
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 June 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

(State or other jurisdiction of incorporation or organization)

47-1052611

(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, 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>	Non-accelerated filer	<input checked="" type="checkbox"/>
Smaller reporting company	<input checked="" type="checkbox"/>	Emerging growth company	<input checked="" type="checkbox"/>		

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 August 4, 2023, 61,544,672 shares of the registrant's common stock, \$0.001 par value per share, were outstanding.

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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,” “the Company,” and similar references 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;
- 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 or investment 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 listed under "Risk Factors" and 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)

	June 30, 2023	December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	\$ 12,035	\$ 19,473
Marketable securities, short-term	127,444	61,779
Accounts receivable, net of allowance for doubtful accounts of \$707 and \$735 as of June 30, 2023 and December 31, 2022, respectively	27,232	29,196
Inventories	26,101	19,330
Prepaid expenses and other current assets	5,284	3,624
Total current assets	198,096	133,402
Property and equipment, net	19,435	15,338
Intangible assets, net	9,500	—
Goodwill	12,815	—
Operating lease right-of-use assets	9,651	10,138
Other non-current assets	146	146
Total assets	\$ 249,643	\$ 159,024
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 8,146	\$ 8,668
Accrued liabilities	7,072	6,216
Accrued commissions	5,661	7,356
Accrued compensation	5,368	7,666
Other liabilities	3,775	339
Total current liabilities	30,022	30,245
Long-term debt, net of discount of \$1,141 and \$1,289 as of June 30, 2023 and December 31, 2022, respectively	52,859	52,711
Operating lease liabilities, net of current portion	16,766	15,539
Other long-term liabilities	37	—
Total liabilities	99,684	98,495
Commitments and contingencies (Note 8)		
Stockholders' equity		
Common stock, \$0.001 par value, 300,000,000 shares authorized; 61,528,409 issued and outstanding as of June 30, 2023; 300,000,000 shares authorized; 55,628,208 issued and outstanding as of December 31, 2022	62	55
Additional paid-in capital	260,561	145,221
Accumulated deficit	(110,445)	(84,720)
Accumulated other comprehensive (loss) income	(219)	(27)
Total stockholders' equity	149,959	60,529
Total liabilities and stockholders' equity	\$ 249,643	\$ 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)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Revenue	\$ 41,953	\$ 29,967	\$ 84,148	\$ 59,014
Cost of goods sold	7,675	5,291	15,714	10,421
Gross profit	34,278	24,676	68,434	48,593
Operating expenses				
Sales and marketing	33,773	26,610	67,428	48,909
Research and development	3,526	2,984	6,938	6,036
General and administrative	10,031	7,015	20,896	13,677
Total operating expenses	47,330	36,609	95,262	68,622
Loss from operations	(13,052)	(11,933)	(26,828)	(20,029)
Interest income	1,968	131	3,447	140
Interest expense	(1,282)	(946)	(2,567)	(1,897)
Debt extinguishment loss	—	(4,483)	—	(4,483)
Other income, net	95	(3)	223	(1)
Other non-operating income (expense), net	781	(5,301)	1,103	(6,241)
Net loss	\$ (12,271)	\$ (17,234)	\$ (25,725)	\$ (26,270)
Other comprehensive income (loss):				
Unrealized loss on marketable securities	(163)	—	(192)	—
Comprehensive loss	\$ (12,434)	\$ (17,234)	\$ (25,917)	\$ (26,270)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.20)	\$ (0.31)	\$ (0.43)	\$ (0.48)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	61,382,514	55,308,273	60,060,483	55,071,368

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	Accumulated	Accumulated	Total
	Shares	Amount	Paid-In Capital	Deficit	Other Comprehensive Loss	Stockholders' Equity
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
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

