**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, 2024**

**or**

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

**For the transition period from___ to___**

**Commission file number: 001-40355**

# Treace Medical Concepts, Inc.

*(Exact name of registrant as specified in its charter)*

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

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

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

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

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

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

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

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

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

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

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

As of October 31, 2024, 62,297,078 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, 2024**

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

As used in this Quarterly Report on Form 10-Q ("Quarterly Report"), unless expressly indicated or the context otherwise requires, references to "Treace Medical Concepts," "we," "us," "our," or the "Company," refer to Treace Medical Concepts, Inc. This Quarterly Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as codified in Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act") concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "slated," "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 anticipated future product launches and the timing and market acceptance of such product launches;
- the extensive competition in our industry and new product introductions from other industry participants, both in the Lapidus market and the minimally invasive osteotomy market;
- our ability to effectively respond to and mitigate the impact of challenges in the current market environment, including in response to increased competition;
- the impact of surgical facility restrictions on elective procedures in response to recent hurricane-related shortages of IV fluids and other products used in bunion corrective surgeries;
- the anticipated pace of growth in the foot and ankle market and our ability to increase our market share;
- our ability to control and reduce expenses to help offset changes in revenue growth rates and other events;
- our plans and expected timeline related to our products, or developing or acquiring new products, to address additional indications or otherwise;
- our ability to maintain sufficient balance sheet strength and flexibility to continue executing on our strategic investments and growth initiatives for the foreseeable future;
- expected seasonality;
- our expectations regarding government and third-party payor coverage and reimbursement;
- the economic success and viability of the hospitals, ambulatory surgery centers and other health care facilities and surgeons that use our products;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our need for, or ability to obtain, additional financing or refinance outstanding debt;
- our expected uses of our existing cash, cash equivalents and marketable securities and the sufficiency of such resources to fund our planned operations;
- the impact on our operations, business, supply chain, patient demand for elective surgeries, and hospital and surgeon availability as a result of natural or other disasters, including hurricanes such as the recent Hurricane Helene, floods, tornadoes and other climate-related events, power loss, strikes or other events beyond our control;
- our ability to retain and recruit key personnel and optimize our existing sales and marketing infrastructure;
- our ability to obtain an adequate supply of materials and components for our products, some of which are single-source suppliers;
- our ability to obtain and maintain intellectual property protection for our products;

- our ability to protect and enforce our intellectual property, and the time and expense involved in monitoring unauthorized uses of our intellectual property, including in connection with the lawsuit we initiated in October 2024;
- our ability to successfully defend against infringement of our intellectual property by third parties, including our competitors;
- our ability to accurately forecast our future results of operations and financial goals or targets, including as a result of fluctuations in demand for our products and increased competition;
- our ability to realize the anticipated benefits of our acquisitions, including the acquisition of MIOS Marketing, LLC d/b/a RedPoint Medical3D ("RPM-3D") assets, as rapidly or to the extent anticipated, if at all;
- our ability to obtain, maintain and expand regulatory clearances for our products and any new products we develop or acquire;
- our ability to expand our business in current and new geographic markets;
- our compliance with Nasdaq requirements and government laws, rules and regulations;
- the impact of inflationary pressures, interest rate changes, and general economic conditions on our business;
- the impact of geopolitical tensions and international conflicts on the economy and our business;
- the impact of a bankruptcy filing by any of our customers;
- our plans to conduct further clinical studies;
- the impact of failures, defaults or instability of financial institutions where we have cash accounts; and
- the effect of any infectious disease outbreak and its impact or potential impact on our business or on the healthcare industry, particularly elective surgeries where our products are used.

