weighted average grant-date fair value of RSUs granted during the nine months ended September 30, 2023 and 2022 was $22.84 and $18.46, respectively.

Performance Share Units

The Company granted performance-based restricted stock unit awards in the third quarter of 2023 subject to market and service vesting conditions to certain executives under the Company's 2021 Incentive Award Plan. The actual number of performance share units ("PSUs") that will vest at the end of the measurement period is determined based on the Company's total shareholder return ("TSR") ranking relative to the TSR of a published index of the Company's peers. The measurement period is two years. The grant date value of each target PSU award was determined using a Monte Carlo valuation model. If the service vesting conditions are met, the actual number of PSUs earned may vary from zero, if performance thresholds are not met, to as much as 250% of target PSUs.

During the nine months ended September 30, 2023 the Company granted 509,600 target PSUs. The weighted average grant-date fair value of the PSUs granted during the nine months ended September 30, 2023 was $30.90.

The table below summarizes the assumptions used to estimate the grant date fair value of the PSUs granted:

	Nine Months Ended September 30,
	2023
Weighted average expected volatility of common stock	61.12%
Expected volatility of peer index	21.61% to 95.93%
Correlation coefficient of peer index	0.08 to 1
Weighted average risk-free interest rate	4.76%
Dividend yield	0%

As of September 30, 2023, unrecognized compensation expense for PSUs was $13.0 million; the expense is expected to be recognized over the weighted-average period of 1.8 years.

Share-Based Compensation Expense

Share-based compensation expense is reflected in operating expenses in the condensed statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Cost of goods sold	$ 63	$ —	$ 192	$ —
Sales and marketing expense	1,202	809	3,087	2,030
Research and development expense	642	174	1,274	500
General and administrative expense	3,285	1,286	6,927	3,111
Total	$ 5,192	$ 2,269	$ 11,480	$ 5,641

10. Net Loss Per Share Attributable to Common Stockholders

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders which is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period. As the Company reported a net loss for the three and nine months ended September 30, 2023 and 2022, basic net loss per share attributable to common stockholders was the same as diluted net loss per share attributable to common stockholders as the inclusion of potentially dilutive shares would have been antidilutive if included in the calculation (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Numerator				
Net loss	$ (17,521)	$ (12,133)	$ (43,246)	$ (38,403)
Denominator				
Weighted-average common stock outstanding, basic and diluted	61,562,494	55,429,211	60,566,655	55,190,587
Net loss per share attributable to common stockholders, basic and diluted	$ (0.28)	$ (0.22)	$ (0.71)	$ (0.70)

The following potentially dilutive securities outstanding have been excluded from the computation of diluted weighted average shares outstanding because such securities have an antidilutive impact due to the Company's net loss, in common stock equivalent shares:

	September 30, 2023	December 31, 2022
Common stock options issued and outstanding	7,542,275	7,150,755
Unvested full value awards	1,250,478	595,048
Total	8,792,753	7,745,803

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

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed financial statements and related notes thereto included in this Quarterly Report on Form 10-Q (this "Quarterly Report") and our audited financial statements and related notes thereto for the year ended December 31, 2022, included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission on March 8, 2023 (our "Annual Report"). This discussion and other parts of this Quarterly Report contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions that are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in our Annual Report under "Part I, Item 1A—Risk Factors," our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 under "Part II, Item 1A—Risk Factors" and in the section titled "Risk Factors" included elsewhere in this Quarterly Report. Please also see the section of this Quarterly Report titled "Special Note Regarding Forward-Looking Statements."

Overview

We are a medical technology company with the goal of advancing the standard of care for the surgical management of bunion and related midfoot deformities. We have pioneered our proprietary Lapiplasty® 3D Bunion Correction System—a combination of instruments, implants and surgical methods designed to surgically correct all three planes of the bunion deformity and secure the unstable joint, addressing the root cause of the bunion and helping patients get back to their active lifestyles. Although bunions are deformities typically caused by an unstable joint in the middle of the foot that leads to a three-dimensional ("3D") misalignment in the foot's anatomical structure, the majority of traditional surgical approaches focus on correcting the deformity from a two-dimensional ("2D") perspective and therefore fail to address the root cause of the disorder. To effectively restore the normal anatomy of bunion patients and improve clinical outcomes, we believe addressing the root cause of the bunion is critical and have developed the Lapiplasty System to correct the deformity across all three anatomic dimensions. Our mission is to be the leader in the surgical treatment of bunions by establishing the Lapiplasty System as the standard of care. In 2021, we expanded our offerings with the Adductoplasty® Midfoot Correction System, designed for reproducible correction of the midfoot to provide further support to hallux valgus patients.

We were formed in 2013 and since receiving 510(k) clearance for the Lapiplasty System in March 2015, we have sold more than 80,000 Lapiplasty Procedure Kits in the United States. We market and sell our Lapiplasty Systems to physicians, surgeons, ambulatory surgery centers and hospitals. The Lapiplasty Procedure can be performed in either hospital outpatient or ambulatory surgery centers settings, and utilizes existing, well-established reimbursement codes. We currently market and sell the Lapiplasty System through a combination of a direct employee sales force and independent sales agencies across 228 territories in the United States. As of September 30, 2023, we had 204 direct sales representatives and 24 independent sales agencies. In the three months ended September 30, 2023, employee sales representatives generated approximately 81% of revenues while approximately 19% of revenues came through independent sales agencies.

On February 10, 2023, we completed a follow-on public offering of 5,476,190 shares of our common stock, which included the exercise in full of the underwriters' option to purchase additional shares, at a price to the public of $21.00 per share. This offering resulted in net proceeds of $107.5 million after deducting underwriting discounts and commissions of $6.9 million and offering expenses of $0.6 million, adding additional funds to our liquidity. As of September 30, 2023, we had cash and cash equivalents of $7.3 million and marketable securities available-for-sale of $114.9 million to fund operations, an accumulated deficit of $128.0 million, and $54.0 million of principal outstanding under our term loan and revolving loan agreements.

On June 12, 2023, we acquired certain assets of RPM-3D used in providing pre-operative planning and patient-specific guides for the surgical correction of foot and ankle deformities for $20.0 million in cash. In addition, we are obligated to pay additional amounts of up to $10.0 million in cash upon completion of certain milestones. This acquisition adds FDA-cleared patient specific instrumentation ("PSI") technologies and capabilities to our portfolio, building upon our pioneering 3D bunion correction and related midfoot solutions, as well as 22 additional patent applications that further expand and reinforce our global intellectual property portfolio covering technologies for the correction of bunion and related deformities.

Economic Environment

There is continuing uncertainty in the macro-economic environment. Inflationary pressures, rising interest rates, recession fears and reduced consumer confidence and ongoing supply chain challenges have resulted, and may continue to result, in higher costs and longer lead times from suppliers and potentially reduced demand for our Lapiplasty Procedure Kits. General economic conditions may also negatively impact demand for elective surgeries. While we continuously work with suppliers to mitigate higher costs and longer lead times and continue to invest in our direct sales channel, patient education initiatives, clinical evidence and product innovations to build demand for our products, we expect these macro-economic challenges to continue for the foreseeable future, which likely will impact our results of operations.

Key Business Metrics

We regularly review a number of operating and financial metrics, including the number of Lapiplasty Procedure Kits sold, blended average revenue per Lapiplasty Procedure Kits sold, the number of active surgeons using the Lapiplasty System and the surgeon utilization rate, to evaluate our business, measure our performance, identify trends affecting our business, formulate our business plans and make strategic decisions. The number of Lapiplasty Procedure Kits sold during the three months ended September 30, 2023, increased by 754 or 13% over the same period in 2022. The blended average sales price per Lapiplasty Procedure Kits sold was $6,311 during the three months ended September 30, 2023, a 9% increase over the same period in 2022. We define the blended average sales price as revenue divided by Lapiplasty Procedure Kits sold that includes the revenue for ancillary products sold from our expanding product line. The number of active surgeons as of September 30, 2023, was 2,691, an increase of 21.3% from the prior year. We define the number of active surgeons as the number of surgeons that performed at least one procedure using the Lapiplasty System in the trailing twelve-month period. The surgeon utilization rate for the nine months ended September 30, 2023, increased by 4.3% over the same period in 2022, to an average of 10.6 Lapiplasty Procedure Kits per active surgeon.