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

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

	Six Months Ended June 30,	
	2023	2022
Cash flows from operating activities		
Net loss	\$ (25,725)	\$ (26,270)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization expense	2,019	757
(Recovery) provision for allowance for doubtful accounts	78	(45)
Share-based compensation expense	6,288	3,372
Non-cash lease expense	1,264	1,165
Amortization of debt issuance costs	148	95
Recovery of inventory obsolescence	—	(197)
Gain on fair value adjustment to derivative liability	—	(173)
Debt extinguishment loss	—	4,483
Accretion (amortization) of discount (premium) on marketable securities, net	(663)	—
Other, net	5	—
Net changes in operating assets and liabilities, net of acquisitions:		
Accounts Receivable	1,886	2,112
Inventory	(6,704)	(2,410)
Prepaid expenses and other assets	(1,641)	(1,039)
Other non-current assets	—	(134)
Other liabilities	1,072	2,392
Accounts payable	(522)	(957)
Accrued liabilities	(3,137)	(958)
Other, net	38	—
Net cash used in operating activities	<u>(25,594)</u>	<u>(17,807)</u>
Cash flows from investing activities		
Purchases of available-for-sale marketable securities	(120,957)	—
Sales and maturities of available-for-sale marketable securities	55,763	—
Purchases of property and equipment	(5,709)	(6,649)
Acquisition, net of cash acquired	(20,000)	—
Net cash used in investing activities	<u>(90,903)</u>	<u>(6,649)</u>
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	1,532	1,537
Net cash provided by financing activities	<u>109,059</u>	<u>20,156</u>
Net decrease in cash and cash equivalents	<u>(7,438)</u>	<u>(4,300)</u>
Cash and cash equivalents at beginning of period	<u>19,473</u>	<u>105,833</u>
Cash and cash equivalents at end of period	<u>\$ 12,035</u>	<u>\$ 101,533</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 2,567	\$ 1,897
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	\$ (13)	\$ —
Noncash investing activities:		
Unrealized losses on marketable securities	\$ 192	\$ —

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

TREACE MEDICAL CONCEPTS, INC.

Notes to Condensed Financial Statements

(unaudited)

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. In 2021, the Company expanded its offerings with the Adductoplasty® Midfoot Correction System, designed for reproducible correction of the midfoot to provide further support to hallux valgus patients. 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 \$110.4 million as of June 30, 2023. During the six months ended June 30, 2023 and 2022, the Company used \$25.6 million and \$17.8 million of cash in its operating activities, respectively. As of June 30, 2023, the Company had cash and cash equivalents of \$12.0 million and marketable securities available-for-sale of \$127.4 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 six months ended June 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 six months ended June 30, 2022 for \$0.4 million and \$0.7 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 June 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 including the income approach, the cost approach, and 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 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, such as the takeover of Silicon Valley Bank, where the Company did hold cash as deposits, 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 at Silicon Valley Bank at the time of the FDIC takeover or as of June 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. The Company performs ongoing credit evaluations of its customers' financial condition. On June 30, 2023 and December 31, 2022, no customer accounted for more than 10% of accounts receivable. For the six months ended June 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 June 30, 2023 and December 31, 2022 (in thousands):

	June 30, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents				
Money market funds	\$ 9,084	\$ —	\$ —	\$ 9,084
Short-term marketable securities at fair value				
U.S. treasury and government agencies	33,733	21,428	—	55,161
Commercial paper	—	347	—	347
Corporate debt	—	28,384	—	28,384
Asset-backed securities	—	30,820	—	30,820
Yankee CD	—	12,732	—	12,732
Total assets	<u>\$ 42,817</u>	<u>\$ 93,711</u>	<u>\$ —</u>	<u>\$ 136,528</u>
Liabilities:				
Contingent consideration	\$ —	\$ —	\$ 2,814	\$ 2,814
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,814</u>	<u>\$ 2,814</u>
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	<u>\$ 26,014</u>	<u>\$ 51,976</u>	<u>\$ —</u>	<u>\$ 77,990</u>

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 fair value of the level 3 contingent consideration was recorded at fair value on the date of the acquisition 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.

