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

Form 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2022
or

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

For the transition period from___ to___

Commission file number: 001-40355

Treace Medical Concepts, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

Title of each class	**Trading symbol(s)**	**Name of each exchange on which registered**
Common stock, $0.001 par value	TMCI	The Nasdaq Global Select Market

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

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

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

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

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

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

As of November 3, 2022, 55,501,742 shares of the registrant's common stock, $0.001 par value per share, were outstanding.

TREACE MEDICAL CONCEPTS, INC.

FORM 10-Q FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2022

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SPECIAL NOTES 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 and cash equivalents 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 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 obtain, maintain and expand regulatory clearances for our products and any new products we create;
- our ability to expand our business into new geographic markets;
- our compliance with Nasdaq requirements and government laws, rules and regulations both in the United States and internationally;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our need for, or ability to obtain, additional financing;
- the effect of the COVID-19 pandemic and its impact on our business;
- the impact of inflationary pressures, higher interest rates and general economic conditions on our business;
- developments and projections relating to our competitors or our industry;
- our plans to conduct further clinical trials; and
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act.

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" 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.

Item 1. Financial Statements (Unaudited).

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

	September 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 88,546	$ 105,833
Accounts receivable, net of allowance for doubtful accounts of $423 and $414 as of September 30, 2022 and December 31, 2021, respectively	18,548	18,568
Inventories	16,794	10,561
Prepaid expenses and other current assets	4,014	3,010
Total current assets	127,902	137,972
Property and equipment, net	14,148	2,849
Operating lease right-of-use assets	14,247	—
Other non-current assets	146	—
Total assets	$ 156,443	$ 140,821
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 7,881	$ 4,056
Accrued liabilities	5,189	4,518
Accrued commissions	4,131	5,181
Accrued compensation	5,049	4,455
Operating lease liabilities	330	—
Total current liabilities	22,580	18,210
Derivative liability on term loan	—	173
Long-term debt, net of discount of $1,364 and $635 as of September 30, 2022 and December 31, 2021, respectively	52,636	29,365
Operating lease liabilities, net of current portion	19,026	—
Total liabilities	94,242	47,748
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred stock, $0.001 par value, 5,000,000 shares authorized as of September 30, 2022 and December 31, 2021; 0 shares issued and outstanding as of September 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value, 300,000,000 shares authorized; 55,499,242 issued and outstanding as of September 30, 2022; 300,000,000 shares authorized; 54,181,082 issued and outstanding as of December 31, 2021	46	45
Additional paid-in capital	142,463	134,933
Accumulated deficit	(80,308)	(41,905)
Total stockholders' equity	62,201	93,073
Total liabilities and stockholders' equity	$ 156,443	$ 140,821

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue	$ 33,055	$ 21,619	$ 92,069	$ 60,980
Cost of goods sold	6,624	4,248	17,781	11,519
Gross profit	26,431	17,371	74,288	49,461
Operating expenses				
Sales and marketing	25,034	15,984	73,207	42,142
Research and development	3,799	2,537	9,835	6,827
General and administrative	8,916	4,310	22,593	11,405
Total operating expenses	37,749	22,831	105,635	60,374
Loss from operations	(11,318)	(5,460)	(31,347)	(10,913)
Interest and other income, net	375	5	514	12
Interest expense	(1,190)	(963)	(3,087)	(3,032)
Debt extinguishment loss	—	—	(4,483)	—
Other expense, net	(815)	(958)	(7,056)	(3,020)
Net loss and comprehensive loss	(12,133)	(6,418)	(38,403)	(13,933)
Convertible preferred stock cumulative and undeclared dividends	—	—	—	(196)
Net loss attributable to common stockholders	$ (12,133)	$ (6,418)	$ (38,403)	$ (14,129)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.22)	$ (0.12)	$ (0.70)	$ (0.30)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	55,429,211	52,766,150	55,190,587	46,603,487

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balances at December 31, 2021	—	$ —	54,181,082	$ 45	$ 134,933	$ (41,905)	$ 93,073
Issuance of common stock upon exercise of stock options	—	—	1,097,860	1	1,371	—	1,372
Share-based compensation expense	—	—	—	—	1,409	—	1,409
Net loss	—	—	—	—	—	(9,036)	(9,036)
Balances at March 31, 2022	—	—	55,278,942	46	137,713	(50,941)	86,818
Issuance of common stock upon exercise of stock options	—	—	112,367	—	165	—	165
Share-based compensation expense	—	—	—	—	1,963	—	1,963
Net loss	—	—	—	—	—	(17,234)	(17,234)
Balances at June 30, 2022	—	—	55,391,309	46	139,841	(68,175)	71,712
Issuance of common stock upon exercise of stock options	—	—	107,933	—	353	—	353
Share-based compensation expense	—	—	—	—	2,269	—	2,269
Net loss	—	—	—	—	—	(12,133)	(12,133)
Balances at September 30, 2022	—	$ —	55,499,242	$ 46	$ 142,463	$ (80,308)	$ 62,201
Balances at December 31, 2020	6,687,475	$ 7,935	37,366,865	$ 28	$ 14,166	$ (21,353)	$ 776
Issuance of common stock upon exercise of stock options	—	—	690,551	2	568	—	570
Share-based compensation expense	—	—	—	—	402	—	402
Net loss	—	—	—	—	—	(2,432)	(2,432)
Balances at March 31, 2021	6,687,475	7,935	38,057,416	30	15,136	(23,785)	(684)
Issuance of common stock upon exercise of stock options	—	—	272,082	—	193	—	193
Vesting of restricted stock awards	—	—	5,866	—	—	—	—
Share-based compensation expense	—	—	—	—	875	—	875
Issuance of common stock from initial public offering, net of issuance costs and underwriting discount of $10.6 million	—	—	6,953,125	7	107,603	—	107,610
Issuance of common stock upon net exercise of warrants	—	—	621,570	1	(1)	—	—
Conversion of convertible preferred stock and accrued dividends on convertible preferred stock into common stock	(6,687,475)	(7,935)	6,845,922	7	7,928	—	—
Net loss	—	—	—	—	—	(5,083)	(5,083)
Balances at June 30, 2021	—	—	52,755,981	45	131,734	(28,868)	102,911
Issuance of common stock upon exercise of stock options	—	—	—	—	41	—	41
Share-based compensation expense	—	—	—	—	839	—	839
Net loss	—	—	—	—	—	(6,418)	(6,418)
Balances at September 30, 2021	—	$ —	52,755,981	$ 45	$ 132,614	$ (35,286)	$ 97,373

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

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

	Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (38,403)	$ (13,933)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization expense	1,216	409
Recovery for allowance for doubtful accounts	(38)	(56)
Share-based compensation expense	5,641	2,116
Non-cash lease expense	2,010	—
Amortization of debt issuance costs	169	133
(Recovery of) provision for inventory obsolescence	(206)	179
Gain on fair value adjustment to derivative liability	(173)	(72)
Debt extinguishment loss	4,483	—
Other, net	25	—
Net changes in operating assets and liabilities:		
Accounts Receivable	58	2,747
Inventory	(6,027)	(2,710)
Prepaid expenses and other assets	(1,058)	(3,168)
Other non-current assets	(146)	—
Operating lease liabilities	3,112	—
Accounts payable	3,825	177
Accrued liabilities	222	737
Net cash used in operating activities	(25,290)	(13,441)
Cash flows from investing activities		
Purchases of property and equipment	(12,506)	(1,805)
Net cash used in investing activities	(12,506)	(1,805)
Cash flows from financing activities		
Repayment of PPP loan	—	(1,788)
Proceeds from interest bearing term debt	49,651	—
Proceeds from interest bearing revolving debt	3,850	—
Debt issuance costs paid to third parties	(989)	—
Repayment of term loan	(33,893)	—
Proceeds from issuance of common stock upon initial public offering, net of issuance costs and underwriting fees of $10.6 million	—	107,610
Proceeds from exercise of employee stock options	1,890	804
Net cash provided by financing activities	20,509	106,626
Net (decrease) increase in cash and cash equivalents	(17,287)	91,380
Cash and cash equivalents at beginning of period	105,833	18,079
Cash and cash equivalents at end of period	$ 88,546	$ 109,459
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 3,087	$ 2,917
Operating lease right-of-use assets obtained in exchange for new lease liabilities	$ 15,300	$ —
Supplemental disclosure of noncash financing activities:		
Issuance of common stock upon exercise of warrants	$ —	$ 1
Conversion of convertible preferred stock and accrued dividends on convertible preferred stock into common stock	$ —	$ 7,935

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

1. Formation and Business of the Company

The Company

Treace Medical Concepts, LLC was formed on July 29, 2013 as a Florida limited liability company. Effective July 1, 2014, the entity converted to a Delaware corporation and changed its name to Treace Medical Concepts, Inc. (the "Company"). The Company is a medical technology company driving a fundamental shift in the surgical treatment of *Hallux Valgus* (commonly known as "bunions"). 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 innovative instruments, implants and surgical methods designed to improve the inconsistent clinical outcomes of traditional approaches to bunion surgery. In addition, the Company offers other advanced instrumentation and implants for use in the Lapiplasty Procedure or other ancillary procedures performed in high frequency with bunion surgery. The Company 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

On April 27, 2021, the Company completed its initial public offering ("IPO") of 12,937,500 shares of its 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 the Company (inclusive of 703,125 shares pursuant to the exercise of the underwriters' option) and 5,984,375 shares of common stock that 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. The Company received net proceeds of approximately $107.6 million, after deducting underwriting discounts and commissions of $8.3 million and offering expenses payable by the Company of $2.3 million. The Company did not receive any proceeds from the sale of the shares by the selling stockholders. Upon the completion of the IPO, all 6,687,475 shares of Series A convertible preferred stock then outstanding were converted into shares of common stock on a one-to-one basis plus 158,447 shares of common stock were issued to pay accrued cumulative dividends on Series A convertible preferred stock of $2.5 million.