We believe that the number of Lapiplasty Procedure Kits sold, blended average revenue per Lapiplasty Procedure Kits sold, number of active surgeons using the Lapiplasty System and the surgeon utilization rate are useful indicators of our ability to drive adoption of the Lapiplasty System and generate revenue and are helpful in tracking the progress of our business. While we believe these metrics are representative of our current business, we anticipate these metrics may be substituted for additional or different metrics as our business grows.

Factors Affecting Our Business

We believe that our financial performance has been and in the foreseeable future, will continue to depend on many factors, including the macro-economic conditions as described above, those described below, those referenced in the section titled “Special Note Regarding Forward-Looking Statements” and those set forth in our Annual Report in the section titled “Part I, Item 1A—Risk Factors”, in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 in the section titled "Part II, Item 1A—Risk Factors," and in the section titled “Risk Factors” included elsewhere in this Quarterly Report.

Adoption of the Lapiplasty System

The growth of our business depends on our ability to gain broader acceptance of the Lapiplasty System by successfully marketing and distributing the Lapiplasty System and ancillary products. We currently have approval at over 2,100 facilities across the United States and plan to continue to increase access by convincing more surgeons and facility administrators that our products are alternatives to traditional products used in bunion surgical procedures. While surgeon adoption of the Lapiplasty Procedure remains critical to supporting procedure growth, hospital and ambulatory surgery center facility approvals are necessary for both existing and future surgeon customers to access our products. To facilitate greater access to our products and drive future sales growth, we intend to continue educating hospitals and facility administrators on the differentiated benefits associated with the Lapiplasty System, supported by our robust portfolio of clinical data. If we are unable to successfully continue to commercialize our Lapiplasty System, we may not be able to generate sufficient revenue to achieve or sustain profitability. In the near term, we expect we will continue to operate at a loss, and we anticipate we will finance our operations principally through the use of our cash and cash equivalents, and marketable securities. We may also raise funds by incurring debt and through offerings of our capital stock.

Investments in Innovation and Growth

We expect to continue to focus on long-term revenue growth through investments in our business. In sales and marketing, we are dedicating meaningful resources to expand our sales force and management team in the United States, as well as our patient focused outreach and education campaigns. We have hired over 250 employee sales representatives and employee field sales management strategically accessing more regions with high densities of prospective patients, and we are continuing to expand our sales team and its market coverage. In research and development, our team and our Surgeon Advisory Board are continually working on next-generation innovations of the Lapiplasty System and related products. In addition to expanding our Lapiplasty offerings with products like the Lapiplasty Mini-Incision and Micro-Lapiplasty Minimally Invasive Systems, we are continually exploring opportunities to advance our core Lapiplasty System instrumentation and implants to further improve surgical efficiency, enhance reproducibility of outcomes and speed surgical recovery for patients. In 2022, we introduced (i) the 3-n-1™ Guide, which combines three separate instruments and three procedure steps into one instrument and step, (ii) the S4A™ plating system, which features advanced 3D contours designed to accommodate variations in patient anatomy, and (iii) the SpeedRelease™ Instrument, which is a single-use instrument designed to make a challenging soft tissue release performed in the majority of Lapiplasty cases easier to perform and more reproducible for the surgeon. In June 2023, we acquired the assets of RPM-3D, which, using patient CT scan data, applies software technologies to develop a three-dimensional pre-operative plan for correcting the patient's deformity and produces a 3D-printed, patient-specific cut guide designed to deliver accurate surgical correction of deformities customized to the patient's unique foot anatomy. We plan to integrate RPM-3D software and systems with our instrumentation and implant systems for bunion and midfoot surgeries in 2023, with commercial introduction of patient-specific products expected in the second half of 2024. In September 2023, we began the market release of (1) SpeedPlate™ fixation platform, (2) a new Hammertoe PEEK Fixation System designed to address hammertoe, claw toe and mallet toe deformities, which often present concomitantly with bunions, and (3) LapiTome™ and RazorTome™ Osteotomes, which are two new sterile, single-use instruments that are designed to facilitate more efficient removal and release of bone slices and soft tissues in Lapiplasty and Adductoplasty cases.

We are also pursuing the development and potential commercialization, if regulatory clearance is achieved, of new products to address ancillary surgical procedures performed routinely in connection with the Lapiplasty Procedure. For example, to help address midfoot deformities that can occur in up to 30% of bunion patients, we developed and, in September 2021, announced the commercial launch of the Adductoplasty System. The Adductoplasty System brings together our implants and instrumentation to provide a comprehensive system designed for reproducible realignment, stabilization, and fusion of the midfoot and thus, provides surgeons with a precision, instrumented approach to treat both the bunion and coexisting midfoot deformities.

Moreover, in our general and administrative functions, we expect to continue to hire personnel and expand our infrastructure to both drive and support our anticipated growth and operations as a public company. Accordingly, in the near term, we expect to have net losses from these activities, but in the longer term we anticipate they will positively impact our business and results of operations.

Seasonality

We have experienced and expect to continue to experience seasonality in our business, with higher sales volumes in the fourth calendar quarter, historically accounting for approximately 35% to 40% of full year revenues, and lower sales volumes in the subsequent first calendar quarter. Our sales volumes in the fourth quarter tend to be higher as many patients elect to have surgery after meeting their annual deductible and having time to recover over the winter holidays. Our sales volumes in subsequent first calendar quarters also tend to be lower as a result of adverse weather and by resetting annual patient healthcare insurance plan deductibles, both of which may cause patients to delay elective procedures; however, in some years the first quarter may benefit from additional sales volumes when high patient demand for surgeries in the fourth quarter cannot be fully accommodated and those surgical procedures are rolled over into the first quarter. Similar to the rest of the orthopaedic industry, we have experienced and expect to continue to experience lower sales volumes in the third quarter than throughout the rest of the year as elective procedures generally decline during the summer months.

Coverage and Reimbursement

Hospitals, ambulatory surgery centers and surgeons that purchase or use our products generally rely on third-party payors to reimburse for all or part of the costs and fees associated with procedures using our products. As a result, sales of our products depend, in part, on the extent to which the procedures using our products are covered by third-party payors, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. Based on historical claims data from 2017, approximately 63% of Lapidus cases and 60% of all bunion surgical cases were paid by private payors.

Medicare payment rates to hospital outpatient departments are set under the Medicare hospital outpatient prospective payment system, which groups clinically similar hospital outpatient procedures and services with similar costs to ambulatory payment classifications (“APCs”). Each APC is assigned a single lump sum payment rate, which includes payment for the primary procedure as well as any integral, ancillary, and adjunctive services. The primary Current Procedure Terminology ("CPT") codes for the Lapiplasty Procedure, CPT 28297 and CPT 28740, are grouped together under APC 5114. For Lapiplasty Procedures in which fusion is performed on multiple tarsometatarsal joints, CPT 28730 applies and is classified under APC 5115.

Emerging Growth Company

As an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”), we are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We have elected to avail ourselves of this exemption and, therefore, while we are an emerging growth company, we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies. As a result, our financial statements and interim financial statements may not be comparable to companies that comply with new or revised accounting pronouncements. However, on June 30, 2023, our public float exceeded $700 million and as such we will be deemed to be a large accelerated filer under Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), commencing with the Company’s Annual Report on Form 10-K for the 2023 fiscal year. The Company will retain its current filer status until the end of 2023. As a large accelerated filer, the Company will no longer qualify as an emerging growth company nor be eligible to rely on the benefits afforded to emerging growth companies under the JOBS Act.