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 many of which are 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 for the year ended December 31, 2023 and any subsequent Quarterly Reports on Form 10-Q filed with the U.S. Securities and Exchange Commission ("SEC"), and this Quarterly Report under "Risk Factors" and elsewhere in this Quarterly Report. Readers 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. If we update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

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

## PART I—FINANCIAL INFORMATION

**Item 1. Condensed Financial Statements.**

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

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| **Assets** | | |
| Current assets | | |
| Cash and cash equivalents | $ 12,110 | $ 12,982 |
| Marketable securities, short-term | 70,689 | 110,216 |
| Accounts receivable, net of allowance for credit losses of $743 and $980 as of September 30, 2024 and December 31, 2023, respectively | 24,177 | 38,063 |
| Inventories | 43,611 | 29,245 |
| Prepaid expenses and other current assets | 7,015 | 7,853 |
| Total current assets | 157,602 | 198,359 |
| Property and equipment, net | 25,168 | 22,298 |
| Intangible assets, net of accumulated amortization of $1,188 and $475 as of September 30, 2024 and December 31, 2023, respectively | 8,312 | 9,025 |
| Goodwill | 12,815 | 12,815 |
| Operating lease right-of-use assets | 8,569 | 9,264 |
| Other non-current assets | 458 | 146 |
| Total assets | $ 212,924 | $ 251,907 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities | | |
| Accounts payable | $ 18,649 | $ 11,835 |
| Accrued liabilities | 8,098 | 10,458 |
| Accrued commissions | 5,347 | 10,759 |
| Accrued compensation | 5,598 | 7,549 |
| Other liabilities | 571 | 4,432 |
| Total current liabilities | 38,263 | 45,033 |
| Long-term debt, net of discount of $769 and $992 as of September 30, 2024 and December 31, 2023, respectively | 53,231 | 53,008 |
| Operating lease liabilities, net of current portion | 16,487 | 15,891 |
| Other long-term liabilities | 37 | 37 |
| Total liabilities | 108,018 | 113,969 |
| Commitments and contingencies (Note 7) | | |
| Stockholders' equity | | |
| Preferred stock, $0.001 par value, 5,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 0 shares issued and outstanding as of September 30, 2024 and December 31, 2023 | — | — |
| Common stock, $0.001 par value, 300,000,000 shares authorized; 62,294,975 and 61,749,654 issued, and 62,275,371 and 61,749,654 outstanding as of September 30, 2024 and December 31, 2023, respectively | 62 | 62 |
| Additional paid-in capital | 294,392 | 271,973 |
| Accumulated deficit | (189,489) | (134,247) |
| Accumulated other comprehensive (loss) income | 191 | 163 |
| Treasury stock, at cost; 19,604 and 1,218 shares as of September 30, 2024 and December 31, 2023, respectively | (250) | (13) |
| Total stockholders' equity | 104,906 | 137,938 |
| Total liabilities and stockholders' equity | $ 212,924 | $ 251,907 |

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

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| Revenue | $ 45,086 | $ 40,758 | $ 140,649 | $ 124,906 |
| Cost of goods sold | 8,954 | 7,998 | 27,862 | 23,712 |
| Gross profit | 36,132 | 32,760 | 112,787 | 101,194 |
| Operating expenses | | | | |
| Sales and marketing | 32,775 | 33,542 | 110,784 | 100,970 |
| Research and development | 4,963 | 4,350 | 15,379 | 11,288 |
| General and administrative | 13,528 | 12,686 | 42,108 | 33,582 |
| Total operating expenses | 51,266 | 50,578 | 168,271 | 145,840 |
| Loss from operations | (15,134) | (17,818) | (55,484) | (44,646) |
| Interest income | 1,067 | 1,570 | 3,978 | 5,017 |
| Interest expense | (1,313) | (1,296) | (3,942) | (3,863) |
| Other income, net | 20 | 23 | 206 | 246 |
| Other non-operating income (expense), net | (226) | 297 | 242 | 1,400 |
| Net loss | $ (15,360) | $ (17,521) | $ (55,242) | $ (43,246) |
| | | | | |
| Other comprehensive income (loss) | | | | |
| Unrealized gain (loss) on marketable securities | 217 | 71 | 28 | (121) |
| Comprehensive loss | $ (15,143) | $ (17,450) | $ (55,214) | $ (43,367) |
| | | | | |
| Net loss per share, basic and diluted | $ (0.25) | $ (0.28) | $ (0.89) | $ (0.71) |
| Weighted-average shares used in computing net loss per share, basic and diluted | 62,229,463 | 61,562,494 | 62,035,293 | 60,566,655 |