Liquidity and Capital Resources

The Company has incurred operating losses to date and has an accumulated deficit of $80.3 million as of September 30, 2022. During the nine months ended September 30, 2022 and 2021, the Company used $25.3 million and $13.4 million of cash in its operating activities, respectively. As of September 30, 2022, the Company had cash and cash equivalents of $88.5 million.

Management believes that the Company's existing cash and cash equivalents 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, 2021 filed with the SEC on March 4, 2022. The unaudited condensed financial statements included herein reflect all adjustments, including normal recurring adjustments, which are, in the opinion of management, necessary for a fair presentation of the financial position, results of operations and cash flows for the periods presented. The results of operations for the nine months ended

September 30, 2022 are not necessarily indicative of the results that may be expected for future quarters or for the fiscal year ending December 31, 2022.

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 reserves and write-downs related to accounts receivable, inventories, the recoverability of long-term assets, valuation of equity instruments, valuation of common stock, stock-based compensation, deferred tax assets and related valuation allowances and impact of contingencies. The Company had no accrued contingent liabilities as of September 30, 2022 and December 31, 2021.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of risk consist principally of cash, cash equivalents 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 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. At September 30, 2022 and December 31, 2021, no customer accounted for more than 10% of accounts receivable. For the nine months ended September 30, 2022 and 2021, there were no customers that represented 10% or more of revenue.

Leases

The Company determines whether an arrangement is or contains a lease at the inception of the arrangement and whether such a lease is classified as a financing lease or operating lease at the commencement date of the lease. Lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The Company determines the commencement date of a lease to be the date on which a lessor makes an underlying asset available for use by the Company. Leases with a term greater than one year are recognized on the balance sheet as operating lease right-of-use assets, operating lease liabilities and operating lease liabilities, net of current portion. The Company elected not to recognize right-of-use assets and lease liabilities for leases with terms of 12 months or less (short-term leases). As the interest rates implicit in our lease contracts are not readily determinable, the Company utilizes its incremental borrowing rate based on the information available at the commencement date to determine the present value of lease payments. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid, incentives received, or impairment charges if the Company determines the right-of-use asset is impaired.

The Company considers the lease term to be the noncancelable period that the Company has the right to use the underlying asset, together with any periods where it is reasonably certain the Company will exercise an option to extend (or not terminate) the lease.

Rent expense for operating leases is recognized on a straight-line basis over the lease term and is presented in operating expenses on the statements of operations and comprehensive loss. The Company has elected to not separate lease and non-lease components for its real estate leases and instead accounts for each separate lease component and the non-lease components associated with that lease component as a single lease component. Variable lease payments are recognized as lease expense as incurred and are recorded in operating expenses on the statements of operations and comprehensive loss.

The Company has no finance leases.

3. Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses*. This guidance will require 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 is currently evaluating the impact of this standard on its financial statements.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842) ("ASC 842")*. The update establishes principles for recognition, measurement, presentation, and disclosure intended to increase transparency and comparability for the accounting of lease transactions. The standard requires lessees to recognize leases with terms greater than 12 months on the balance sheet and disclose key information about leasing arrangements. ASC 842 is effective for the Company for fiscal years beginning after December 15, 2021 and early application is permitted. The Company adopted the new standard as of January 1, 2022, using the required modified retrospective approach. Comparative periods were not adjusted and continue to be presented under the previous accounting guidance. The Company elected the package of practical expedients permitted under the ASC 842 transition guidance, which among other things, allowed it to carry forward the historical lease classification.

The impact of adoption was the recognition of right-of-use assets and lease liabilities of $1.9 million for real estate operating leases at January 1, 2022. In addition, ASC 842 requires new disclosures for lease transactions.

Refer to Note 8, "Operating Leases", for new lease disclosures.

4. Fair Value Measurements

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

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

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

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

Assets and Liabilities Measured and Recorded at Fair Value on a Recurring Basis – The following assets and liabilities are measured at fair value on a recurring basis as of September 30, 2022 and December 31, 2021:

	September 30, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds[(1)]	$ 85,839	$ —	$ —	$ 85,839
Total	$ 85,839	$ —	$ —	$ 85,839

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds[(1)]	$ 105,220	$ —	$ —	$ 105,220
Total	$ 105,220	$ —	$ —	$ 105,220
Liabilities:				
Derivative liability	$ —	$ —	$ 173	$ 173
Total	$ —	$ —	$ 173	$ 173

(1) Money market funds are included in cash and cash equivalents in the condensed balance sheets as of September 30, 2022 and December 31, 2021.

On April 29, 2022, in connection with the refinancing of its long-term debt, the Company repaid the outstanding principal and interest under its term loan facility with CRG Group LP ("CRG") which also extinguished the embedded derivative liability.

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

	Derivative liability
Fair value as of January 1, 2022	$ 173
Change in fair value included in other expense, net	(173)
Fair value as of September 30, 2022	$ —

There were no assets or liabilities measured at fair value on a nonrecurring basis as of September 30, 2022 and December 31, 2021.

5. Balance Sheet Components

Cash and Cash Equivalents

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

	September 30, 2022	December 31, 2021
Cash	$ 2,707	$ 613
Cash equivalents:		
Money market funds	85,839	105,220
Total cash and cash equivalents	$ 88,546	$ 105,833

Included in cash as of September 30, 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 December 31, 2021. In the fourth quarter of 2022, the Company sold $65.0 million of money market funds and will invest the proceeds in various investments that are classified as either cash equivalents or available-for-sale marketable securities.

Property and equipment, net

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

	September 30, 2022	December 31, 2021
Furniture and fixtures, and equipment	$ 1,443	$ 180
Construction in progress	723	126
Machinery and equipment	768	274
Capitalized surgical equipment	7,950	4,442
Computer equipment	426	160
Leasehold improvements	6,231	268
Software	138	138
Total property and equipment	17,679	5,588
Less: accumulated depreciation and amortization	(3,531)	(2,739)
Property and equipment, net	$ 14,148	$ 2,849

Depreciation and amortization expense on property and equipment was $0.4 million and $0.2 million for the three months ended September 30, 2022 and 2021, respectively. Depreciation and amortization expense on property and equipment was $1.2 million and $0.4 million for the nine months ended September 30, 2022 and 2021, respectively.

Accrued liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2022	December 31, 2021
Accrued royalty expense	$ 1,659	$ 1,522
Accrued interest	381	975
Accrued professional services	1,027	941
Other accrued expense	2,122	1,080
Total accrued liabilities	$ 5,189	$ 4,518

6. Long-Term Debt

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

	September 30, 2022	December 31, 2021
Revolving line of credit		
MidCap revolving credit facility	$ 4,000	$ —
Term loans		
CRG term loan facility	—	30,000
MidCap term loan facility	50,000	—
Total term and revolving loans	54,000	30,000
Less: debt discount and issuance costs	(1,364)	(635)
Total long-term debt, net	$ 52,636	$ 29,365

As of September 30, 2022, future payments of long-term debt were as follows (in thousands):

Fiscal Year		
2022 (remaining six months)	$	—
2023		—
2024		—
2025		—
2026		33,333
2027		20,667
Total principal payments		54,000
Less: Unamortized debt discount and debt issuance costs		(1,364)
Total long-term debt, net	$	52,636

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

The term loan provides for a 60-month term loan facility 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.

The revolving credit 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. At loan closing, the Company drew $4.0 million under the revolving credit facility. The Company may request a $20.0 million increase in the revolving loan facility for a total commitment of up to $50.0 million. The Company is required to either (1) maintain a minimum drawn balance under the revolving facility agreement or (2) 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 (1) 50% of the revolving borrowing capacity or (2) 50% of the borrowing base, or the Company is in default, MidCap will apply funds collected from the Company's lockbox account to reduce the outstanding balance of the revolving loan facility ("Lockbox Deductions"). As of September 30, 2022, 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 (1) 6.0% under the term loan agreement and (2) 4.0% under the revolving credit facility. Interest is payable monthly in arrears on the first day of each month and on the maturity of the loan agreements. 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 credit 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 credit 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.