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

5. Business Combination

On June 12, 2023 ("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 June 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	\$	<u>22,814</u>

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		<u>9,500</u>
Total identifiable assets acquired		9,999
Goodwill		<u>12,815</u>
Total assets acquired	\$	<u>22,814</u>

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 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 amortization for the three months and six months ended June 30, 2023 was not material.

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 months and six months ended June 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):

	June 30, 2023	December 31, 2022
Cash	\$ 2,951	\$ 3,262
Cash equivalents:		
Money market funds	9,084	13,141
Commercial paper	—	323
Corporate debt	—	2,197
Yankee CD	—	550
Total cash and cash equivalents	<u>\$ 12,035</u>	<u>\$ 19,473</u>

Included in cash as of December 31, 2022 is \$0.9 million pledged to Silicon Valley Bank ("SVB") as collateral for the Company's corporate credit card program and is restricted from use by the Company. There was no cash pledged to SVB as of June 30, 2023.

Marketable Securities

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

	June 30, 2023			Fair Value
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	
Marketable securities - short-term				
U.S. treasury and government agencies	\$ 55,305	\$ —	\$ (144)	\$ 55,161
Commercial paper	347	—	—	347
Corporate debt	28,391	22	(29)	28,384
Asset-backed securities	30,876	20	(76)	30,820
Yankee CD	12,744	—	(12)	12,732
Total marketable securities - short-term	<u>\$ 127,663</u>	<u>\$ 42</u>	<u>\$ (261)</u>	<u>\$ 127,444</u>

	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	<u>\$ 61,806</u>	<u>\$ 79</u>	<u>\$ (106)</u>	<u>\$ 61,779</u>

Property and equipment, net

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

	June 30, 2023	December 31, 2022
Furniture and fixtures, and equipment	\$ 1,586	\$ 1,577
Construction in progress	3,067	705
Machinery and equipment	2,079	928
Capitalized surgical equipment	11,511	9,248
Computer equipment	697	571
Leasehold improvements	6,351	6,434
Software	138	138
Total property and equipment	25,429	19,601
Less: accumulated depreciation and amortization	(5,994)	(4,263)
Property and equipment, net	<u>\$ 19,435</u>	<u>\$ 15,338</u>

Depreciation and amortization expense on property and equipment were \$1.1 million and \$0.4 million for the three months ended June 30, 2023 and 2022, respectively. Depreciation and amortization expense on property and equipment were \$2.0 million and \$0.8 million for the six months ended June 30, 2023 and 2022, respectively.

Accrued liabilities

Accrued liabilities consist of the following (in thousands):

	June 30, 2023	December 31, 2022
Accrued royalties expense	\$ 1,740	\$ 2,299
Accrued interest	398	412
Accrued professional services	930	1,727
Other accrued expense	4,004	1,778
Total accrued liabilities	<u>\$ 7,072</u>	<u>\$ 6,216</u>

Other liabilities

Other liabilities consist of the following (in thousands):

	June 30, 2023	December 31, 2022
Current portion of operating lease liabilities	\$ 961	\$ 339
Contingent consideration	2,814	—
Total other liabilities	<u>\$ 3,775</u>	<u>\$ 339</u>

7. Long-Term Debt

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

	June 30, 2023	December 31, 2022
<i>Revolving line of credit</i>		
MidCap revolving loan facility	\$ 4,000	\$ 4,000
<i>Term loans</i>		
MidCap term loan facility	50,000	50,000
Total term and revolving loans	54,000	54,000
Less: debt discount and issuance costs	(1,141)	(1,289)
Total long-term debt, net	<u>\$ 52,859</u>	<u>\$ 52,711</u>

As of June 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	(1,141)
Total long-term debt, net	<u>\$ 52,859</u>

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 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 June 30, 2023, the borrowing base allows a total of \$22.5 million available to the Company under the revolving loan facility. The balance drawn as of June 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 June 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 June 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 June 30, 2023.