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

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

| | Common Stock | | Additional Paid-In Capital | Accumulated Deficit | Accumulated Other Comprehensive Income (Loss) | Treasury Stock | Total Stockholders' Equity |
|---|---|---|---|---|---|---|---|
| | Outstanding Shares | Amount | | | | | |
| **Balances at December 31, 2023** | 61,749,654 | $ 62 | $ 271,973 | $ (134,247) | $ 163 | $ (13) | $ 137,938 |
| Issuance of common stock upon exercise of stock options | 20,294 | — | 52 | — | — | — | 52 |
| Issuance of common stock for vesting of restricted stock units | 177,610 | — | — | — | — | — | — |
| Share-based compensation expense | — | — | 7,408 | — | — | — | 7,408 |
| Net loss | — | — | — | (18,676) | — | — | (18,676) |
| Unrealized loss on available-for-sale marketable securities | — | — | — | — | (94) | — | (94) |
| Shares directly withheld from employees for tax payment | (18,386) | — | — | — | — | (237) | (237) |
| **Balances at March 31, 2024** | 61,929,172 | $ 62 | $ 279,433 | $ (152,923) | $ 69 | $ (250) | $ 126,391 |
| Issuance of common stock upon exercise of stock options | 209,288 | — | 311 | — | — | — | 311 |
| Issuance of common stock for vesting of restricted stock units | 36,781 | — | — | — | — | — | — |
| Share-based compensation expense | — | — | 6,740 | — | — | — | 6,740 |
| Net loss | — | — | — | (21,206) | — | — | (21,206) |
| Unrealized loss on available-for-sale marketable securities | — | — | — | — | (95) | — | (95) |
| **Balances at June 30, 2024** | 62,175,241 | $ 62 | $ 286,484 | $ (174,129) | $ (26) | $ (250) | $ 112,141 |
| Issuance of common stock upon exercise of stock options | 35,371 | — | 8 | — | — | — | 8 |
| Issuance of common stock for vesting of restricted stock units | 64,759 | — | — | — | — | — | — |
| Share-based compensation expense | — | — | 7,900 | — | — | — | 7,900 |
| Net loss | — | — | — | (15,360) | — | — | (15,360) |
| Unrealized gain on available-for-sale marketable securities | — | — | — | — | 217 | — | 217 |
| **Balances at September 30, 2024** | 62,275,371 | $ 62 | $ 294,392 | $ (189,489) | $ 191 | $ (250) | $ 104,906 |
| | | | | | | | |
| **Balances at December 31, 2022** | 55,628,208 | $ 55 | $ 145,221 | $ (84,720) | $ (27) | $ — | $ 60,529 |
| Issuance of common stock upon exercise of stock options | 125,890 | — | 352 | — | — | — | 352 |
| Issuance of common stock for vesting of restricted stock units | 50,415 | — | — | — | — | — | — |
| Share-based compensation expense | — | — | 2,692 | — | — | — | 2,692 |
| Issuance of common stock from public offering, net of issuance costs and underwriting discount of $7.5 million | 5,476,190 | 6 | 107,521 | — | — | — | 107,527 |
| Net loss | — | — | — | (13,454) | — | — | (13,454) |
| Unrealized loss on available-for-sale marketable securities | — | — | — | — | (29) | — | (29) |
| **Balances at March 31, 2023** | 61,280,703 | $ 61 | $ 255,786 | $ (98,174) | $ (56) | $ — | $ 157,617 |
| Issuance of common stock upon exercise of stock options | 205,244 | 1 | 1,179 | — | — | — | 1,180 |
| Issuance of common stock for vesting of restricted stock units | 42,462 | — | — | — | — | — | — |
| Share-based compensation expense | — | — | 3,596 | — | — | — | 3,596 |
| Net loss | — | — | — | (12,271) | — | — | (12,271) |
| Unrealized loss on available-for-sale marketable securities | — | — | — | — | (163) | — | (163) |
| **Balances at June 30, 2023** | 61,528,409 | $ 62 | $ 260,561 | $ (110,445) | $ (219) | $ — | $ 149,959 |
| Issuance of common stock upon exercise of stock options | 46,001 | — | 159 | — | — | — | 159 |
| Issuance of common stock for vesting of restricted stock units | 32,516 | — | — | — | — | — | — |
| Share-based compensation expense | — | — | 5,192 | — | — | — | 5,192 |
| Net loss | — | — | — | (17,521) | — | — | (17,521) |
| Unrealized gain on available-for-sale marketable securities | — | — | — | — | 71 | — | 71 |
| **Balances at September 30, 2023** | 61,606,926 | $ 62 | $ 265,912 | $ (127,966) | $ (148) | $ — | $ 137,860 |