7. Commitments and Contingencies

License and Royalty Commitments

As of September 30, 2022 and December 31, 2021, 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 $1.1 million for the three months ended September 30, 2022 and 2021, respectively, and $4.3 million and $2.8 million for the nine months

ended September 30, 2022 and 2021, respectively. For the three months ended September 30, 2022 and 2021, the aggregate royalty rates were 4.8% and 5.3% respectively. For the nine months ended September 30, 2022 and 2021, the aggregate royalty rates were 4.7% and 4.5%, respectively.

Contingencies

From time to time, the Company may be a party to various litigation claims in the normal course of business. Legal fees and other costs associated with such actions are expensed as incurred. The Company assesses, in conjunction with legal counsel, the need to record a liability for litigation and contingencies. Accrual estimates are recorded when and if it is determinable that such a liability for litigation and contingencies are both probable and reasonably estimable. There were no accrued contingent liabilities as of September 30, 2022 and December 31, 2021.

8. Operating Leases

The Company's leases consist of real estate leases in Ponte Vedra, Florida.

On February 9, 2022, the Company entered into a 10-year operating lease for a new corporate headquarters building in Ponte Vedra, Florida, with a lease commencement date of March 1, 2022. The Company's obligation to make cash payments for the new headquarters building started in the third quarter of 2022.

The Company's leases contain various options to renew, none of which the Company is reasonably certain to exercise. The lease agreements do not contain any residual value guarantees or restrictive covenants. For the new headquarters lease, the Company is provided a tenant improvement allowance for the construction of leasehold improvements. In exchange for construction management and supervision services related to these improvements, the Company pays the lessor a fee equal to one and a half percent (1.5%) of total construction costs.

In addition to base rent, the Company will pay variable costs related to its share of operating expenses under certain of its lease arrangements. These variable costs are recorded as lease expense as incurred and presented as operating expenses in the statements of operations and comprehensive loss. Variable lease costs were $0.1 million and $0.1 million for the three and nine months ended as of September 30, 2022.

Rent expense was $0.3 and $0.5 for the three and nine months ended September 30, 2021, respectively.

Operating lease cost was $0.8 million and $1.9 million for the three and nine months ended September 30, 2022, respectively. During the three and nine months ended September 30, 2022, cash paid for amounts included in operating lease liabilities of $0.5 million and $0.8 million, respectively, was included in cash flows from operating activities on the condensed statements of cash flows.

Additional information related to operating leases is as follows:

	September 30, 2022
Weighted average remaining lease term (years)	9.4
Weighted average discount rate	9.2%

The following table summarizes future minimum lease payments on operating leases as of December 31, 2021 (in thousands):

Fiscal Year		
2022	$	627
2023		444
2024		458
2025		472
2026		321
Total	$	2,322

The following table summarizes a maturity analysis of operating lease liabilities showing the aggregate lease payments as of September 30, 2022 (in thousands):

Fiscal Year	
2022 remaining *	$ 308
2023	2,161
2024	2,932
2025	3,421
2026	3,339
Thereafter	18,094
Total undiscounted lease payments	30,255
Less: imputed interest	(10,899)
Total discounted lease payments	19,356
Less: Current portion of lease liability	(330)
Noncurrent portion of lease liability	$ 19,026

* Includes the tenant improvement allowance

9. Stockholders' Equity

Stock Option Plans

During the nine months ended September 30, 2022 and 2021, the Company granted stock options to employees to purchase an aggregate of 1,237,675 and 1,787,761 shares respectively, of the Company's common stock. The weighted-average grant-date fair value of the employee stock options granted during the nine months ended September 30, 2022 and 2021 were $7.32 and $6.90 per share, respectively.

Restricted Stock Units

During the nine months ended September 30, 2022, the Company granted 499,244 restricted stock units ("RSUs") The weighted average grant-date fair value of RSUs granted during the nine months ended September 30, 2022 was $18.46. The Company did not grant RSUs during the nine months ended September 30, 2021.

Share-Based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Sales and marketing	$ 809	$ 278	$ 2,030	$ 795
Research and development	174	129	500	295
General and administrative	1,286	432	3,111	1,026
Total	$ 2,269	$ 839	$ 5,641	$ 2,116

10. Net Loss Per Share Attributable to Common Stockholders

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders which is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period. As the Company reported a net loss for the three and nine months ended September 30, 2022 and 2021, basic net loss per share attributable to common stockholders was the same as

diluted net loss per share attributable to common stockholders as the inclusion of potentially dilutive shares would have been antidilutive if included in the calculation (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Numerator				
Net loss	$ (12,133)	$ (6,418)	$ (38,403)	$ (13,933)
Adjust: Convertible preferred stock cumulative and undeclared dividends	—	—	—	(196)
Net loss attributable to common stockholders	(12,133)	(6,418)	(38,403)	(14,129)
Denominator				
Weighted-average common stock outstanding, basic and diluted	55,429,211	52,766,150	55,190,587	46,603,487
Net loss per share attributable to common stockholders, basic and diluted	$ (0.22)	$ (0.12)	$ (0.70)	$ (0.30)

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

	September 30, 2022	December 31, 2021
Common stock options issued and outstanding	7,209,997	7,464,580
Unvested restricted stock units	499,284	29,024
Total	7,709,281	7,493,604

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 and our audited financial statements and related notes thereto for the year ended December 31, 2021, included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission on March 4, 2022 (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". Please also see the section titled "Special Note Regarding Forward-Looking Statements."

Overview

We are a medical technology company driving a fundamental shift in the surgical treatment of *Hallux Valgus* (commonly known as bunions). We have pioneered our proprietary Lapiplasty® 3D Bunion Correction™ System—a combination of innovative instruments, implants and surgical methods designed to improve the inconsistent clinical outcomes of traditional approaches to bunion surgery. 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 57,000 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 172 territories in the United States. As of September 30, 2022, we had 143 direct sales representatives and 29 independent sales agencies. In the three months ended September 30, 2022, employee sales representatives generated approximately 74% of revenues while approximately 26% of revenues came through independent sales agencies. In the nine months ended September 30, 2022, employee sales representatives generated approximately 69% of revenues while approximately 31% of revenues came through independent sales agencies.

On April 27, 2021, we completed our initial public offering ("IPO") of 12,937,500 shares of common stock, which included the exercise in full of the underwriters' option to purchase additional shares. Before our IPO, our primary sources of capital had been private placements of common stock and convertible preferred stock, debt financing agreements and revenue from the sale of our products. As part of the IPO, we received net proceeds of approximately $107.6 million. Upon the completion of the IPO, all 6,687,475 shares of our Series A convertible preferred stock then outstanding were converted into shares of common stock on a one-to-one basis plus 158,447 shares of common stock were issued to pay accrued dividends on Series A convertible preferred stock of $2.5 million. As of September 30, 2022, we had cash and cash equivalents of $88.5 million, an accumulated deficit of $80.3 million and $54.0 million of principal outstanding under our term and revolving loan agreements.

In April 2022, we entered a new five-year $150.0 million loan arrangement, comprising up to $120.0 million in term loans and $30.0 million in a revolving credit facility with entities affiliated with MidCap Financial Trust ("MidCap"). On the closing date for these loan agreements, we borrowed $50.0 million under the term loan and $4.0 million under the revolving credit facility. The term loan proceeds were partially used to repay our entire obligation under our term loan facility with CRG Group LP ("CRG") amounting to $34.1 million, including principal of $30.0 million, accrued but unpaid interest of $0.4 million and fees of $3.7 million. In April 2022, we also terminated our revolving credit facility with Silicon Valley Bank ("SVB"), which had no outstanding balance when terminated. We recognized a loss from the extinguishment of the CRG term loan facility and the SVB revolving credit facility of $4.5 million (including fees paid of $3.7 million).

COVID-19 Impact and Economic Environment

Our business has been and may continue to be impacted by the COVID-19 pandemic. We are aware that the actual and perceived impact of COVID-19 has been changing and cannot be predicted. Since the pandemic began, we have experienced elective surgery delays and cancellations and hospital staffing and capacity constraints, primarily related to surges of infections and hospitalizations as variants of COVID-19 have emerged. We believe we may continue to experience market variability as a result of the pandemic that could influence sales, suppliers, patients, and customers. There is still uncertainty around the duration and severity of business disruptions related to COVID-19 and how it will impact our operations which could be significant.