8. Commitments and Contingencies

License and Royalty Commitments

As of June 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 \$1.6 million and \$1.3 million for the three months ended June 30, 2023 and 2022, respectively, and \$3.2 million and \$2.7 million for the six months ended June 30, 2023 and 2022, respectively. For the three months ended June 30, 2023 and 2022, the aggregate royalty rates were 3.7% and 4.6%, respectively. For the six months ended June 30, 2023 and 2022, the aggregate royalty rates were 3.8% and 4.6%, 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 June 30, 2023 and December 31, 2022.

9. Stockholders' Equity

Stock Options

During the six months ended June 30, 2023 and 2022, the Company granted stock options to employees to purchase an aggregate of 771,785 and 1,171,175 shares of the Company's common stock, respectively. The weighted-average grant-date fair value of the employee stock options granted during the six months ended June 30, 2023 and 2022 was \$10.63 and \$7.37 per share, respectively.

Restricted Stock Units

During the three months ended June 30, 2023 and 2022, the Company granted 651,396 and 359,534 restricted stock units ("RSUs"), respectively. The weighted average grant-date fair value of RSUs granted during the three months ended June 30, 2023 and 2022 was \$24.26 and \$18.28, respectively.

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Cost of goods sold	\$ 53	\$ —	\$ 129	\$ —
Sales and marketing expense	1,063	690	1,885	1,221
Research and development expense	375	176	632	326
General and administrative expense	2,105	1,097	3,642	1,825
Total	<u>\$ 3,596</u>	<u>\$ 1,963</u>	<u>\$ 6,288</u>	<u>\$ 3,372</u>

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 six months ended June 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Numerator				
Net loss	\$ (12,271)	\$ (17,234)	\$ (25,725)	\$ (26,270)
Denominator				
Weighted-average common stock outstanding, basic and diluted	61,382,514	55,308,273	60,060,483	55,071,368
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.20)</u>	<u>\$ (0.31)</u>	<u>\$ (0.43)</u>	<u>\$ (0.48)</u>

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:

	June 30, 2023	December 31, 2022
Common stock options issued and outstanding	7,529,046	7,150,755
Unvested full value awards	1,107,408	595,048
Total	<u>8,636,454</u>	<u>7,745,803</u>

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 (the "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 on Form 10-Q. 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 75,000 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 224 territories in the United States. As of June 30, 2023, we had 200 direct sales representatives and 23 independent sales agencies. In the three months ended June 30, 2023, employee sales representatives generated approximately 79% of revenues while approximately 21% 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 June 30, 2023, we had cash and cash equivalents of \$12.0 million and marketable securities available-for-sale of \$127.4 million to fund operations, an accumulated deficit of \$110.4 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 MIOS Marketing, LLC d/b/a RedPoint Medical3D ("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 throughout 2023, 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 June 30, 2023, increased by 1,546 or 29% over the same period in 2022. The blended average sales price per Lapiplasty Procedure Kits sold was \$6,176 during the three months ended June 30, 2023, an 8% 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 June 30, 2023, was 2,581, an increase of 26.1% 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 six months ended June 30, 2023, increased by 5.9% over the same period in 2022, to an average of 10.7 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 2,000 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 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.

We are also pursuing the development and potential commercialization, if cleared, 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. The orthopaedic industry traditionally experiences lower sales volumes in the third quarter than throughout the rest of the year as elective procedures generally decline during the summer months. Although we follow orthopaedic industry trends generally, to date our third quarter sales volumes have not been lower than other quarters, but we may experience relatively lower sales volumes during third quarters in the future.