Components of Our Results of Operations

Revenue

We currently derive significant amounts of our revenue from the sale of our proprietary Lapiplasty System, and to a lesser extent from the Adductoplasty System, which we introduced in the third quarter of 2021, as well as our ancillary products. The Lapiplasty and Adductoplasty Systems are comprised of single-use implant kits and reusable instrument trays. We sell the Lapiplasty and Adductoplasty Systems to physicians, surgeons, hospitals, and ambulatory surgery centers in the United States through a network of employee sales representatives and independent sales agencies. Our primary product is the Lapiplasty System, which is an instrumented, reproducible approach to 3D bunion correction that helps patients rapidly return to weight-bearing in a post-operative boot. We also offer other advanced instrumentation and implants for use in the Lapiplasty and Adductoplasty Procedures or other ancillary procedures performed in high frequency with bunion surgery.

No single customer accounted for 10% or more of our revenue during the three and nine months ended September 30, 2023. We expect our revenue to increase in absolute dollars in the foreseeable future as we expand our sales territories, new accounts and trained physician base and as existing physician customers perform more Lapiplasty Procedures, though it may fluctuate from quarter to quarter due to a variety of factors, including seasonality and the macro-economic environment.

Cost of Goods Sold

Cost of goods sold consists primarily of manufacturing costs for the purchase of our Lapiplasty and Adductoplasty Systems and other products from third-party manufacturers. Direct costs from our third-party manufacturers include costs for materials plus the markup for the assembly of the components. Cost of goods sold also includes royalties, allocated overhead for indirect labor, certain direct costs such as those incurred for shipping our products and personnel costs. We expense all provisions for excess and obsolete inventories as cost of goods sold. We record adjustments to our inventory valuation for estimated excess, obsolete and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes and overall market conditions. We expect our cost of goods sold to increase in absolute dollars in the foreseeable future to the extent more of our products are sold, though it may fluctuate from quarter to quarter.

Gross Profit and Gross Margin

We calculate gross profit as revenue less cost of goods sold, and gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily average selling prices, production, and ordering volumes, change in mix of customers, third-party manufacturing costs and cost-reduction strategies. We expect our gross profit to increase in the foreseeable future as our revenue grows, though our gross margin may fluctuate from quarter to quarter due to changes in average selling prices as we introduce new products, and as we adopt new manufacturing processes and technologies.

Operating Expenses

Sales and Marketing

Sales and marketing expenses consist primarily of compensation for personnel, including salaries, bonuses, benefits, sales commissions and share-based compensation, related to selling and marketing functions, surgical instrument expense, physician education programs, training, shipping costs related to sending products to our sales representatives, travel expenses, marketing initiatives including our direct-to-patient outreach program and advertising, market research and analysis and conferences and trade shows. We expect sales and marketing expenses to continue to increase in absolute dollars in the foreseeable future as we continue to invest in our direct sales force and expand our marketing efforts, and as we continue to expand our sales and marketing infrastructure to both drive and support anticipated sales growth, though it may fluctuate from quarter to quarter.

Research and Development

Research and development (“R&D”) expenses consist primarily of engineering, product development, clinical studies to develop and support our products, regulatory expenses, and other costs associated with products and technologies that are in development. These expenses include compensation for personnel, including salaries, bonuses, benefits and share-based compensation, supplies, consulting, prototyping, testing, materials, travel expenses, depreciation, and an allocation of facility overhead expenses. We expect R&D expenses to continue to increase in absolute dollars in the foreseeable future as we continue to hire personnel and invest in next-generation innovations of the Lapiplasty System and related products, though it may fluctuate from quarter to quarter due to a variety of factors, including the level and timing of our new product development efforts, as well as our clinical development, clinical trial and other related activities.

General and Administrative

General and administrative expenses consist primarily of compensation for personnel, including salaries, bonuses, benefits, and share-based compensation, related to finance, information technology ("IT"), legal and human resource functions, as well as professional services fees (including legal, audit and tax fees), insurance costs, general corporate expenses, rent expenses and allocated facilities-related expenses. We expect general and administrative expenses to continue to increase in absolute dollars in the foreseeable future as we hire personnel and expand our infrastructure to drive and support the anticipated growth in our organization. Moreover, we have incurred, and expect to continue to incur, additional general and administrative expenses associated with operating as a public company, including legal, accounting, insurance, compliance with the rules and regulations of the SEC and those of any stock exchange on which our securities are traded, investor relations and other administrative and professional services expenses.

Interest income

Interest income consists of interest received on our money market funds and marketable securities.

Interest Expense

Interest expense consists of interest incurred and amortization of debt discount and issuance costs related to outstanding borrowings during the reported periods.

Results of Operations

Comparison of the three and nine months ended September 30, 2023 and 2022

The following table summarizes our results of operations for the periods presented below ($ in thousands):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2023	2022	Amount	%	2023	2022	Amount	%
Revenue	$ 40,758	$ 33,055	$ 7,703	23.3%	$ 124,906	$ 92,069	$ 32,837	35.7%
Cost of goods sold	7,998	6,090	1,908	31.3%	23,712	16,511	7,201	43.6%
Gross profit	32,760	26,965	5,795	21.5%	101,194	75,558	25,636	33.9%
Operating expenses								
Sales and marketing	33,542	25,568	7,974	31.2%	100,970	74,477	26,493	35.6%
Research and development	4,350	3,799	551	14.5%	11,288	9,835	1,453	14.8%
General and administrative	12,686	8,916	3,770	42.3%	33,582	22,593	10,989	48.6%
Total operating expenses	50,578	38,283	12,295	32.1%	145,840	106,905	38,935	36.4%
Loss from operations	(17,818)	(11,318)	(6,500)	57.4%	(44,646)	(31,347)	(13,299)	42.4%
Interest income	1,570	420	1,150	*	5,017	560	4,457	*
Interest expense	(1,296)	(1,190)	(106)	8.9%	(3,863)	(3,087)	(776)	25.1%
Debt extinguishment loss	—	—	—	*	—	(4,483)	4,483	*
Other income, net	23	(45)	68	*	246	(46)	292	*
Other non-operating income (expense), net	297	(815)	1,112	(136.4)%	1,400	(7,056)	8,456	(119.8)%
Net loss	$ (17,521)	$ (12,133)	$ (5,388)	44.4%	$ (43,246)	$ (38,403)	$ (4,843)	12.6%

* Not meaningful

Comparison of the three months ended September 30, 2023 and 2022

Revenue. Revenue increased by $7.7 million, or 23.3%, for the three months ended September 30, 2023 as compared to the same period in 2022. The increase was partially driven by an increase in the number of Lapiplasty Procedure Kits sold, which was 13% and 44% for the three months ended September 30, 2023 and 2022, respectively, as a result of expanded surgeon customer base and increased utilization. The increase in the volume of Lapiplasty Procedure Kits sold resulted in 45.4% and 70.2% of the revenue growth for the three months ended September 30, 2023 and 2022, respectively. In the three months ended September 30, 2023, the remaining revenue growth was primarily a result of increased adoption of our newer technologies and selling more ancillary products used in bunion cases that resulted in an 9% increase in average blended revenue per Lapiplasty Procedure Kit sold compared to the prior year.

Cost of Goods Sold, Gross Profit and Gross Margin. Cost of goods sold increased by $1.9 million, or 31.3%, for the three months ended September 30, 2023 as compared to the same period in 2022. The increase in cost of goods sold was primarily due to a $1.2 million increase in direct costs of goods sold resulting from increased sales, a $0.3 million increase in overhead expenses resulting from increased headcount, and $0.2 million increase in reserves for inventory provision and obsolescence. During the three months ended September 30, 2023, gross profit increased by $5.8 million, or 21.5%, as compared to the same period in 2022, due to increased sales. Gross profit margin for the three months ended September 30, 2023 decreased from 81.6% to 80.4%, as compared to the same period in 2022, primarily due to changes in product mix, an increase in inventory and obsolescence provisions, and an increase in overhead, partially offset by lower royalty rates on newer products.