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

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2024 | 2023 |
| **Cash flows from operating activities** | | |
| Net loss | $ (55,242) | $ (43,246) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Depreciation and amortization expense | 6,182 | 3,583 |
| Provision for allowance for credit losses | 2,381 | 79 |
| Share-based compensation expense | 22,048 | 11,480 |
| Non-cash lease expense | 607 | 1,868 |
| Amortization of debt issuance costs | 223 | 223 |
| Accretion (amortization) of discount (premium) on marketable securities, net | (918) | (1,031) |
| Other, net | 180 | 164 |
| Net changes in operating assets and liabilities, net of acquisitions | | |
| Accounts receivable | 11,505 | 4,121 |
| Inventory | (14,366) | (9,915) |
| Prepaid expenses and other assets | 838 | (1,028) |
| Other non-current assets | (312) | — |
| Operating lease liabilities | (147) | 497 |
| Accounts payable | 6,814 | 12 |
| Accrued liabilities | (12,753) | (1,954) |
| Other, net | — | 40 |
| Net cash provided by (used in) operating activities | (32,960) | (35,107) |
| **Cash flows from investing activities** | | |
| Purchases of available-for-sale marketable securities | (52,890) | (140,075) |
| Sales and maturities of available-for-sale marketable securities | 93,363 | 82,979 |
| Purchases of property and equipment | (8,519) | (9,210) |
| Acquisition, net of cash acquired | — | (20,000) |
| Net cash provided by (used in) investing activities | 31,954 | (86,306) |
| **Cash flows from financing activities** | | |
| Proceeds from issuance of common stock from public offering, net of issuance costs and underwriting discount of $7.5 million | — | 107,527 |
| Proceeds from exercise of employee stock options | 371 | 1,691 |
| Taxes from withheld shares | (237) | — |
| Net cash provided by (used in) financing activities | 134 | 109,218 |
| Net increase (decrease) in cash and cash equivalents | (872) | (12,195) |
| Cash and cash equivalents at beginning of period | 12,982 | 19,473 |
| Cash and cash equivalents at end of period | $ 12,110 | $ 7,278 |
| **Supplemental disclosure of cash flow information** | | |
| Cash paid for interest | $ 3,732 | $ 3,863 |
| Operating lease right-of-use asset and lease liability adjustment due to lease incentive | $ 88 | $ (22) |
| **Noncash investing activities** | | |
| Unrealized (gains) losses, net on marketable securities | $ (28) | $ 121 |
| Unsettled marketable security purchase and payable to broker | $ — | $ (1,100) |
| Unsettled matured marketable security and receivable from broker | $ — | $ 6,000 |

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

**TREACE MEDICAL CONCEPTS, INC.**
**Notes to Condensed Financial Statements**
**(unaudited)**

## 1. Formation and Business of the Company

### *The Company*

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

### *Initial Public Offering and Follow-on Offering*

On April 27, 2021, the Company completed its initial public offering ("IPO"). The Company received net proceeds of $107.6 million from the IPO. On February 10, 2023, the Company completed a follow-on offering that resulted in net proceeds of $107.5 million.