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 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 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 six months ended June 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 six months ended June 30, 2023 and 2022

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

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2023	2022	Amount	%	2023	2022	Amount	%
Revenue	\$ 41,953	\$ 29,967	\$ 11,986	40.0%	\$ 84,148	\$ 59,014	\$ 25,134	42.6%
Cost of goods sold	7,675	5,291	2,384	45.1%	15,714	10,421	5,293	50.8%
Gross profit	34,278	24,676	9,602	38.9%	68,434	48,593	19,841	40.8%
Operating expenses								
Sales and marketing	33,773	26,610	7,163	26.9%	67,428	48,909	18,519	37.9%
Research and development	3,526	2,984	542	18.2%	6,938	6,036	902	14.9%
General and administrative	10,031	7,015	3,016	43.0%	20,896	13,677	7,219	52.8%
Total operating expenses	47,330	36,609	10,721	29.3%	95,262	68,622	26,640	38.8%
Loss from operations	(13,052)	(11,933)	(1,119)	9.4%	(26,828)	(20,029)	(6,799)	33.9%
Interest income	1,968	131	1,837	*	3,447	140	3,307	*
Interest expense	(1,282)	(946)	(336)	35.5%	(2,567)	(1,897)	(670)	35.3%
Debt extinguishment loss	—	(4,483)	4,483	*	—	(4,483)	4,483	*
Other income, net	95	(3)	98	*	223	(1)	224	*
Other non-operating income (expense), net	781	(5,301)	6,082	(114.7)%	1,103	(6,241)	7,344	(117.7)%
Net loss	(12,271)	(17,234)	4,963	(28.8)%	(25,725)	(26,270)	545	(2.1)%

* Not meaningful

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

Revenue. Revenue increased by \$12.0 million, or 40.0%, for the three months ended June 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 29% and 38% for the three months ended June 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 59.7% and 72.5% of the revenue growth for the three months ended June 30, 2023 and 2022, respectively. In the three months ended June 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 8% increase in average blended revenue per case compared to the prior year.

Cost of Goods Sold, Gross Profit and Gross Margin. Cost of goods sold increased by \$2.4 million, or 45.1%, for the three months ended June 30, 2023 as compared to the same period in 2022. The increase in cost of goods sold was primarily due to a \$1.6 million increase in direct costs of goods sold and a \$0.2 million increase in royalty expense resulting from increased sales, a \$0.3 million increase in reserves for inventory provision and obsolescence, and a \$0.1 million increase in overhead expenses resulting from increased headcount. During the three months ended June 30, 2023, gross profit increased by \$9.6 million, or 38.9%, as compared to the same period in 2022, due to increased sales. Gross profit margin for the three months ended June 30, 2023 decreased from 82.3% to 81.7%, as compared to the same period in 2022, primarily due to changes in product mix 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 \$7.2 million, or 26.9%, for the three months ended June 30, 2023 as compared to the same period in 2022. Sales and marketing expenses increased as a result of an increase of \$4.0 million in payroll and related expenses primarily from increased headcount of sales and marketing personnel, an increase of \$1.9 million primarily due to higher commissions from increased sales by our employee sales representatives and independent sales agencies, and an increase of \$0.5 million in surgeon training and clinical-related expenses.

Research and Development Expenses. R&D expenses increased by \$0.5 million, or 18.2%, for the three months ended June 30, 2023 as compared to the same period in 2022. The increase in R&D expenses was primarily due to a \$0.9 million increase in payroll and related costs resulting from increased headcount of research and development personnel, partially offset by a decrease of \$0.3 million in clinical expenses resulting primarily from decreased purchases of materials used in our prototypes.

General and Administrative Expenses. General and administrative expenses increased by \$3.0 million, or 43.0%, for the three months ended June 30, 2023 as compared to the same period in 2022. The increase in general and administrative expenses was primarily due to an increase of \$2.0 million in payroll and related costs as we increased headcount to support our growing business, and an increase of \$0.9 million in professional services primarily related to an increase of \$0.6 million in legal expenses from patents and the RPM-3D acquisition and \$0.3 million in compensation expense related to the milestone payments for the RPM-3D acquisition.