There is also uncertainty in the macro-economic environment. Inflationary pressures, rising interest rates, reduced consumer confidence, and ongoing supply chain challenges may result in higher costs and longer lead times from suppliers and reduced demand for our Lapiplasty Procedure Kits. General economic conditions may also affect 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 channels, patient education initiatives, clinical evidence and product innovations to build demand for our products, we expect these macro-economic challenges to continue throughout 2022 and into 2023, which may 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, the number of active surgeons using the Lapiplasty System and utilization rate, to evaluate our business, measure our performance, identify trends affecting our business, formulate our business plans and make strategic decisions. The number of Lapiplasty Procedure Kits sold during the three months ended September 30, 2022 increased by 1,742 or 44% over the same period of 2021, and the number of active surgeons as of September 30, 2022 was 2,218 an increase of 39% from the prior year. We define the number of active surgeons as the number of surgeons that performed at least one procedure using the Lapiplasty System in the trailing twelve-month period. The surgeon utilization rate for the nine months ended September 30, 2022 increased by 1.6% over the same period of 2021, to an average of 10.1 Lapiplasty Procedure Kits per active surgeon.

We believe that the number of Lapiplasty Procedure Kits sold, number of active surgeons using the Lapiplasty System and 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 COVID-19 and other macro-economic impacts 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” and in the section titled “Risk Factors” included elsewhere in this Quarterly Report on Form 10-Q.

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 1,850 facilities across the United States and plan to continue to increase access by convincing even 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 driving 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 offerings of our capital stock and by incurring debt.

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 are hiring additional direct sales representatives and employee field sales management to strategically access more regions with high densities of prospective patients and by focusing the efforts of our independent sales channel on our products. 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-Incision 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. As an example of our investments in innovation and growth, in 2022 alone, we introduced (a) our Lapiplasty S4A Anatomic Plating Kit, an advanced, three-dimensional contoured plate; (b) our Lapiplasty 3-n-1™ Guide, an advanced instrument that combines three separate instruments into one precision tool aimed to reduce surgical time and increase the reproducibility and efficiency of the Lapiplasty Procedure; and (c) the SpeedRelease™ and TriTome™ Tissue Release Instruments, which are sterile-packaged, single-use tissue cutting instruments specially designed to provide a more accurate and complete surgical release of key soft tissue anatomy commonly involved in the Lapiplasty and Adductoplasty Procedures.

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 these activities to increase our net losses, 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 first calendar quarter. Our sales volumes in the fourth calendar 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 the first calendar quarter 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. 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.

Components of Our Results of Operations

Revenue

We currently derive nearly all 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, and 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 agencies. Our primary product is the Lapiplasty System, which is an instrumented, reproducible approach to 3D bunion correction that helps patients rapidly return to weight-bearing in a post-operative boot. We also offer other advanced instrumentation and implants for use in the Lapiplasty and Adductoplasty Procedures or other ancillary procedures performed in high frequency with bunion surgery.

No single customer accounted for 10% or more of our revenue during the three and nine months ended September 30, 2022. We expect our revenue to increase in absolute dollars in the foreseeable future as we expand our sales territories, new accounts and trained surgeon base and as existing surgeon customers perform more Lapiplasty Procedures, though it may fluctuate from quarter to quarter due to a variety of factors, including seasonality and COVID-19 pandemic events.

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 includes costs for raw materials plus the markup for the assembly of the components. Cost of goods sold also includes royalties, allocated overhead for indirect labor, depreciation, 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, physician education programs, training, 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 these expenses 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

these expenses 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, though these expenses may fluctuate from quarter to quarter.

Interest and other income, net

Interest income and other income, net consists of interest received on our money market funds.

Interest Expense

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

Results of Operations

Comparison of the three and nine months ended September 30, 2022 and 2021

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

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2022	2021	Amount	%	2022	2021	Amount	%
Revenue	$ 33,055	$ 21,619	$ 11,436	52.9%	$ 92,069	$ 60,980	$ 31,089	51.0%
Cost of goods sold	6,624	4,248	2,376	55.9%	17,781	11,519	6,262	54.4%
Gross profit	26,431	17,371	9,060	52.2%	74,288	49,461	24,827	50.2%
Operating expenses								
Sales and marketing	25,034	15,984	9,050	56.6%	73,207	42,142	31,065	73.7%
Research and development	3,799	2,537	1,262	49.7%	9,835	6,827	3,008	44.1%
General and administrative	8,916	4,310	4,606	106.9%	22,593	11,405	11,188	98.1%
Total operating expenses	37,749	22,831	14,918	65.3%	105,635	60,374	45,261	75.0%
Loss from operations	(11,318)	(5,460)	(5,858)	107.3%	(31,347)	(10,913)	(20,434)	187.2%
Interest and other income, net	375	5	370	*	514	12	502	*
Interest expense	(1,190)	(963)	(227)	23.6%	(3,087)	(3,032)	(55)	1.8%
Debt extinguishment loss	—	—	—	*	(4,483)	—	(4,483)	*
Other expense, net	(815)	(958)	143	(14.9%)	(7,056)	(3,020)	(4,036)	133.6%
Net loss and comprehensive loss	$ (12,133)	$ (6,418)	$ (5,715)	89.0%	$ (38,403)	$ (13,933)	$ (24,470)	175.6%

* Not meaningful

Comparison of the three months ended September 30, 2022 and 2021

Revenue. Revenue increased by $11.4 million, or 52.9%, for the three months ended September 30, 2022 as compared to the same period in 2021. The increase in revenue was primarily due to an increased number of Lapiplasty Procedure Kits sold as the result of an expanded surgeon customer base, and to a slightly higher blended average sales price from a product mix shift due to increased adoption of our newer technologies and selling more ancillary products.

Cost of Goods Sold, Gross Profit and Gross Margin. Cost of goods sold increased by $2.4 million, or 55.9%, for the three months ended September 30, 2022 as compared to the same period in 2021. The increase in cost of goods sold was primarily due to a $1.3 million increase in direct costs of goods sold and a $0.5 million increase in royalty expense resulting from our increased sales, a $0.3 million increase in overhead expenses resulting from increased headcount, and a $0.3 million increase in depreciation expense from our surgical instruments. During the three months ended September 30, 2022, gross profit increased by $9.1 million, or 52.2%, as compared to the same period in 2021 due to increased sales. Gross profit margin for the three months ended September 30, 2022 decreased from 80.4% to 80.0%, as compared to the same period of 2021, primarily due to an increase in allocations of payroll and related expenses, and an increase in capitalized surgical instruments depreciation partially offset by a decrease in royalty expense in relation to products sold in the quarter and lower inventory and obsolescence provisions.

Sales and Marketing Expenses. Sales and marketing expenses increased by $9.1 million, or 56.6%, for the three months ended September 30, 2022 as compared to the same period in 2021. Sales and marketing expenses increased as a result of an increase of $5.7 million in payroll and related expenses resulting from increased headcount of sales personnel, a $0.7 million increase in advertising and marketing-related expenses primarily due to higher advertising fees, an increase of $1.8 million in professional services primarily for higher commissions from increased sales by our direct sales representatives and independent sales agencies, and $0.7 million in other marketing-related expenses resulting from increased sales efforts. These increases in sales and marketing expenses were as a result of our ongoing investment in our direct sales force and our patient focused outreach and education campaigns.

Research and Development Expenses. R&D expenses increased by $1.3 million, or 49.7%, for the three months ended September 30, 2022 as compared to the same period in 2021. The increase in R&D expenses was due to increases of $0.9 million in payroll and related costs resulting from increased headcount of research and development personnel, and an increase of $0.3 million in clinical expenses resulting primarily from increased purchases of materials used in our prototypes.

General and Administrative Expenses. General and administrative expenses increased by $4.6 million, or 106.9%, for the three months ended September 30, 2022 as compared to the same period in 2021. The increase in general and administrative expenses was primarily due to an increase of $2.6 million in payroll and related costs as we increased headcount to support our growing business, an increase of $0.5 million in rent expense and occupancy costs related to moving into our new headquarters' building during the quarter, and an increase of $1.1 million in professional services primarily related to legal and IT expenses related to conversion to a new service provider.

Interest and other income, net. Interest and other income, net increased $0.4 million. The increase is due to a significant increase in money market fund interest rates during the current period.

Interest Expense. Interest expense increased by $0.2 million, or 23.6%, for the three months ended September 30, 2022 as compared to the same period of 2021. The increase in interest expense was due to higher debt balances slightly offset by lower interest rates in the three months ended September 30, 2022, as compared to the same period of 2021, as a result of the debt refinancing in the second quarter of this year.

Comparison of the nine months ended September 30, 2022 and 2021

Revenue. Revenue increased by $31.1 million, or 51.0%, for the nine months ended September 30, 2022 as compared to the same period of 2021. The increase in revenue was primarily due to an increased number of Lapiplasty Procedure Kits sold as the result of an expanded surgeon customer base, and to a slightly higher blended average sales price from a product mix shift due to increased adoption of our newer technologies and selling more ancillary products.