### *Acquisition of RedPoint Medical3D*

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

The Company paid $20.0 million in exchange for certain assets used in providing pre-operative planning and patient-specific guides for the surgical correction of foot and ankle deformities and agreed to make additional payments upon completion of certain milestones. The original terms are as follows: $3.5 million upon completion of certain transition services at 12 months from the closing date, $3.5 million upon completion of certain technological advancements milestone within 12 months of the closing date, and, subject to prior completion of the transition services and the technological advancements milestone, up to $3.0 million upon the issuance of certain patent claims. Payments made for the transition services and patent claims require satisfaction of such milestones, as well as the continued service of key individuals.

In the first quarter of 2024, the Company and RPM-3D evaluated the status of the three milestones and amended the original terms associated with the milestone payments. The maximum amount to be paid upon the achievement of the milestone payments has been reduced from $10.0 million to $8.1 million and is subject to successful completion of the transition services milestone at the first anniversary date of the acquisition. Upon successful completion of the transition services milestone, the payments were scheduled as follows: $6.0 million on July 15, 2024 ($3.5 million for the transition services milestone and $2.5 million for the technological advancements milestone) and $2.1 million on January 15, 2025 ($1.0 million for the technological advancements milestone and $1.1 million for the patent milestone). No milestone payments would have been made if the transition services milestone was not achieved by the acquisition anniversary date. The Company paid RPM-3D $6.0 million on July 15, 2024 upon completion of the transition services milestone.

## 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 ("SEC") 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, 2023, filed with the SEC on

February 27, 2024. The 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, 2024 are not necessarily indicative of the results that may be expected for future quarters or for the fiscal year ending December 31, 2024.

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 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 financial statements and the reported amounts of revenues and expenses during the reporting periods. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Significant estimates and assumptions include valuation of intangible assets and goodwill, reserves and write-downs related to accounts receivable, inventories, the recoverability of long-term assets, deferred tax assets and related valuation allowances, contingencies, and stock-based compensation. The Company had no accrued contingent liabilities as of September 30, 2024 and December 31, 2023.

***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to concentrations of risk consist principally of cash, cash equivalents, marketable securities, and accounts receivable. The Company maintains its cash with established financial institutions and, at times, such balances with any one financial institution may be in excess of the Federal Deposit Insurance Corporation ("FDIC") insured limits. The Company's available-for-sale securities portfolio primarily consists of U.S. treasury and agency securities, money market funds, commercial paper, Yankee CDs, high credit quality asset-backed securities and corporate debt securities. The Company's investment policy requires its available-for-sale securities to meet certain criteria including investment type, credit ratings, and a maximum portfolio duration of one year.

The Company earns revenue from the sale of its products to customers such as hospitals and ambulatory surgery centers. The Company's accounts receivable is derived from revenue earned from customers. On September 30, 2024 and December 31, 2023, no customer accounted for more than 10% of accounts receivable. For the nine months ended September 30, 2024 and 2023, there were no customers that represented 10% or more of revenue.