Sales and Marketing Expenses. Sales and marketing expenses increased by $8.0 million, or 31.2%, for the three months ended September 30, 2023 as compared to the same period in 2022. The increase in sales and marketing expenses was due to investment in our direct sales force and our patient focused outreach and education campaigns. Sales and marketing expenses increased as a result of increases of $3.7 million in payroll and related expenses primarily from increased headcount of sales and marketing personnel, $1.6 in commissions from increased sales by our employee sales representatives and independent sales agencies, $0.9 million in surgeon training and clinical-related expenses, $0.7 million primarily due to increased marketing and advertising, $0.5 million for professional services related to marketing, and $0.3 million in surgical instrument expense.

Research and Development Expenses. R&D expenses increased by $0.6 million, or 14.5%, for the three months ended September 30, 2023 as compared to the same period in 2022. The increase in R&D expenses was primarily due to a $0.2 million increase in payroll and related costs resulting from increased headcount of research and development personnel and a $0.2 million increase in product testing and validation costs.

General and Administrative Expenses. General and administrative expenses increased by $3.8 million, or 42.3%, for the three months ended September 30, 2023 as compared to the same period in 2022. The increase in general and administrative expenses was primarily related to $2.2 million in higher payroll and related costs as we increased headcount to support our growing business, and $1.5 million in compensation expense related to the milestone payments for the RPM-3D acquisition in the second quarter 2023.

Interest income. Interest income increased by $1.2 million, for the three months ended September 30, 2023 as compared to the same period in 2022. The increase in interest income was due to higher cash balances invested in marketable securities during the third quarter of 2023 due to our equity offering in the first quarter of 2023 and higher interest rates in the three months ended September 30, 2023, as compared to the same period in 2022.

Interest Expense. Interest expense increased by $0.1 million, or 8.9%, for the three months ended September 30, 2023 as compared to the same period in 2022. The increase in interest expense was due to slightly higher interest rates on our outstanding debt in the three months ended September 30, 2023, as compared to the same period in 2022.

Comparison of the nine months ended September 30, 2023 and 2022

Revenue. Revenue increased by $32.8 million, or 35.7%, for the nine months ended September 30, 2023 as compared to the same period in 2022. The increase was partially driven by growth rates of Lapiplasty Procedure Kits sold, which was 23% and 44% for the nine months ended September 30, 2023 and 2022, respectively, as a result of an expanded surgeon customer base and increased utilization. The increase in the volume of Lapiplasty Procedure Kits sold resulted in 53.0% and 73.7% of the revenue growth for the nine months ended September 30, 2023 and 2022, respectively. In the nine months ended September 30, 2023, the remaining revenue growth was primarily a result of increased adoption of our newer technologies and selling more ancillary products used in bunion cases resulting in a 10% increase in average blended revenue per Lapiplasty Procedure Kit sold compared to the same period in the prior year.

Cost of Goods Sold, Gross Profit and Gross Margin. Cost of goods sold increased by $7.2 million, or 43.6%, for the nine months ended September 30, 2023 as compared to the same period in 2022. The increase in cost of goods sold was primarily due to increases of $4.5 million from direct costs of goods sold, $1.2 million from overhead expenses resulting from an increase in our headcount, $0.7 million from reserves for inventory provision and obsolescence, and $0.4 million from royalty expense resulting from our increased sales. During the nine months ended September 30, 2023, the gross profit increased by $25.6 million, or 33.9%, as compared to the same period in 2022 due to increased sales. Gross profit margin for the nine months ended September 30, 2023 decreased from 82.1% to 81.0%, as compared to the same period in 2022, primarily due to changes in product mix, increased overhead, and an increase in inventory and obsolescence provisions, partially offset by lower royalty rates on newer products.

Sales and Marketing Expenses. Sales and marketing expenses increased by $26.5 million, or 35.6%, for the nine months ended September 30, 2023 as compared to the same period in 2022. The increase in sales and marketing expenses was due to investment in our direct sales force and our patient focused outreach and education campaigns. Sales and marketing expenses increased by $12.6 million in payroll and related expenses primarily from increased headcount of sales and marketing personnel, $7.3 million in higher commissions from increased sales by our direct sales representatives and independent sales agencies, $2.0 million in surgeon training and clinical-related expenses, $1.6 million in marketing and advertising expenses, $1.1 million in surgical instrument expense, $0.9 million for professional services related to marketing, and a $0.6 million increase in allocated rent expense resulting from the occupancy of the new corporate headquarters lease in the third quarter of 2022.

Research and Development Expenses. R&D expenses increased by $1.5 million, or 14.8%, for the nine months ended September 30, 2023 as compared to the same period in 2022. The increase in R&D expenses was due to $0.5 million in higher payroll and related costs resulting from increased headcount of research and development personnel, $0.5 million in product testing and validation costs, and $0.4 million increase in allocated rent expense resulting from the occupancy of the new corporate headquarters lease in the third quarter of 2022.

General and Administrative Expenses. General and administrative expenses increased by $11.0 million, or 48.6%, for the nine months ended September 30, 2023 as compared to the same period in 2022. The increase in general and administrative expenses was primarily due to increases of $6.5 million in payroll and related costs as we increased headcount to support the growing business, $3.9 million in professional services primarily related to $1.8 million of legal fees and $1.8 million in compensation expense related to the milestone payments for the RPM-3D acquisition in the second quarter 2023, and $0.8 million in rent expense and other facilities costs resulting from the new corporate headquarters lease that commenced for accounting purposes in the first quarter of 2022.

Interest Income. Interest income increased $4.5 million during the nine months ended September 30, 2023. The increase in interest income was due to higher cash balances invested in marketable securities during the current year period due to our equity offering in the first quarter of 2023 and higher interest rates in the nine months ended September 30, 2023, as compared to the same period in 2022.

Interest Expense. Interest expense increased by $0.8 million, or 25.1%, for the nine months ended September 30, 2023 as compared to the same period in 2022. The increase in interest expense was due to higher debt balances as a result of the debt refinancing in the second quarter of 2022 and slightly higher interest rates on our outstanding debt in the nine months ended September 30, 2023, as compared to the same period in 2022.

Debt Extinguishment Loss. Debt extinguishment loss decreased by $4.5 million for the nine months ended September 30, 2023 as compared to the same period of 2022 due to our debt refinancing during the prior year period.

Liquidity and Capital Resources

Overview

Before our IPO, our primary sources of capital were private placements of common stock and convertible preferred stock, debt financing agreements and revenue from the sale of our products. In April 2021, we received net proceeds of $107.6 million from our IPO. In April 2022, we entered a new five-year $150.0 million loan arrangement, consisting of up to $120.0 million in term loans and up to $30.0 million in a revolving loan facility with entities affiliated with MidCap Financial Trust ("MidCap"). On the closing date in April 2022, we borrowed $50.0 million under the term loan and $4.0 million under the revolving loan facility. The term loan proceeds were partly used to repay our term loan obligation with CR Group, LP ("CRG") and an early termination fee to Silicon Valley Bank ("SVB") amounting to $34.1 million, including principal of $30.0 million, interest of $0.4 million and fees of $3.7 million. There was no outstanding principal at termination of the SVB revolving loan facility. On February 10, 2023, we completed a follow-on public offering of 5,476,190 shares of our common stock, which included the exercise in full of the underwriters' option to purchase additional shares, at a price to the public of $21.00 per share. This offering resulted in net proceeds of $107.5 million after deducting underwriting discounts and commissions of $6.9 million and offering expenses of $0.6 million.

As of September 30, 2023, we had cash and cash equivalents of $7.3 million and marketable securities of $114.9 million available for sale, an accumulated deficit of $128.0 million and $54.0 million principal outstanding under the term and revolving loans with MidCap. We believe that our existing cash and cash equivalents, marketable securities and available debt borrowings and expected revenues will be sufficient to meet our capital requirements and fund our operations for at least twelve months from the issuance of our condensed financial statements. We may be required or decide to raise additional financing to support further growth of our operations.