Cost of Goods Sold, Gross Profit and Gross Margin. Cost of goods sold increased by $6.3 million, or 54.4%, for the nine months ended September 30, 2022 as compared to the same period in 2021. The increase in cost of goods sold was primarily due to $3.6 million increase in direct costs of goods sold resulting from increased sales, $1.6 million increase in royalty expense resulting from our increased sales, $0.8 million increase in depreciation expense from our surgical instruments, and $0.7 million increase in overhead expenses resulting from increase in our headcount offset by $0.4 million decrease in provision for inventory and instrument obsolescence. During the nine months ended September 30, 2022, our gross profit increased by $24.8 million, or 50.2%, as compared to the same period of 2021 due to increased sales. Gross profit margin for the nine months ended September 30, 2022 decreased from 81.1% to 80.7%, as compared to the same period of 2021, primarily due to an increase in depreciation expense from an increase in capitalized surgical instruments, an increase in allocations of payroll and related costs partially offset by a decrease in inventory and obsolescence provisions.

Sales and Marketing Expenses. Sales and marketing expenses increased by $31.1 million, or 73.7%, for the nine months ended September 30, 2022 as compared to the same period in 2021. Sales and marketing expenses increased by $15.1 million in payroll and related expenses from increased headcount of sales personnel, $7.8 million in advertising and marketing-related expenses primarily due to higher advertising fees and a new television commercial campaign, $6.3 million in professional services primarily for higher commissions from increased sales by our direct sales representatives and independent sales agencies, and $1.7 million in other marketing-related expenses resulting from increased sales efforts. These increases in sales and marketing expense were as a result of our ongoing investment in our direct sales force and our patient focused outreach and education campaigns.

Research and Development Expenses. R&D expenses increased by $3.0 million, or 44.1%, for the nine months ended September 30, 2022 as compared to the same period in 2021. The increase in R&D expenses was due to $2.2 million in payroll and related costs resulting from increased headcount of research and development personnel, $0.8 million in clinical expenses resulting from primarily increased purchases of materials used in our prototypes.

General and Administrative Expenses. General and administrative expenses increased by $11.2 million, or 98.1%, for the nine months ended September 30, 2022 as compared to the same period in 2021. The increase in general and administrative expenses was primarily due to increases of $5.4 million in payroll and related costs as we increased headcount to support the growing business, a $2.0 million in business-related expenses primarily resulting from increased insurance costs and fees, $2.4 million in professional services primarily related to legal and audit fees, and expenses related to IT optimization that included a new service provider, $1.4 million in rent expense and occupancy costs related to moving into our new headquarters.

Interest Income and other, net. Interest and other income, net increased $0.5 million. The increase is primarily due to an increase in money market fund interest rates during the current period.

Interest Expense. Interest expense decreased by $0.1 million, or 1.8%, for the nine months ended September 30, 2022 as compared to the same period of 2021. The decrease in interest expense was due to significantly lower interest rates on higher debt balances during the nine months ended September 30, 2022 as compared to the same period of 2021 as a result of the debt refinancing in second quarter of this year.

Debt Extinguishment Loss. Debt extinguishment loss increased by $4.5 million, for the nine months ended September 30, 2022 as compared to the same period of 2021 due to our debt refinancing during the second quarter of this year.

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, comprising up to $120.0 million in term loans and $30.0 million in a revolving credit facility with entities affiliated with MidCap. On the closing date in April 2022, we borrowed $50.0 million under the term loan and $4.0 million under the revolving credit facility. The term loan proceeds were partly used to repay our term loan facility obligation with CRG and an early termination fee to 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 credit facility.

As of September 30, 2022, we had cash and cash equivalents of $88.5 million, an accumulated deficit of $80.3 million, and the $54 million principal outstanding under the term and revolving loans with MidCap. We believe that our existing cash and cash equivalents, 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 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. From time to time, 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 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 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;
- 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 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; and
- the impact of the COVID-19 pandemic, hospital staffing shortages, inflation, interest rate changes, and other general economic conditions on our operations and business.

Based upon our current operating plan, we believe that our existing cash and cash equivalents, 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 period presented below (in thousands):

	Nine Months Ended September 30,	
	2022	2021
Net cash (used in) provided by:		
Operating activities	$ (25,290)	$ (13,441)
Investing activities	(12,506)	(1,805)
Financing activities	20,509	106,626
Net (decrease) increase in cash and cash equivalents	$ (17,287)	$ 91,380

Net Cash Used in Operating Activities

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

Net cash used in operating activities for the nine months ended September 30, 2021 was $13.4 million, consisting primarily of a net loss of $13.9 million, adjusted for non-cash charges of $2.7 million and an increase of $2.2 million in net operating assets. The non-cash charges primarily consisted of share-based compensation expense of $2.1 million and depreciation and amortization expense of $0.4 million. The increase in net operating assets was primarily due to an increase in inventory during third quarter for higher expected fourth quarter sales and an increase in prepaid expense and other current assets offset by a decrease of $2.7 million in accounts receivable resulting from higher receivables from fourth quarter 2020 sales and increase 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 $12.5 million for the nine months ended September 30, 2022, consisting primarily of $7.2 million of leasehold improvements and furniture and equipment for our new headquarters' building and $3.6 million for purchases of capitalized surgical instruments for our reusable instrument trays.

Net cash used in investing activities was $1.8 million for the nine months ended September 30, 2021, 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 $20.5 million for the nine months ended September 30, 2022, consisting of $53.5 million of net cash proceeds from the new term loan agreement and revolving credit facility with MidCap and $1.9 million from exercise of stock options offset by the $33.9 million repayment of the CRG term loan and $1 million of debt issuance costs paid to third parties.

Net cash provided in financing activities was $106.6 million for the nine months ended September 30, 2021, consisting primarily of net cash proceeds of $107.6 million from the issuance of shares of common stock, net of $10.6 million in issuance costs, upon completion of our IPO on April 27, 2021, offset by the repayment of our PPP loan from the Small Business Administration of $1.8 million in March 2021 and proceeds from exercise of stock options of $0.8 million.

Surgeon Advisory Board Royalty Agreements

We recognized royalty expense of $1.6 million and $1.1 million for the three months ended September 30, 2022 and 2021, respectively, and $4.3 million and $2.8 million for the nine months ended September 30, 2022 and 2021, respectively. For the three months ended September 30, 2022 and 2021, the aggregate royalty rate was 4.8% and 5.3%, respectively. For the nine months ended September 30, 2022 and 2021, the aggregate royalty rate was 4.7% and 4.5%, 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 $30.3 million under these leases as of September 30, 2022.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our condensed financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these condensed financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

Our critical accounting policies and estimates are described in "Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies and Estimates" in our Annual Report. There had been no material changes to these accounting policies during the nine months ended September 30, 2022.

Recently Issued Accounting Pronouncements

Refer to Note 3, "Recent Accounting Pronouncements", to our condensed financial statements included elsewhere in this Quarterly Report for new accounting pronouncements not yet adopted as of the date of this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

The primary objectives of our investment activities are to preserve principal and provide liquidity. The risk associated with fluctuating interest rates is primarily limited to our cash equivalents, which are carried at quoted market prices. Since our results of operations are not dependent on investments, the risk associated with fluctuating interest rates is limited to our investment portfolio, and we believe that a hypothetical 10% change in interest rates would not have a significant impact on our condensed financial statements included elsewhere in this Quarterly Report. As of September 30, 2022, our investments consisted only of low-yield overnight sweep investments. We do not currently use or plan to use financial derivatives in our investment portfolio.

Foreign Currency Risk

Our business is conducted in U.S. dollars. We do not currently maintain a program to hedge exposures to non-U.S. dollar currencies. Any transactions that may be conducted in foreign currencies are not expected to have a material effect on our results of operations, financial position or cash flows.

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, have evaluated 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 are 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 Rule 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 from 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.

As of the date of this Quarterly Report, there have been no material changes from the risk factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 4, 2022. Any of these factors could result in a significant or material adverse effect on our result of operations or financial conditions. Additional risk factors not presently known to us or that we currently deem immaterial may also impair our business or results of operations. We may disclose changes to such factors or disclose additional factors from time to time in our future filings with the SEC.

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

(a) Sales of Unregistered Securities

None.

(b) Use of Proceeds from Public Offering of Common Stock

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 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 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).

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
10.1	Amendment No. 1 dated October 5, 2022 to Credit and Security Agreement (Revolving Loan) dated as of April 29, 2022,by and among Treace Medical Concepts, Inc. and Midcap Funding IV Trust.
10.2	Amendment No. 1 dated October 5, 2022 to Credit and Security Agreement (Term Loan) dated as of April 29, 2022 by and among Treace Medical Concepts, Inc. and Midcap Financial Trust.
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1†	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2†	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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

SIGNATURES

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

Treace Medical Concepts, Inc.