**3. Recent Accounting Pronouncements**

***Recent Accounting Pronouncements Not Yet Adopted***

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280) ("ASC 280")*. The update requires all public business entities to identify their reportable segments, including the basis of organization, types of products and services from which each reportable segment derives its revenues, and the title and position of the individual or the name of the group or committee identified as the chief operating decision maker ("CODM") and an explanation of how the CODM uses the reported measure(s) of segment profit or loss in assessing segment performance and deciding how to allocate resources. Public entities shall disclose on an annual and interim basis for each reportable segment including entities that only have one reportable segment, certain significant expense categories and amounts that are regularly provided to the CODM and included in reported segment profit or loss. ASC 280 is applied retrospectively to all prior periods presented in the financial statements. This new guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The Company is currently evaluating the impact of the new standard on its financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740) ("ASC 740")*. The update requires all public business entities on an annual basis to (1) disclose specific categories in the rate reconciliation and (2) provide additional information for reconciling items that meet a quantitative threshold and an explanation, if not otherwise evident, of the individual reconciling items disclosed, such as the nature, effect, and underlying causes of the reconciling items and the judgment used in categorizing the reconciling items. In addition, the update requires certain new disclosures of the amount of

income taxes paid (net of refunds received) disaggregated by federal, state, and foreign taxes and the amount of income taxes paid (net of refunds received) disaggregated by individual jurisdictions in which income taxes paid is equal to or greater than five percent of total income taxes paid (net of refunds received). Other new disclosures required include income (or loss) from continuing operations before income tax expense (or benefit) disaggregated between domestic and foreign and income tax expense (or benefit) from continuing operations disaggregated by federal, state, and foreign. The new guidance is effective for annual periods beginning after December 15, 2024. Early adoption is permitted. The amendments are to be applied on a prospective basis, with retrospective application permitted. The Company is currently evaluating the impact of the new standard on its financial statements and related 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, 2024 and December 31, 2023 (in thousands):

| | September 30, 2024 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Cash equivalents | | | | |
| Money market funds | $ 7,775 | $ — | $ — | $ 7,775 |
| Short-term marketable securities at fair value | | | | |
| U.S. treasury and government agencies | 10,635 | 1,000 | — | 11,635 |
| Corporate debt | — | 39,200 | — | 39,200 |
| Asset-backed securities | — | 16,698 | — | 16,698 |
| Yankee CD | — | 3,156 | — | 3,156 |
| Total assets | $ 18,410 | $ 60,054 | $ — | $ 78,464 |

| | December 31, 2023 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Cash and cash equivalents | | | | |
| Money market funds | $ 3,160 | $ — | $ — | $ 3,160 |
| Short-term marketable securities at fair value | | | | |
| U.S. treasury and government agencies | 14,005 | 15,364 | — | 29,369 |
| Commercial paper | — | 2,895 | — | 2,895 |
| Corporate debt | — | 46,586 | — | 46,586 |
| Asset-backed securities | — | 24,756 | — | 24,756 |
| Yankee CD | — | 6,610 | — | 6,610 |
| Total assets | $ 17,165 | $ 96,211 | $ — | $ 113,376 |
| | | | | |
| Liabilities: | | | | |
| Contingent consideration | $ — | $ — | $ 2,977 | $ 2,977 |
| Total liabilities | $ — | $ — | $ 2,977 | $ 2,977 |

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

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

| | | |
|---|---|---|
| Fair value as of December 31, 2023 | $ | 2,977 |
| Change in fair value prior to contract modification | | 53 |
| Reclassification of contingent consideration due to contract modification | | (3,030) |
| Fair value as of September 30, 2024 | $ | - |

Contingent consideration is included in other liabilities on the Condensed Balance Sheets. As of December 31, 2023, the balance was classified as current due to the timing of the expected payment. The change in fair value for the contingent consideration related to the technological advancements milestone payment was classified as research and development expense within the Condensed Statements of Operations and Comprehensive Loss.

During the first quarter of 2024, the Company renegotiated with RPM-3D the terms for payment of the technological advancements milestone that was initially accounted for as contingent consideration. The renegotiated contract specifies that the technological advancements milestone payment will not be paid unless the transition services milestone is achieved. The technological advancements milestone payment is now tied to the continued service of key individuals from the date of the new contract until the transition services milestone determination date (which is the first anniversary date of the acquisition). Therefore, the Company is no longer accounting for the technological advancements milestone payment as contingent consideration at fair value, but rather as research and development expense over the remaining service period. The Company expects to pay the full amount for the technological advancements milestone of $3.5 million, of which $2.5 million was paid on July 15, 2024 and the remaining $1.0 million will be paid on January 15, 2025. See Note 1, "Formation and Business of the Company" of the Notes to Condensed Financial Statements for additional information on the acquisition of RPM-3D.