Interest income. Interest income increased by \$1.8 million, for the three months ended June 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 second quarter of 2023 due to our equity offering in the first quarter of 2023 and higher interest rates in the three months ended June 30, 2023, as compared to the same period in 2022.

Interest Expense. Interest expense increased by \$0.3 million, or 35.5%, for the three months ended June 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 three months ended June 30, 2023, as compared to the same period in 2022.

Debt Extinguishment Loss. Debt extinguishment loss decreased by \$4.5 million, for the three months ended June 30, 2023 as compared to the same period in 2022 due to our debt refinancing during the second quarter of 2022.

Comparison of the six months ended June 30, 2023 and 2022

Revenue. Revenue increased by \$25.1 million, or 42.6%, for the six months ended June 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 29% and 44% for the six months ended June 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 55.5% and 75.7% of the revenue growth for the six months ended June 30, 2023 and 2022, respectively. In the six months ended June 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 11% increase in average blended revenue per case compared to the same period in the prior year.

Cost of Goods Sold, Gross Profit and Gross Margin. Cost of goods sold increased by \$5.3 million, or 50.8%, for the six months ended June 30, 2023 as compared to the same period in 2022. The increase in cost of goods sold was primarily due to a \$3.3 million increase in direct costs of goods sold and a \$0.4 million increase in royalty expense resulting from our increased sales, \$0.9 million increase in overhead expenses resulting from an increase in our headcount, and a \$0.5 million increase in provision for inventory and instrument obsolescence. During the six months ended June 30, 2023, the gross profit increased by \$19.8 million, or 40.8%, as compared to the same period in 2022 due to increased sales. Gross profit margin for the six months ended June 30, 2023 decreased from 82.3% to 81.3%, as compared to the same period in 2022, primarily due to changes in product mix 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 \$18.5 million, or 37.9%, for the six months ended June 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 \$8.6 million in payroll and related expenses primarily from increased headcount of sales and marketing personnel, a \$6.3 million increase in professional services primarily from higher commissions from increased sales by our direct sales representatives and independent sales agencies, a \$1.2 million increase in surgeon training and clinical-related expenses, a \$1.1 million increase in advertising and marketing-related expenses primarily due to an increase in advertising, and a \$0.6 million increase in surgical instrument expense.

Research and Development Expenses. R&D expenses increased by \$0.9 million, or 14.9%, for the six months ended June 30, 2023 as compared to the same period in 2022. The increase in R&D expenses was due to a \$0.3 million increase in payroll and related costs resulting from increased headcount of research and development personnel, a \$0.3 million increase for rent and other occupancy costs allocations, and a \$0.3 million increase in product testing and validation costs.

General and Administrative Expenses. General and administrative expenses increased by \$7.2 million, or 52.8%, for the six months ended June 30, 2023 as compared to the same period in 2022. The increase in general and administrative expenses was primarily due to an increase of \$4.2 million in payroll and related costs as we increased headcount to support

the growing business, a \$2.5 million increase in professional services primarily related to legal fees, and \$1.0 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, partially offset by a \$0.3 million reduction in insurance costs.

Interest Income. Interest income increased \$3.3 million during the six months ended June 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 six months ended June 30, 2023, as compared to the same period in 2022.

Interest Expense. Interest expense increased by \$0.7 million, or 35.3%, for the six months ended June 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 six months ended June 30, 2023, as compared to the same period in 2022.