Date: November 9, 2022

By: /s/ John T. Treace

Name: John T. Treace

Title: Chief Executive Officer and Director (Principal Executive Officer)

Date: November 9, 2022

By: /s/ Mark L. Hair

Name: Mark L. Hair

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

Exhibit 10.1

Execution Version

AMENDMENT NO. 1 TO CREDIT AND SECURITY AGREEMENT (REVOLVING LOAN)

This AMENDMENT NO. 1 TO CREDIT AND SECURITY AGREEMENT (REVOLVING LOAN) (this "**Agreement**") is made as of October 5, 2022, by and among TREACE MEDICAL CONCEPTS, INC., a Delaware corporation ("**Borrower**"), MidCap Funding IV Trust, a Delaware statutory trust, as Agent (in such capacity, together with its successors and assigns, "**Agent**") and the other financial institutions or other entities from time to time parties to the Credit Agreement referenced below, each as a Lender.

RECITALS

A. Agent, Lenders, and Borrower have entered into that certain Credit and Security Agreement (Revolving Loan), dated as of April 29, 2022 (the "**Original Credit Agreement**" and as amended hereby and as it may be further amended, modified, supplemented and restated from time to time, the "**Credit Agreement**"), pursuant to which the Lenders have agreed to make certain advances of money and to extend certain financial accommodations to Borrower in the amounts and manner set forth in the Credit Agreement.

B. Borrower has requested, and Agent and all Lenders have agreed, to amend certain provisions of the Original Credit Agreement, all in accordance with the terms and subject to the conditions set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing, the terms and conditions set forth in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Agent, Lenders and Borrower hereby agree as follows:

1. **Recitals**. This Agreement shall constitute a Financing Document and the Recitals and each reference to the Credit Agreement, unless otherwise expressly noted, will be deemed to reference the Credit Agreement as amended hereby. The Recitals set forth above shall be construed as part of this Agreement as if set forth fully in the body of this Agreement and capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Credit Agreement (including those capitalized terms used in the Recitals hereto).

2. **Amendment to Original Credit Agreement**. Subject to the terms and conditions of this Agreement, including, without limitation, the conditions to effectiveness set forth in Section 4 below, Section 1.1 of the Original Credit Agreement is hereby amended by deleting the definition of "Cash Equivalents" in its entirety and restating it to read as follows:

> ""**Cash Equivalents**" means, as of any date of determination, any of the following: (a) marketable securities (i) issued or directly and unconditionally guaranteed as to interest and principal by the United States government, or (ii) issued by any agency of the United States the obligations of which are backed by the full faith and credit of the United States, in each case maturing within twenty five (25) months after such date; (b) marketable direct obligations issued by any state of the United States or any political subdivision of any such state or any public instrumentality thereof, in each

case maturing within twenty five (25) months after such date and having, at the time of the acquisition thereof, a rating of at least A-1 from S&P or at least P-1 from Moody's; (c) commercial paper maturing no more than twenty five (25) months from the date of creation thereof and having, at the time of the acquisition thereof, a rating of at least A-1 from S&P or at least P-1 from Moody's, or carrying an equivalent rating by a nationally recognized rating agency, if both of the two named rating agencies cease publishing ratings of commercial paper issuers generally; (d) certificates of deposit or bankers' acceptances maturing within twenty five (25) months after such date and issued or accepted by any Lender or by any commercial bank organized under the laws of the United States or any state thereof or the District of Columbia that (i) is at least "adequately capitalized" (as defined in the regulations of its primary federal banking regulator), and (ii) has Tier 1 capital (as defined in such regulations) of not less than $100,000,000; (e) shares of any money market mutual fund that (i) has substantially all of its assets invested continuously in the types of investments referred to in clauses (a) and (b) above, (ii) has net assets of not less than $500,000,000, and (iii) has the highest rating obtainable from either S&P or Moody's; (f) corporate bonds rated at least BBB+ from S&P or at least Baa1 from Moody's with a remaining maturity of twenty five (25) months or less or an estimated life of less than two years; (g) non-agency asset-backed securities rated AAA from S&P or Aaa from Moody's with an estimated life of less than 1.08 years; and (h) debt investments as described in (a), (b), (d), (f) and (g) above with a floating interest rate and a remaining maturity of two-years or less or an estimated life of less than two years. The average maturity of the aggregate of all Cash Equivalents shall not be greater than twelve (12) months."

3. **Representations and Warranties; Reaffirmation of Security Interest.** Borrower hereby confirms that all of the representations and warranties set forth in the Credit Agreement are true and correct in all material respects (without duplication of any materiality qualifier in the text of such representation or warranty) with respect to Borrower as of the date hereof except to the extent that any such representation or warranty relates to a specific date in which case such representation or warranty shall be true and correct as of such earlier date. Nothing herein is intended to impair or limit the validity, priority or extent of Agent's security interests in and Liens on the Collateral. Borrower acknowledges and agrees that the Credit Agreement, the other Financing Documents and this Agreement constitute the legal, valid and binding obligation of Borrower, and are enforceable against Borrower in accordance with its terms, except as the enforceability thereof may be limited by bankruptcy, insolvency or other similar laws relating to the enforcement of creditors' rights generally and by general equitable principles.

4. **Conditions to Effectiveness.** This Agreement shall become effective as of the date on which each of the following conditions have been satisfied, as determined by Agent in its sole discretion:

(a) Borrower shall have delivered to Agent this Agreement executed by an authorized officer of Borrower;

(b) all representations and warranties of Borrower contained herein shall be true and correct in all material respects (without duplication of any materiality qualifier in the text of such representation or warranty) as of the date hereof except to the extent that any such representation or warranty relates to a specific date in which case such representation or warranty shall be true and correct as of such earlier date (and such parties' delivery of their respective signatures hereto shall be deemed to be its certification thereof); and

(c) prior to and after giving effect to the agreements set forth herein, no Default or Event of Default shall exist under any of the Financing Documents.

5. **Costs and Fees**. Borrower agrees to promptly pay, or reimburse upon demand for, all reasonable and documented out-of-pocket costs and expenses of Agent (including, without limitation, the reasonable and documented fees, costs and expenses of counsel to Agent) in connection with the

preparation, negotiation, execution and delivery of this Agreement and any other Financing Documents or other agreements prepared, negotiated, executed or delivered in connection with this Agreement.

6. **Release**. In consideration of the agreements of Agent and Lenders contained herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Borrower, voluntarily, knowingly, unconditionally and irrevocably, with specific and express intent, for and on behalf of itself and all of its respective predecessors, successors, and assigns, and each of its respective current and former directors, officers, shareholders, agents, and employees, and each of its respective predecessors, successors, heirs, and assigns (individually and collectively, the "**Releasing Parties**") does hereby fully and completely release, acquit and forever discharge each of Agent, Lenders, and each of their respective parents, subsidiaries, affiliates, members, managers, shareholders, directors, officers and employees, and each of their respective predecessors, successors, heirs, and assigns (individually and collectively, the "**Released Parties**"), of and from any and all actions, causes of action, suits, debts, disputes, damages, claims, obligations, liabilities, costs, expenses and demands of any kind whatsoever, at law or in equity, whether matured or unmatured, liquidated or unliquidated, vested or contingent, choate or inchoate, known or unknown that the Releasing Parties (or any of them) has against the Released Parties or any of them (whether directly or indirectly), based in whole or in part on facts, whether or not now known, existing on or before the date hereof, that relate to, arise out of or otherwise are in connection with: (i) any or all of the Financing Documents or transactions contemplated thereby or any actions or omissions in connection therewith or (ii) any aspect of the dealings or relationships between or among Borrower, on the one hand, and any or all of the Released Parties, on the other hand, relating to any or all of the documents, transactions, actions or omissions referenced in clause (i) hereof. Borrower acknowledges that the foregoing release is a material inducement to Agent's and each Lender's decision to enter into this Agreement and agree to the modifications contemplated hereunder, and has been relied upon by Agent and the Lenders in connection therewith.

7. **No Waiver or Novation.** The execution, delivery and effectiveness of this Agreement shall not, except as expressly provided in this Agreement, operate as a waiver of any right, power or remedy of Agent, nor constitute a waiver of any provision of the Credit Agreement, the Financing Documents or any other documents, instruments and agreements executed or delivered in connection with any of the foregoing. Nothing herein is intended or shall be construed as a waiver of any existing Defaults or Events of Default under the Credit Agreement or the other Financing Documents or any of Agent's rights and remedies in respect of such Defaults or Events of Default. This Agreement (together with any other document executed in connection herewith) is not intended to be, nor shall it be construed as, a novation of the Credit Agreement.

8. **Affirmation.** Except as specifically amended pursuant to the terms hereof, Borrower hereby acknowledges and agrees that the Credit Agreement and all other Financing Documents (and all covenants, terms, conditions and agreements therein) shall remain in full force and effect, and are hereby ratified and confirmed in all respects by Borrower. Borrower covenants and agrees to comply with all of the terms, covenants and conditions of the Credit Agreement and the Financing Documents, notwithstanding any prior course of conduct, waivers, releases or other actions or inactions on Agent's or any Lender's part which might otherwise constitute or be construed as a waiver of or amendment to such terms, covenants and conditions.

9. **Miscellaneous**.