There were no assets or liabilities measured at fair value on a nonrecurring basis as of September 30, 2024 and December 31, 2023.

**5. Balance Sheet Components**

***Cash and Cash Equivalents***

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

| | | September 30, 2024 | | December 31, 2023 |
|---|---|---|---|---|
| Cash | $ | 4,335 | $ | 9,822 |
| Cash equivalents: | | | | |
| Money market funds | | 7,775 | | 3,160 |
| Total cash and cash equivalents | $ | 12,110 | $ | 12,982 |

***Marketable Securities***

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

| | September 30, 2024 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
| Marketable securities - short-term | | | | |
| U.S. treasury and government agencies | $ 11,621 | $ 14 | $ — | $ 11,635 |
| Corporate debt | 39,074 | 126 | — | 39,200 |
| Asset-backed securities | 16,647 | 51 | — | 16,698 |
| Yankee CD | 3,156 | — | — | 3,156 |
| Total marketable securities - short-term | $ 70,498 | $ 191 | $ — | $ 70,689 |

| | December 31, 2023 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
| Marketable securities - short-term | | | | |
| U.S. treasury and government agencies | $ 29,377 | $ 8 | $ (16) | $ 29,369 |
| Commercial paper | 2,893 | 2 | — | 2,895 |
| Corporate debt | 46,467 | 123 | (4) | 46,586 |
| Asset-backed securities | 24,712 | 56 | (12) | 24,756 |
| Yankee CD | 6,604 | 7 | (1) | 6,610 |
| Total marketable securities - short-term | $ 110,053 | $ 196 | $ (33) | $ 110,216 |

As of September 30, 2024, there were no available-for-sale securities with unrealized losses greater than 12 months. There was not an allowance for credit losses required for available-for-sale securities as of September 30, 2024 and December 31, 2023.

As of September 30, 2024, the Company had no plans to sell securities with unrealized losses, and believes it is more likely than not that it would not be required to sell such securities before recovery of their amortized cost. For the three and nine months ended September 30, 2024 and 2023, there were no material gains or losses from sales of available-for-sale securities.

As of September 30, 2024 and December 31, 2023, accrued interest of $0.6 million and $1.1 million, respectively, is excluded from the amortized cost basis of available-for-sale securities in the tables above and is recorded in prepaid expenses and other current assets on the Condensed Balance Sheets.

As of September 30, 2024, all marketable securities mature within two years, except for asset-backed securities. Asset-backed securities are not due at a single maturity date. As such, these securities were not included.

***Property and equipment, net***

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

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Furniture and fixtures | $ 2,565 | $ 2,494 |
| Construction in progress | 686 | 1,115 |
| Machinery and equipment | 3,052 | 2,423 |
| Capitalized surgical equipment[1] | 20,878 | 14,253 |
| Computer equipment | 1,115 | 1,020 |
| Leasehold improvements | 10,244 | 9,425 |
| Software and website development | 682 | 316 |
| Total property and equipment | 39,222 | 31,046 |
| Less: accumulated depreciation and amortization | (14,054) | (8,748) |
| Property and equipment, net | $ 25,168 | $ 22,298 |

[1] Capitalized surgical equipment includes $16.6 million and $12.2 million that is ready for its intended use and have started depreciating and $4.3 million and $2.1 million that is not ready for its intended use and have not started depreciation as of September 30, 2024 and December 31, 2023, respectively.