Debt Extinguishment Loss. Debt extinguishment loss decreased by \$4.5 million, for the six months ended June 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 June 30, 2023, we had cash and cash equivalents of \$12.0 million and marketable securities of \$127.4 million available for sale, an accumulated deficit of \$110.4 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):

	Six Months Ended June 30,	
	2023	2022
Net cash (used in) provided by:		
Operating activities	\$ (25,594)	\$ (17,807)
Investing activities	(90,903)	(6,649)
Financing activities	109,059	20,156
Net decrease in cash and cash equivalents	<u>\$ (7,438)</u>	<u>\$ (4,300)</u>

Net Cash Used in Operating Activities

Net cash used in operating activities for the six months ended June 30, 2023 was \$25.6 million, consisting primarily of a net loss of \$25.7 million, adjusted for non-cash charges of \$9.1 million and an increase in net operating assets. The non-cash charges consist primarily of share-based compensation expense of \$6.3 million, depreciation and amortization expense of \$2.0 million and non-cash lease expense of \$1.3 million. The increase in net operating assets was primarily due to an increase of \$6.7 million in inventories for added safety stock to meet demand for new products and to avoid potential supply chain issues, an increase of \$1.6 million in prepaid expenses and other assets, and a decrease of \$3.7 million in accrued liabilities and accounts payable due to timing of payments, which were partially offset by a \$1.9 million decrease in accounts receivable from higher sales in the fourth quarter of 2022 and a \$1.1 million increase to operating lease liabilities primarily due to timing of lease incentives.

Net cash used in operating activities for the six months ended June 30, 2022, was \$17.8 million, consisting primarily of a net loss of \$26.3 million, adjusted for non-cash charges of \$9.5 million and a decrease of \$1.0 million in net operating assets. The non-cash charges primarily consisted of a \$4.5 million loss on the extinguishment of the CRG term loan, share-based compensation expense of \$3.4 million, non-cash lease expense of \$1.2 million, and depreciation and amortization expense of \$0.8 million. The decrease in net operating assets was primarily due to a decrease in accounts receivable resulting from higher sales in fourth quarter 2021, an increase in operating lease liabilities, which were more than offset by increases in inventories, prepaid expenses and other assets, and decreases 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 \$90.9 million for the six months ended June 30, 2023, consisting primarily of \$121.0 million in purchases of marketable securities available for sale, \$20.0 million for the acquisition of the RPM-3D assets, and \$5.7 million in purchases of property and equipment, partially offset by \$55.8 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 \$2.1 million in capitalized surgical instruments for our reusable instrument trays and \$3.6 million for furniture, equipment, and leasehold improvements to continue to complete our new corporate headquarters.

Net cash used in investing activities was \$6.6 million for the six months ended June 30, 2022, consisting primarily of purchases of capitalized surgical instruments for our reusable instrument trays.

Net Cash Provided by Financing Activities

Net cash provided in financing activities was \$109.1 million for the six months ended June 30, 2023, consisting primarily of \$107.5 million of net cash proceeds from our public offering of common stock and \$1.5 million from exercise of stock options.

Net cash provided in financing activities was \$20.2 million for the six months ended June 30, 2022, consisting of \$53.5 million of net cash proceeds from the term loan agreement and revolving credit facility with MidCap and \$1.5 million from exercise of stock options partially offset by the \$33.9 million repayment of the CRG term loan.

Surgeon Advisory Board Royalty Agreements

We recognized royalty expense of \$1.6 million and \$1.3 million for the three months ended June 30, 2023 and 2022, and \$3.2 million and \$2.7 million for the six months ended June 30, 2023 and 2022, respectively. For the three months ended June 30, 2023 and 2022, the aggregate royalty rate was 3.7% and 4.6%, respectively. For the six months ended June 30, 2023 and 2022, the aggregate royalty rate was 3.8% and 4.6%, 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 \$27.0 million under these leases as of June 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 six months ended June 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, the result of which 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 and Use of Proceeds.

(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
31.1	<u>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.</u>
31.2	<u>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.</u>
32.1†	<u>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.</u>
32.2†	<u>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.</u>
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)

† 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: August 9, 2023

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

Date: August 9, 2023

By: /s/ Mark L. Hair
Name: Mark L. Hair
Title: Chief Financial Officer (Principal Financial and Accounting Officer)

**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: August 9, 2023

By: _____

/s/ Mark L. Hair

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