(a) Reference to the Effect on the Credit Agreement. Upon the effectiveness of this Agreement, each reference in the Credit Agreement to "this Agreement," "hereunder," "hereof," "herein," or words of similar import shall mean and be a reference to the Credit Agreement, as amended by this Agreement. Except as specifically amended above, the Credit Agreement, and all other Financing

Documents (and all covenants, terms, conditions and agreements therein), shall remain in full force and effect, and are hereby ratified and confirmed in all respects by Borrower.

(b) Governing Law. THIS AGREEMENT AND ALL DISPUTES AND OTHER MATTERS RELATING HERETO OR ARISING THEREFROM (WHETHER SOUNDING IN CONTRACT LAW, TORT LAW OR OTHERWISE), SHALL BE GOVERNED BY, AND SHALL BE CONSTRUED AND ENFORCED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK, WITHOUT REGARD TO CONFLICTS OF LAWS PRINCIPLES (OTHER THAN SECTION 5-1401 OF THE GENERAL OBLIGATIONS LAW).

(c) Incorporation of Credit Agreement Provisions. The provisions contained in Section 11.6 (Indemnification), Section 12.8(b) (Submission to Jurisdiction) and Section 12.9 (Waiver of Jury Trial) of the Credit Agreement are incorporated herein by reference to the same extent as if reproduced herein in their entirety.

(d) Headings. Section headings in this Agreement are included for convenience of reference only and shall not constitute a part of this Agreement for any other purpose.

(e) Counterparts. This Agreement may be signed in any number of counterparts, each of which shall be deemed an original and all of which when taken together shall constitute one and the same instrument. Signatures by facsimile or by electronic mail delivery of an electronic version of any executed signature page shall bind the parties hereto.

(f) Entire Agreement. This Agreement constitutes the entire agreement and understanding among the parties hereto and supersedes any and all prior agreements and understandings, oral or written, relating to the subject matter hereof.

(g) Severability. In case any provision of or obligation under this Agreement shall be invalid, illegal or unenforceable in any applicable jurisdiction, the validity, legality and enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdiction, shall not in any way be affected or impaired thereby.

(h) Successors/Assigns. This Agreement shall bind, and the rights hereunder shall inure to, the respective successors and assigns of the parties hereto, subject to the provisions of the Credit Agreement and the other Financing Documents.

[SIGNATURES APPEAR ON FOLLOWING PAGES]

IN WITNESS WHEREOF, intending to be legally bound, and intending that this document constitute an agreement executed under seal, the undersigned have executed this Agreement under seal as of the day and year first hereinabove set forth.

AGENT: MIDCAP FUNDING IV TRUST,
as Agent

By: Apollo Capital Management, L.P.,
its investment manager

By: Apollo Capital Management GP, LLC,
its general partner

By: /s/ Maurice Amsellem
Name: Maurice Amsellem
Title: Authorized Signatory

[Signatures Continue on Following Page]

LENDER:

MIDCAP FUNDING IV TRUST

By: Apollo Capital Management, L.P.,
its investment manager

By: Apollo Capital Management GP, LLC,
its general partner

By: ___/s/ Maurice Amsellem_____
Name: Maurice Amsellem
Title: Authorized Signatory

[Signatures Continue on Following Page]

LENDER:

MIDCAP FINANCIAL INVESTMENT CORPORATION
(formerly known as Apollo Investment Corporation)

By:____/s/ Kristin Hester_____
Name: Kristin Hester
Title: Chief Legal Officer

[Signatures Continue on Following Page]

LENDER: **APOLLO DEBT SOLUTIONS BDC**

By: /s/ Kristin Hester
Name: Kristin Hester
Title: Chief Legal Officer

[Signatures Continue on Following Page]

BORROWER:

TREACE MEDICAL CONCEPTS, INC.

By: /s/ Mark L. Hair
Name Mark L. Hair
Title: Chief Financial Officer

[End of Signature Pages]

Exhibit 10.2

Execution Version

AMENDMENT NO. 1 TO CREDIT AND SECURITY AGREEMENT (TERM LOAN)

This AMENDMENT NO. 1 TO CREDIT AND SECURITY AGREEMENT (TERM LOAN) (this "**Agreement**") is made as of October 5, 2022, by and among TREACE MEDICAL CONCEPTS, INC., a Delaware corporation ("**Borrower**"), MidCap Financial Trust, a Delaware statutory trust, as Agent (in such capacity, together with its successors and assigns, "**Agent**") and the other financial institutions or other entities from time to time parties to the Credit Agreement referenced below, each as a Lender.

RECITALS

A. Agent, Lenders, and Borrower have entered into that certain Credit and Security Agreement (Term Loan), dated as of April 29, 2022 (the "**Original Credit Agreement**" and as amended hereby and as it may be further amended, modified, supplemented and restated from time to time, the "**Credit Agreement**"), pursuant to which the Lenders have agreed to make certain advances of money and to extend certain financial accommodations to Borrower in the amounts and manner set forth in the Credit Agreement.

B. Borrower has requested, and Agent and all Lenders have agreed, to amend certain provisions of the Original Credit Agreement, all in accordance with the terms and subject to the conditions set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing, the terms and conditions set forth in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Agent, Lenders and Borrower hereby agree as follows:

1. **Recitals**. This Agreement shall constitute a Financing Document and the Recitals and each reference to the Credit Agreement, unless otherwise expressly noted, will be deemed to reference the Credit Agreement as amended hereby. The Recitals set forth above shall be construed as part of this Agreement as if set forth fully in the body of this Agreement and capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Credit Agreement (including those capitalized terms used in the Recitals hereto).

2. **Amendment to Original Credit Agreement**. Subject to the terms and conditions of this Agreement, including, without limitation, the conditions to effectiveness set forth in Section 4 below, Section 1.1 of the Original Credit Agreement is hereby amended by deleting the definition of "Cash Equivalents" in its entirety and restating it to read as follows:

> ""**Cash Equivalents**" means, as of any date of determination, any of the following: (a) marketable securities (i) issued or directly and unconditionally guaranteed as to interest and principal by the United States government, or (ii) issued by any agency of the United States the obligations of which are backed by the full faith and credit of the United States, in each case maturing within twenty five (25) months after such date; (b) marketable direct obligations issued by any state of the United States or any political subdivision of any such state or any public instrumentality thereof, in each

case maturing within twenty five (25) months after such date and having, at the time of the acquisition thereof, a rating of at least A-1 from S&P or at least P-1 from Moody's; (c) commercial paper maturing no more than twenty five (25) months from the date of creation thereof and having, at the time of the acquisition thereof, a rating of at least A-1 from S&P or at least P-1 from Moody's, or carrying an equivalent rating by a nationally recognized rating agency, if both of the two named rating agencies cease publishing ratings of commercial paper issuers generally; (d) certificates of deposit or bankers' acceptances maturing within twenty five (25) months after such date and issued or accepted by any Lender or by any commercial bank organized under the laws of the United States or any state thereof or the District of Columbia that (i) is at least "adequately capitalized" (as defined in the regulations of its primary federal banking regulator), and (ii) has Tier 1 capital (as defined in such regulations) of not less than $100,000,000; (e) shares of any money market mutual fund that (i) has substantially all of its assets invested continuously in the types of investments referred to in clauses (a) and (b) above, (ii) has net assets of not less than $500,000,000, and (iii) has the highest rating obtainable from either S&P or Moody's; (f) corporate bonds rated at least BBB+ from S&P or at least Baa1 from Moody's with a remaining maturity of twenty five (25) months or less or an estimated life of less than two years; (g) non-agency asset-backed securities rated AAA from S&P or Aaa from Moody's with an estimated life of less than 1.08 years; and (h) debt investments as described in (a), (b), (d), (f) and (g) above with a floating interest rate and a remaining maturity of two-years or less or an estimated life of less than two years. The average maturity of the aggregate of all Cash Equivalents shall not be greater than twelve (12) months."

3. **Representations and Warranties; Reaffirmation of Security Interest.** Borrower hereby confirms that all of the representations and warranties set forth in the Credit Agreement are true and correct in all material respects (without duplication of any materiality qualifier in the text of such representation or warranty) with respect to Borrower as of the date hereof except to the extent that any such representation or warranty relates to a specific date in which case such representation or warranty shall be true and correct as of such earlier date. Nothing herein is intended to impair or limit the validity, priority or extent of Agent's security interests in and Liens on the Collateral. Borrower acknowledges and agrees that the Credit Agreement, the other Financing Documents and this Agreement constitute the legal, valid and binding obligation of Borrower, and are enforceable against Borrower in accordance with its terms, except as the enforceability thereof may be limited by bankruptcy, insolvency or other similar laws relating to the enforcement of creditors' rights generally and by general equitable principles.