Funding Requirements

We use our cash to fund our operations, which primarily include the costs of manufacturing our Lapiplasty and Adductoplasty Systems and ancillary products, as well as our sales and marketing and R&D expenses and related personnel costs. We expect our sales and marketing expenses to increase for the foreseeable future as we continue to invest in our direct sales force and expand our marketing efforts, and as we continue to expand our sales and marketing infrastructure to both drive and support anticipated sales growth. We also expect R&D expenses to increase for the foreseeable future as we continue to hire personnel and invest in next-generation innovations of the Lapiplasty System and related products. In addition, we expect our general and administrative expenses to increase for the foreseeable future as we hire personnel and expand our infrastructure to both drive and support the anticipated growth in our organization. We will also incur additional expenses as a result of operating as a public company. In the second quarter of 2023, funds were used for the acquisition of the RPM-3D, and from time to time in the future, we may also consider additional investments in technologies, assets, and businesses to expand or enhance our product offerings. The timing and amount of our operating and capital expenditures will depend on many factors, including:

- the scope and timing of our investment in our commercial infrastructure and sales force;
- the costs of our ongoing commercialization activities including product sales, marketing, manufacturing, and distribution;
- the scope of our marketing efforts, including the degree to which we utilize direct to consumer campaigns;
- the degree and rate of market acceptance of the Lapiplasty and Adductoplasty Systems, PSI technologies and our ancillary products;
- the costs of filing, prosecuting, defending, and enforcing any patent claims and other intellectual property rights, including enforcing our intellectual property rights against infringing products or technologies or enforcing contractual rights against parties breaching agreements with us;
- our need to implement additional infrastructure and internal systems;
- the research and development activities we intend to undertake in order to improve the Lapiplasty System, to commercialize PSI technologies, and to develop or acquire additional products;
- the investments we make in acquiring other technologies, assets, or businesses to expand our product portfolio;
- the success or emergence of new competing technologies or other adverse market developments;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the impact of hospital staffing shortages, surgical capacity, patient demand and other factors affecting elective procedures; and
- the effect of inflation, interest rate changes, banking sector instability, and other general economic conditions on our operations and business.

Based upon our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months. We have based this estimate on assumptions that may prove to be wrong or that may change in the future, and we could utilize our available capital resources sooner than we expect. We may seek to raise any necessary additional capital through public or private equity offerings or debt financings, credit or loan facilities or a combination of one or more of these or other funding sources. Additional funds may not be available to us on acceptable terms or at all. If we fail to obtain necessary capital when needed on acceptable terms, or at all, we could be forced to delay, limit, reduce or terminate our product development programs, commercialization efforts, sales and marketing initiatives, or other operations. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution, and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets.

Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for the periods presented below (in thousands):

	Nine Months Ended September 30,	
	2023	2022
Net cash (used in) provided by:		
Operating activities	$ (35,107)	$ (25,290)
Investing activities	(86,306)	(12,506)
Financing activities	109,218	20,509
Net decrease in cash and cash equivalents	$ (12,195)	$ (17,287)

Net Cash Used in Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2023 was $35.1 million, consisting primarily of a net loss of $43.2 million, adjusted for non-cash charges of $16.4 million and an increase in net operating assets. The non-cash charges consist primarily of share-based compensation expense of $11.5 million, depreciation and amortization expense of $3.6 million and non-cash lease expense of $1.9 million, offset by amortization and accretion of marketable securities of $1.0 million. The increase in net operating assets was primarily due to an increase of $9.9 million in inventories for added safety stock to meet demand for new products and to avoid potential supply chain issues, an increase of $1.0 million in prepaid expenses and other assets (excluding unsettled securities transactions) and a decrease of $2.0 million in accrued liabilities, which were partially offset by a $4.1 million decrease in accounts receivable from higher sales in the fourth quarter of 2022 and a $0.5 million increase to operating lease liabilities primarily due to timing of lease incentives. The decrease of $2.0 million in accrued liabilities consisted of a decrease of $3.8 million due to timing of payments, offset by an increase of $1.8 million due to increased accrued compensation expense related to our acquisition of RPM-3D in the second quarter 2023.

Net cash used in operating activities for the nine months ended September 30, 2022, was $25.3 million, consisting primarily of a net loss of $38.4 million, adjusted for non-cash charges of $13.1 million and relatively flat net operating assets. The non-cash charges primarily consisted of a $4.5 million loss on extinguishment of the CRG term loan, share-based compensation expense of $5.6 million, non-cash lease expense of $2.0 million and depreciation and amortization expense of $1.2 million. The slight increase in net operating assets was primarily due to an increase in inventory during third quarter for higher expected fourth quarter sales, an increase in prepaid expenses and other current assets, which were offset by increases in accounts payable and accrued liabilities due to timing of payments and growth of our operations.

Net Cash Used in Investing Activities

Net cash used in investing activities was $86.3 million for the nine months ended September 30, 2023, consisting primarily of $140.1 million in purchases of marketable securities available for sale, $20.0 million for the acquisition of the RPM-3D assets, and $9.2 million in purchases of property and equipment, partially offset by $83.0 million in sales and maturities of marketable securities available for sale. The purchases of marketable securities were the result of cash invested from our public offering of common stock during the first quarter of 2023. The purchases in property and equipment were $3.6 million in capitalized surgical instruments for our reusable instrument trays and $5.6 million for furniture, equipment, and leasehold improvements to continue to complete our new corporate headquarters.

Net cash used in investing activities was $12.5 million for the nine months ended September 30, 2022, consisting primarily of $7.2 million of leasehold improvements and furniture and equipment for our new headquarters' building and $3.6 million for purchases of capitalized surgical instruments for our reusable instrument trays.

Net Cash Provided by Financing Activities

Net cash provided in financing activities was $109.2 million for the nine months ended September 30, 2023, consisting primarily of $107.5 million of net cash proceeds from our public offering of common stock and $1.7 million from exercise of stock options.

Net cash provided in financing activities was $20.5 million for the nine months ended September 30, 2022, consisting of $53.5 million of net cash proceeds from the new term loan agreement and revolving credit facility with MidCap and $1.9 million from exercise of stock options offset by the $33.9 million repayment of the CRG term loan and $1 million of debt issuance costs paid to third parties.

Surgeon Advisory Board Royalty Agreements

We recognized royalty expense of $1.5 million and $1.6 million for the three months ended September 30, 2023 and 2022, and $4.7 million and $4.3 million for the nine months ended September 30, 2023 and 2022, respectively. For the three months ended September 30, 2023 and 2022, the aggregate royalty rate was 3.8% and 4.8%, respectively. For the nine months ended September 30, 2023 and 2022, the aggregate royalty rate was 3.8% and 4.7%, respectively. Each of the royalty agreements with our surgeon advisory board members prohibits the payment of royalties on products sold to entities and/or individuals with whom any of the surgeon advisors is affiliated.

Operating Lease

We have commitments for future payments related to our real estate leases located in Ponte Vedra, Florida. We entered into a 10-year lease in February 2022 for our new corporate headquarters location. Lease payments comprise the base rent stated in the lease plus operating costs, which include taxes, insurance, and common area maintenance. The remaining lease obligation was $26.4 million under these leases as of September 30, 2023.

Critical Accounting Policies and Estimates

Management’s discussion and analysis of our financial condition and results of operations is based on our condensed financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these condensed financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses, and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are 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 may differ from these estimates under different assumptions or conditions and any such differences may be material.

Our critical accounting policies and estimates are described in “Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies and Estimates” in our Annual Report. There had been no material changes to these accounting policies during the nine months ended September 30, 2023.

Recently Issued Accounting Pronouncements

Refer to Note 3, “Recent Accounting Pronouncements”, to our condensed financial statements included elsewhere in this Quarterly Report for accounting pronouncements adopted as of this Quarterly Report. There have been no newly issued accounting pronouncements impacting the Company's unaudited interim financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company as defined by Item 10 of Regulation S-K, we are not required to provide the information required by this item.

Item 4. Controls and Procedures.

Evaluation of disclosure controls and procedures

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report, our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in internal control over financial reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Quarterly Report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent limitation on the effectiveness of internal control

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not a party to any legal proceedings which we believe would have a material effect on our business or results of operations. From time to time, we may become involved in various legal proceedings that arise in the ordinary course of our business.

Item 1A. Risk Factors

There have been no material changes from the risk factors previously disclosed in our Annual Report under "Part I, Item 1A—Risk Factors" and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 under "Part II, Item 1A—Risk Factors."

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities.

(a) Recent Sales of Unregistered Securities

None.

(b) Use of Proceeds

The registration statement on Form S-1 (File Nos. 333-254863) and the registration statement on Form S-1 (File No. 333- 255451) filed pursuant to Rule 462(b) relating thereto, each relating to the IPO of shares of our common stock, became effective on April 22, 2021. On April 27, 2021, we completed our IPO of 12,937,500 shares of common stock, which included the exercise in full of the underwriters' option to purchase additional shares. As part of the IPO, 6,953,125 shares of common stock were issued and sold by us (inclusive of 703,125 shares pursuant to the exercise of the underwriters' option) and 5,984,375 shares of common stock were sold by the selling stockholders named in the Prospectus (inclusive of 984,375 shares pursuant to the exercise of the underwriters' option), at a price to the public of $17.00 per share. We received net proceeds of approximately $107.6 million, after deducting underwriting discounts of $8.3 million and commissions and offering expenses payable by us of $2.3 million.

No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

There has been no material change in the planned use of proceeds from our IPO from that described in the Prospectus dated April 22, 2021 filed with the SEC pursuant to Rule 424(b)(4).

(c) Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
10.1+	Form of Performance Stock Unit for Employees under the 2021 Incentive Award Plan
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1†	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2†	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

+ Indicates management contract or compensatory plan.

† The certifications attached as Exhibit 32.1 and 32.2 to this Quarterly Report are deemed furnished and not filed with the U.S. Securities and Exchange Commission and are not to be incorporated by reference into any filing of Treace Medical Concepts, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report, irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

Treace Medical Concepts, Inc.

Date: November 9, 2023

By: /s/ John T. Treace

Name: John T. Treace

Title: Chief Executive Officer (Principal Executive Officer)

Date: November 9, 2023

By: /s/ Mark L. Hair

Name: Mark L. Hair

Title: Chief Financial Officer (Principal Financial and Accounting Officer)

TREACE MEDICAL CONCEPTS, INC.
2021 INCENTIVE AWARD PLAN

PERFORMANCE STOCK UNIT AWARD GRANT NOTICE

Treace Medical Concepts, Inc., a Delaware corporation, (the "***Company***"), pursuant to its 2021 Incentive Award Plan, as amended from time to time (the "***Plan***"), hereby grants to the holder listed below ("***Participant***"), an award of restricted stock units that vest based (in part) on achievement of certain performance conditions ("***Performance Stock Units***" or "***PSUs***"). Each vested Performance Stock Unit represents the right to receive, in accordance with the Performance Stock Unit Award Agreement attached hereto as **Exhibit A**, the Vesting Schedule attached hereto as **Exhibit B** and the Deferral Election Form attached hereto as **Exhibit C** (collectively, the "***Agreement***"), one share of Common Stock ("***Share***"). This award of Performance Stock Units is subject to all of the terms and conditions set forth herein and in the Agreement and the Plan, each of which are incorporated herein by reference. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in this Performance Stock Unit Award Grant Notice (the "***Grant Notice***") and the Agreement.

Participant:	[_____]
Grant Date:	[_____]
Total Number of PSUs at Target ("*Target PSUs*"):	[_____]
Total Number of PSUs at Maximum ("*Maximum PSUs*"):	[_____]
Maximum PSU Value:	$[_____]
Vesting Commencement Date:	[_____]
Vesting Date/Expiration Date ("*Expiration Date*"):	Second anniversary of the Grant Date
Vesting Schedule:	Subject to the termination sections in this Grant Notice and the Agreement, the PSUs shall vest as set forth on **Exhibit B** attached hereto.
Settlement:	Unless Participant delivers to the Company an executed deferral election form substantially in the form set forth on **Exhibit C** (a "***Deferral Election Form***") on or prior to the 30th day following the Grant Date, the shares underlying vested PSUs shall be issued as soon as administratively practicable, and in any event within 30 days, after the date such PSUs vest. Notwithstanding the foregoing, in the event Participant delivers to the Company an executed Deferral Election Form on or prior to the 30th day following the Grant Date, the shares underlying vested PSUs shall be issued in accordance with Participant's election made pursuant to such Deferral Election Form.
Termination:	If Participant experiences a Termination of Service, all PSUs that have not become vested on or prior to the date of such Termination of Service will thereupon be automatically forfeited by Participant without payment of any consideration therefor (except as set forth in a written agreement between the Company (or any Subsidiary that is the employer of Participant) and Participant, including the Plan).

By his or her signature and the Company's signature below, Participant agrees to be bound by the terms and conditions of the Plan, the Agreement and this Grant Notice. Participant has reviewed the Plan, the Agreement and this Grant Notice in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of the Plan, the Agreement and this Grant Notice. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, the Agreement or this Grant Notice. In addition, by signing below, Participant also agrees that the Company, in its sole discretion, may satisfy any withholding obligations in accordance with Section 2.6(b) of the Agreement by (i) withholding shares of Common Stock otherwise issuable to Participant upon vesting of the PSUs, (ii) instructing a broker on Participant's behalf to sell shares of Common Stock otherwise issuable to Participant upon vesting of the PSUs and submit the proceeds of such sale to the Company, or (iii) using any other method permitted by Section 2.6(b) of the Agreement or the Plan.

TREACE MEDICAL CONCEPTS, INC.:		**PARTICIPANT:**	
By:	_____	By:	_____
Print Name:	John T. Treace	Print Name:	_____
Title:	Chief Executive Officer		
Address:	100 Palmetto Park Place Ponte Vedra, FL 32081	Address:	_____

EXHIBIT A
TO PERFORMANCE STOCK UNIT AWARD GRANT NOTICE

PERFORMANCE STOCK UNIT AWARD AGREEMENT

Pursuant to the Performance Stock Unit Award Grant Notice (the "***Grant Notice***") to which this Performance Stock Unit Award Agreement (this "***Agreement***") is attached, Treace Medical Concepts, Inc., a Delaware corporation (the "***Company***"), has granted to Participant the number of restricted stock units that vest based (in part) on achievement of certain performance conditions ("***Performance Stock Units***" or "***PSUs***") set forth in the Grant Notice under the Company's 2021 Incentive Award Plan, as amended from time to time (the "***Plan***"). Each Performance Stock Unit represents the right to receive one share of Common Stock (a "***Share***") upon vesting.

ARTICLE I.
GENERAL

1.1 Defined Terms. Capitalized terms not specifically defined herein shall have the meanings specified in the Plan and the Grant Notice.

1.2 Incorporation of Terms of Plan. The PSUs are subject to the terms and conditions of the Plan, which are incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan shall control.

ARTICLE II.
GRANT OF PERFORMANCE STOCK UNITS

2.1 Grant of PSUs. Pursuant to the Grant Notice and upon the terms and conditions set forth in the Plan and this Agreement, effective as of the Grant Date set forth in the Grant Notice, the Company hereby grants to Participant an award of PSUs under the Plan in consideration of Participant's past and/or continued employment with or service to the Company or any Subsidiaries and for other good and valuable consideration.

2.2 Unsecured Obligation to PSUs. Unless and until the PSUs have vested in the manner set forth in Article 2 hereof, Participant will have no right to receive Common Stock or other property under any such PSUs. Prior to actual payment of any vested PSUs, such PSUs will represent an unsecured obligation of the Company, payable (if at all) only from the general assets of the Company.