4. **Conditions to Effectiveness.** This Agreement shall become effective as of the date on which each of the following conditions have been satisfied, as determined by Agent in its sole discretion:

(a) Borrower shall have delivered to Agent this Agreement executed by an authorized officer of Borrower;

(b) all representations and warranties of Borrower contained herein shall be true and correct in all material respects (without duplication of any materiality qualifier in the text of such representation or warranty) as of the date hereof except to the extent that any such representation or warranty relates to a specific date in which case such representation or warranty shall be true and correct as of such earlier date (and such parties' delivery of their respective signatures hereto shall be deemed to be its certification thereof); and

(c) prior to and after giving effect to the agreements set forth herein, no Default or Event of Default shall exist under any of the Financing Documents.

5. **Costs and Fees**. Borrower agrees to promptly pay, or reimburse upon demand for, all reasonable and documented out-of-pocket costs and expenses of Agent (including, without limitation, the reasonable and documented fees, costs and expenses of counsel to Agent) in connection with the

preparation, negotiation, execution and delivery of this Agreement and any other Financing Documents or other agreements prepared, negotiated, executed or delivered in connection with this Agreement.

6. **Release**. In consideration of the agreements of Agent and Lenders contained herein and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Borrower, voluntarily, knowingly, unconditionally and irrevocably, with specific and express intent, for and on behalf of itself and all of its respective predecessors, successors, and assigns, and each of its respective current and former directors, officers, shareholders, agents, and employees, and each of its respective predecessors, successors, heirs, and assigns (individually and collectively, the "**Releasing Parties**") does hereby fully and completely release, acquit and forever discharge each of Agent, Lenders, and each of their respective parents, subsidiaries, affiliates, members, managers, shareholders, directors, officers and employees, and each of their respective predecessors, successors, heirs, and assigns (individually and collectively, the "**Released Parties**"), of and from any and all actions, causes of action, suits, debts, disputes, damages, claims, obligations, liabilities, costs, expenses and demands of any kind whatsoever, at law or in equity, whether matured or unmatured, liquidated or unliquidated, vested or contingent, choate or inchoate, known or unknown that the Releasing Parties (or any of them) has against the Released Parties or any of them (whether directly or indirectly), based in whole or in part on facts, whether or not now known, existing on or before the date hereof, that relate to, arise out of or otherwise are in connection with: (i) any or all of the Financing Documents or transactions contemplated thereby or any actions or omissions in connection therewith or (ii) any aspect of the dealings or relationships between or among Borrower, on the one hand, and any or all of the Released Parties, on the other hand, relating to any or all of the documents, transactions, actions or omissions referenced in clause (i) hereof. Borrower acknowledges that the foregoing release is a material inducement to Agent's and each Lender's decision to enter into this Agreement and agree to the modifications contemplated hereunder, and has been relied upon by Agent and the Lenders in connection therewith.

7. **No Waiver or Novation.** The execution, delivery and effectiveness of this Agreement shall not, except as expressly provided in this Agreement, operate as a waiver of any right, power or remedy of Agent, nor constitute a waiver of any provision of the Credit Agreement, the Financing Documents or any other documents, instruments and agreements executed or delivered in connection with any of the foregoing. Nothing herein is intended or shall be construed as a waiver of any existing Defaults or Events of Default under the Credit Agreement or the other Financing Documents or any of Agent's rights and remedies in respect of such Defaults or Events of Default. This Agreement (together with any other document executed in connection herewith) is not intended to be, nor shall it be construed as, a novation of the Credit Agreement.

8. **Affirmation.** Except as specifically amended pursuant to the terms hereof, Borrower hereby acknowledges and agrees that the Credit Agreement and all other Financing Documents (and all covenants, terms, conditions and agreements therein) shall remain in full force and effect, and are hereby ratified and confirmed in all respects by Borrower. Borrower covenants and agrees to comply with all of the terms, covenants and conditions of the Credit Agreement and the Financing Documents, notwithstanding any prior course of conduct, waivers, releases or other actions or inactions on Agent's or any Lender's part which might otherwise constitute or be construed as a waiver of or amendment to such terms, covenants and conditions.

9. **Miscellaneous**.

(a) Reference to the Effect on the Credit Agreement. Upon the effectiveness of this Agreement, each reference in the Credit Agreement to "this Agreement," "hereunder," "hereof," "herein," or words of similar import shall mean and be a reference to the Credit Agreement, as amended by this Agreement. Except as specifically amended above, the Credit Agreement, and all other Financing

Documents (and all covenants, terms, conditions and agreements therein), shall remain in full force and effect, and are hereby ratified and confirmed in all respects by Borrower.

(b) Governing Law. THIS AGREEMENT AND ALL DISPUTES AND OTHER MATTERS RELATING HERETO OR ARISING THEREFROM (WHETHER SOUNDING IN CONTRACT LAW, TORT LAW OR OTHERWISE), SHALL BE GOVERNED BY, AND SHALL BE CONSTRUED AND ENFORCED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK, WITHOUT REGARD TO CONFLICTS OF LAWS PRINCIPLES (OTHER THAN SECTION 5-1401 OF THE GENERAL OBLIGATIONS LAW).

(c) Incorporation of Credit Agreement Provisions. The provisions contained in Section 11.6 (Indemnification), Section 12.8(b) (Submission to Jurisdiction) and Section 12.9 (Waiver of Jury Trial) of the Credit Agreement are incorporated herein by reference to the same extent as if reproduced herein in their entirety.

(d) Headings. Section headings in this Agreement are included for convenience of reference only and shall not constitute a part of this Agreement for any other purpose.

(e) Counterparts. This Agreement may be signed in any number of counterparts, each of which shall be deemed an original and all of which when taken together shall constitute one and the same instrument. Signatures by facsimile or by electronic mail delivery of an electronic version of any executed signature page shall bind the parties hereto.

(f) Entire Agreement. This Agreement constitutes the entire agreement and understanding among the parties hereto and supersedes any and all prior agreements and understandings, oral or written, relating to the subject matter hereof.

(g) Severability. In case any provision of or obligation under this Agreement shall be invalid, illegal or unenforceable in any applicable jurisdiction, the validity, legality and enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdiction, shall not in any way be affected or impaired thereby.

(h) Successors/Assigns. This Agreement shall bind, and the rights hereunder shall inure to, the respective successors and assigns of the parties hereto, subject to the provisions of the Credit Agreement and the other Financing Documents.

[SIGNATURES APPEAR ON FOLLOWING PAGES]

IN WITNESS WHEREOF, intending to be legally bound, and intending that this document constitute an agreement executed under seal, the undersigned have executed this Agreement under seal as of the day and year first hereinabove set forth.

AGENT: MIDCAP FINANCIAL TRUST,
as Agent

By: Apollo Capital Management, L.P.,
its investment manager

By: Apollo Capital Management GP, LLC,
its general partner

By:___/s/ Maurice Amsellem_____
Name: Maurice Amsellem
Title: Authorized Signatory

[Signatures Continue on Following Page]

LENDER: **MIDCAP FUNDING XIII TRUST**,
as Agent

By: Apollo Capital Management, L.P.,
its investment manager

By: Apollo Capital Management GP, LLC,
its general partner

By:____/s/ Maurice Amsellem_____
Name: Maurice Amsellem
Title: Authorized Signatory

[Signatures Continue on Following Page]

LENDERS:

ELM 2020-3 TRUST

By: MidCap Financial Services Capital Management, LLC, as Servicer

By: /s/ John O'Dea
Name: John O'Dea
Title: Authorized Signatory

ELM 2020-4 TRUST

By: MidCap Financial Services Capital Management, LLC, as Servicer

By: /s/ John O'Dea
Name: John O'Dea
Title: Authorized Signatory

[Signatures Continue on Following Page]

LENDER:

MIDCAP FINANCIAL INVESTMENT CORPORATION
(formerly known as Apollo Investment Corporation)

By: /s/ Kristin Hester
Name: Kristin Hester
Title: Chief Legal Officer

[Signatures Continue on Following Page]

LENDER: **APOLLO DEBT SOLUTIONS BDC**

By: /s/ Kristin Hester
Name: Kristin Hester
Title: Chief Legal Officer

[Signatures Continue on Following Page]

BORROWER:

TREACE MEDICAL CONCEPTS, INC.

By: /s/ Mark L. Hair
Name Mark L. Hair
Title: Chief Financial Officer

[End of Signature Pages]

Exhibit 31.1

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

I, John T. Treace, certify that:

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

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

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

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

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

    (b) [Reserved];

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

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

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

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

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

Date: November 9, 2022

By: /s/ John T. Treace

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

Exhibit 31.2

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

I, Mark L. Hair, certify that:

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

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

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

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

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

    (b) [Reserved];

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

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

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

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

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

Date: November 9, 2022

By: /s/ Mark L. Hair

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

Exhibit 32.1

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

In connection with the Quarterly Report of Treace Medical Concepts, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 9, 2022

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

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Exhibit 32.2

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

In connection with the Quarterly Report of Treace Medical Concepts, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: November 9, 2022 By: /s/ Mark L. Hair

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