2.3 Vesting Schedule. Subject to Section 2.5 hereof, the PSUs shall vest and become nonforfeitable with respect to the applicable portion thereof according to the vesting schedule set forth in the Grant Notice (rounding down to the nearest whole Share).

2.4 Consideration to the Company. In consideration of the grant of the award of PSUs pursuant hereto, Participant agrees to render faithful and efficient services to the Company or any Subsidiary.

2.5 Forfeiture, Termination and Cancellation upon Termination of Service. Notwithstanding any contrary provision of this Agreement or the Plan, upon Participant's Termination of Service for any or no reason, all Performance Stock Units which have not vested prior to or in connection with such Termination of Service shall thereupon automatically be forfeited, terminated and cancelled as of the

applicable termination date without payment of any consideration by the Company, and Participant, or Participant's beneficiary or personal representative, as the case may be, shall have no further rights hereunder. No portion of the PSUs which has not become vested as of the date on which Participant incurs a Termination of Service shall thereafter become vested, except as may otherwise be provided by the Administrator or as set forth in a written agreement between the Company (or any Subsidiary that is the employer of Participant) and Participant.

2.6 Issuance of Common Stock upon Vesting.

(a) The shares underlying vested PSUs shall be issued in accordance with the Settlement provisions of the Grant Notice. Notwithstanding the foregoing, in the event Shares cannot be issued pursuant to Section 10.7 of the Plan, the Shares shall be issued pursuant to the preceding sentence as soon as administratively practicable after the Administrator determines that Shares can again be issued in accordance with such Section.

(b) As set forth in Section 10.5 of the Plan, the Company shall have the authority and the right to deduct or withhold, or to require Participant to remit to the Company, an amount sufficient to satisfy all applicable Tax Related Items required by law to be withheld with respect to any taxable event arising in connection with the Performance Stock Units. The Company shall not be obligated to deliver any Shares to Participant or Participant's legal representative unless and until Participant or Participant's legal representative shall have paid or otherwise satisfied in full the amount of all Tax Related Items applicable to the taxable income of Participant resulting from the grant or vesting of the Performance Stock Units or the issuance of Shares.

2.7 Conditions to Delivery of Shares. The Shares deliverable hereunder may be either previously authorized but unissued Shares, treasury Shares or issued Shares which have then been reacquired by the Company. Such Shares shall be fully paid and nonassessable. The Company shall not be required to issue Shares deliverable hereunder prior to fulfillment of the conditions set forth in Section 10.7 of the Plan.

2.8 Rights as Stockholder. The holder of the PSUs shall not be, nor have any of the rights or privileges of, a stockholder of the Company, including, without limitation, voting rights and rights to dividends, in respect of the PSUs and any Shares underlying the PSUs and deliverable hereunder unless and until such Shares shall have been issued by the Company and held of record by such holder (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company). No adjustment shall be made for a dividend or other right for which the record date is prior to the date the Shares are issued, except as provided in Article IX of the Plan.

ARTICLE III.
OTHER PROVISIONS

3.1 Administration. The Administrator shall have the power to interpret the Plan and this Agreement and to adopt such rules for the administration, interpretation and application of the Plan as are consistent therewith and to interpret, amend or revoke any such rules. All actions taken and all interpretations and determinations made by the Administrator in good faith shall be final and binding upon Participant, the Company and all other interested persons. No member of the Administrator or the Board shall be personally liable for any action, determination or interpretation made in good faith with respect to the Plan, this Agreement or the PSUs.

3.2 Transferability. The PSUs shall be subject to the restrictions on transferability set forth in Section 10.1 of the Plan.

3.3 Tax Consultation. Participant understands that Participant may suffer adverse tax consequences in connection with the PSUs granted pursuant to this Agreement (and the Shares issuable with respect thereto). Participant represents that Participant has consulted with any tax consultants Participant deems advisable in connection with the PSUs and the issuance of Shares with respect thereto and that Participant is not relying on the Company for any tax advice.

3.4 Binding Agreement. Subject to the limitation on the transferability of the PSUs contained herein, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

3.5 Adjustments Upon Specified Events. The Administrator may accelerate the vesting of the PSUs in such circumstances as it, in its sole discretion, may determine. Participant acknowledges that the PSUs are subject to adjustment, modification and termination in certain events as provided in this Agreement and Article IX of the Plan.

3.6 Notices. Any notice to be given under the terms of this Agreement to the Company shall be addressed to the Company in care of the Secretary of the Company at the Company's principal office, and any notice to be given to Participant shall be addressed to Participant at Participant's last address reflected on the Company's records. By a notice given pursuant to this Section 3.6, either party may hereafter designate a different address for notices to be given to that party. Any notice shall be deemed duly given when sent via email or when sent by certified mail (return receipt requested) and deposited (with postage prepaid) in a post office or branch post office regularly maintained by the United States Postal Service (or similar foreign entity).

3.7 Participant's Representations. If the Shares issuable hereunder have not been registered under the Securities Act or any applicable state laws on an effective registration statement at the time of such issuance, Participant shall, if required by the Company, concurrently with such issuance, make such written representations as are deemed necessary or appropriate by the Company or its counsel.

3.8 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

3.9 Governing Law. The laws of the State of Delaware shall govern the interpretation, validity, administration, enforcement and performance of the terms of this Agreement regardless of the law that might be applied under principles of conflicts of laws.

3.10 Conformity to Securities Laws. Participant acknowledges that the Plan and this Agreement are intended to conform to the extent necessary with all provisions of the Securities Act and the Exchange Act and any other Applicable Law. Notwithstanding anything herein to the contrary, the Plan shall be administered, and the PSUs are granted, only in such a manner as to conform to Applicable Law. To the extent permitted by Applicable Law, the Plan and this Agreement shall be deemed amended to the extent necessary to conform to such Applicable Law.

3.11 Amendment, Suspension and Termination. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Administrator or the Board; *provided, however,* that, except as may otherwise be provided by the Plan, no amendment, modification, suspension or termination of this Agreement shall adversely affect the PSUs in any material way without the prior written consent of Participant.

3.12Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer herein set forth in Section 3.2 hereof, this Agreement shall be binding upon Participant and his or her heirs, executors, administrators, successors and assigns.

3.13Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, then the Plan, the PSUs and this Agreement shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3 of the Exchange Act) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, this Agreement shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

3.14Not a Contract of Service Relationship. Nothing in this Agreement or in the Plan shall confer upon Participant any right to continue to serve as an Employee or other service provider of the Company or any of its Subsidiaries or shall interfere with or restrict in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without cause, except to the extent expressly provided otherwise by Applicable Law or in a written agreement between the Company or a Subsidiary and Participant.

3.15Entire Agreement. The Plan, the Grant Notice and this Agreement (including all Exhibits thereto, if any) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof *provided* that the PSUs shall be subject to any accelerated vesting provisions in any written agreement between Participant and the Company (or any Subsidiary who is the employer of Participant), including, without limitation, any Change in Control Severance Agreement or a Company plan pursuant to which Participant participates, in each case, in accordance with the terms therein.

3.16Section 409A. This Award is not intended to constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code (together with any Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the date hereof, "***Section 409A***"). However, notwithstanding any other provision of the Plan, the Grant Notice or this Agreement, if at any time the Administrator determines that this Award (or any portion thereof) may be subject to Section 409A, the Administrator shall have the right in its sole discretion (without any obligation to do so or to indemnify Participant or any other person for failure to do so) to adopt such amendments to the Plan, the Grant Notice or this Agreement, or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, as the Administrator determines are necessary or appropriate for this Award either to be exempt from the application of Section 409A or to comply with the requirements of Section 409A.

3.17Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and shall not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant shall have only the rights of a general unsecured creditor of the Company and its Subsidiaries with respect to amounts credited and benefits payable, if any, with respect to the PSUs, and rights no greater than the right to receive the Shares as a general unsecured creditor with respect to PSUs, as and when payable hereunder.

* * * * *

EXHIBIT B
TO PERFORMANCE STOCK UNIT AWARD GRANT NOTICE

VESTING SCHEDULE

EXHIBIT C
TO PERFORMANCE STOCK UNIT AWARD GRANT NOTICE

DEFERRAL ELECTION FORM

*Please complete and return this Deferral Election Form through DocuSign so that it is received by Treace Medical Concepts, Inc. (the "**Company**") on or before the 30th day following the Grant Date set forth in the Grant Notice (the "**Grant Notice**") to which this Deferral Election Form is attached (the "**Submission Deadline**") if you intend to defer the issuance of the shares underlying your PSUs. If you do not want to defer the issuance of shares underlying PSUs, you do not need to complete this Deferral Election Form. Capitalized terms used in this Deferral Election Form and not defined herein shall have the meaning ascribed to them in the Grant Notice, the Agreement (as defined in the Grant Notice) and the Company's 2021 Incentive Award Plan (the "**Plan**").*

By your signature to this Deferral Election Form, you agree that this Deferral Election Form will become irrevocable effective as of the Submission Deadline.

I. PERSONAL INFORMATION
Participant Name: _____ (the "***Participant***").

II. DEFERRAL ELECTION
Only complete this Section III if you wish to defer settlement of your PSUs on a tax-deferred basis.

[_] I hereby elect to defer the settlement of _____% of the PSUs covered by the Grant Notice and Agreement that become vested (my "***Deferred PSUs***") (please select a percentage no greater than 100%).

[_] I do not wish to defer settlement of the PSUs covered by the Grant Notice and Agreement. I understand that by not electing to defer the settlement of the PSUs, all of my PSUs will be settled on or within 30 days after vesting as provided in the Agreement.

III. ELECTIVE SETTLEMENT DATES
Subject to the mandatory terms set forth in Section V below:

[_] I elect to have my Deferred PSUs settled in a single lump sum installment in whole shares on the _____ anniversary of the date the PSUs vest (please select between the first and tenth anniversary), or if earlier, as set forth in Section IV below.

[_] I do not select a fixed settlement date for my Deferred PSUs and as a result my Deferred PSUs will be settled as set forth in Section V below.

IV. ELECTION FOR EMPLOYMENT TAX WITHHOLDING
I understand that employment taxes (i.e., FICA) will be due in connection with the vesting of my Deferred PSUs, and such employment taxes must be satisfied on a date selected by the Company between the vesting date and December 31 of the year of vesting (the "***Employment Tax Due Date***"). Subject to the mandatory terms set forth in Section V below:

[_] I elect to have a number of shares otherwise issuable upon settlement of my Deferred PSUs withheld to satisfy such employment tax withholding, with the number of shares withheld equal to that number of shares having a Fair Market Value equal to the sum of the amount of employment taxes required to be withheld plus any additional income and employment tax withholding that becomes due in connection with the Company withholding such shares underlying the Deferred PSUs. Notwithstanding the foregoing, I acknowledge that the Company may, in lieu of withholding shares otherwise issuable upon settlement of my PSUs, settle a number of PSUs equal to the number of shares it would otherwise withhold pursuant to the preceding sentence and instruct a broker on my behalf to sell the shares issued in connection with such settlement.

[_] I elect to satisfy all employment tax withholding obligations in respect of my Deferred PSUs by making a cash payment to the Company in amount equal to such withholding obligations no later than the Employment Tax Due Date. In the event I fail to satisfy such withholding obligations in cash on or before the Employment Tax Due Date, I authorize the Company to deduct such withholding taxes from any other wages due to me after the Employment Tax Due Date.

V. MANDATORY TERMS

Notwithstanding the foregoing:

i. Upon the earlier of a Change in Control that constitutes a "change in control event" within the meaning of Section 409A of the Code and your "separation from service" within the meaning of Section 409A of the Code, all Deferred PSUs that have vested but have not yet been settled as of such date will thereupon be settled.

ii. If settlement is triggered because of your "separation from service" and you are a "specified employee" within the meaning of Section 409A of the Code at the time of your "separation from service", then the settlement that you would otherwise be entitled to receive upon your "separation from service" will not occur until the earlier of the date that is 6 months and 1 day following your "separation from service" or the date of your death.

VI. PARTICIPANT ACKNOWLEDGEMENTS AND SIGNATURE

i. I agree to all of the terms and conditions of this Deferral Election Form.

ii. I acknowledge that I have received and read a copy of the Plan and the Plan's prospectus and that I am familiar with the terms and provisions of the Plan.

iii. I agree to the right of the Administrator to amend or terminate this election at any time and for any reason, with or without notice; *provided* that such termination or amendment is performed in compliance with Section 409A of the Code (as determined by Company legal counsel in its sole and absolute discretion).

iv. I understand that the obligation of the Company to deliver shares of Common Stock in connection with any Deferred PSUs is unfunded and that no assets of any kind have been segregated in a trust or otherwise set aside to satisfy any obligation under this Deferral Election Form. I also understand that any election to defer the

settlement of any PSUs pursuant to this Deferral Election Form will make me only a general, unsecured creditor of the Company.

v. I understand that the fair market value of the shares underlying the Deferred PSUs that are not withheld or sold to cover tax withholding in the year of vesting will constitute ordinary income to me upon settlement and will be subject to income tax withholding, such income tax withholding to be satisfied in accordance with the Grant Notice and the Agreement.

vi. I understand that, upon settlement of any PSUs, including Deferred PSUs, I may owe federal, state, local and other income taxes in excess of the amounts the Company is required to withhold and the Company has advised me to consult with a tax professional prior to submitting this Deferral Election Form.

vii. I understand, acknowledge and agree that the Administrator has the discretion to make all determinations and decisions regarding any elections set forth on this Deferral Election Form.

viii. I understand that this Deferral Election Form and the elections made hereunder are intended to comply with the requirements of Section 409A of the Code so that none of the Deferred PSUs issuable will be subject to the tax acceleration and additional penalty taxes imposed under Section 409A of the Code, and any ambiguities herein will be interpreted to so comply. If applicable, I understand that I am solely responsible for any accelerated income taxes and additional taxes and tax penalties imposed by Section 409A of the Code.

ix. I also understand that this Deferral Election Form and the elections made hereunder will in all respects be subject to the terms and conditions of the Grant Notice, the Agreement and the Plan, as applicable.

By signing this Deferral Election Form, I authorize the implementation of the above elections. I understand that any deferral election in Section II and employment tax withholding election in Section III are irrevocable effective as of the Submission Deadline and may not be changed in the future, except in accordance with the requirements of Section 409A of the Code and the procedures specified by the Administrator.

Signed: _____ Date: _____, _____

Agreed to and accepted:

TREACE MEDICAL CONCEPTS, INC.

By: _____ Date: _____, _____
Name: _____
Title: _____

IMPORTANT DEADLINE: Please remember that if you wish to make any election set forth on this Deferral Election Form, then the properly completed Deferral Election Form must be signed by you through DocuSign and returned ON OR BEFORE THE SUBMISSION DEADLINE.

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John T. Treace, certify that:

1. I have reviewed this Form 10-Q of Treace Medical Concepts, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    (b) [Reserved];

    (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2023

By: /s/ John T. Treace
John T. Treace
Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark L. Hair, certify that:

1. I have reviewed this Form 10-Q of Treace Medical Concepts, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    (b) [Reserved];

    (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2023

By: /s/ Mark L. Hair

Mark L. Hair
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Treace Medical Concepts, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: November 9, 2023 By: /s/ John T. Treace

John T. Treace
Chief Executive Officer
(Principal Executive Officer)

.

Exhibit 32.2

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

In connection with the Quarterly Report of Treace Medical Concepts, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: November 9, 2023 By: /s/ Mark L. Hair

Mark L. Hair
Chief Financial Officer
(Principal Financial and Accounting Officer)