Depreciation and amortization expense on property and equipment was $1.9 million and $1.4 million for the three months ended September 30, 2024 and 2023, respectively. Depreciation and amortization expense on property and equipment was $5.5 million and $3.4 million for the nine months ended September 30, 2024 and 2023, respectively.

The Company did not record impairment charges for its property and equipment, net for the nine months ended September 30, 2024 and 2023.

***Accrued liabilities***

Accrued liabilities consist of the following (in thousands):

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Accrued royalties expense | $ 1,568 | $ 2,305 |
| Accrued interest | 403 | 417 |
| Accrued professional services | 945 | 424 |
| Accrued compensation expense for RPM-3D earn-out | 2,125 | 3,340 |
| Other accrued expense | 3,057 | 3,972 |
| Total accrued liabilities | $ 8,098 | $ 10,458 |

***Other liabilities***

Other liabilities consist of the following (in thousands):

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Current portion of operating lease liabilities | $ 403 | $ 1,404 |
| Contingent consideration | — | 2,977 |
| Other | 168 | 51 |
| Total other liabilities | $ 571 | $ 4,432 |

Due to renegotiated terms, the Company is no longer classifying the technological advancements milestone as contingent consideration. See discussion of RPM-3D renegotiation in Note 4, "Fair Value Measurements" of the Notes to Condensed Financial Statements.

**6. Long-Term Debt**

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

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| *Revolving line of credit* | | |
| MidCap revolving loan facility | $ 4,000 | $ 4,000 |
| *Term loans* | | |
| MidCap term loan facility | 50,000 | 50,000 |
| Total term and revolving loans | 54,000 | 54,000 |
| Less: debt discount and issuance costs | (769) | (992) |
| Total long-term debt, net | $ 53,231 | $ 53,008 |

As of September 30, 2024, future payments of long-term debt were as follows (in thousands):

| Fiscal Year | |
|---|---|
| 2024 | $ — |
| 2025 | — |
| 2026 | 33,333 |
| 2027 | 20,667 |
| Total principal payments | 54,000 |
| Less: Unamortized debt discount and debt issuance costs | (769) |
| Total long-term debt, net | $ 53,231 |

***MidCap Loan and Revolving Loan Facility***

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

The term loan facility provides for a 60-month term loan up to $120.0 million in borrowing capacity to the Company, over four tranches. At term loan closing, the Company drew $50.0 million under tranche one. At September 30, 2024, there is one tranche available for $20.0 million, subject to the achievement of certain revenue targets.

The revolving loan facility provides up to $30.0 million in borrowing capacity to the Company based on the borrowing base. The borrowing base is calculated based on certain accounts receivable and inventory assets. On September 30, 2024, the borrowing base allows a total of $16.7 million available to the Company under the revolving loan facility. The balance drawn as of September 30, 2024 is $4.0 million under the revolving loan facility. The Company may request an increase in the revolving loan facility up to $20.0 million for a total commitment of up to $50.0 million. The Company is required to either (i) maintain a minimum drawn balance under the revolving loan facility or (ii) pay a minimum balance fee that is equal to the amount of the minimum balance deficit multiplied by the applicable interest rate during the period. If the outstanding balance under the revolving loan facility exceeds the lesser of (i) 50% of the revolving borrowing capacity or (ii) 50% of the borrowing base, or the Company is in default, MidCap will apply funds collected from the Company's lockbox account to reduce the outstanding balance of the revolving loan facility ("Lockbox Deductions"). As of September 30, 2024, the Company's borrowing level has not activated the Lockbox Deductions, nor is it expected to for the next 12 months; therefore, the Company has determined that the revolving loan balance is long-term debt.

The loans bear interest at an annual rate based on a 30-day forward looking secured overnight financing rate plus 0.10% (subject to a floor of 1.0% and a cap of 3.0% for both loan agreements) plus (i) 6.0% under the term loan agreement and (ii) 4.0% under the revolving loan facility. Interest is payable monthly in arrears on the first day of each month and on the maturity of the loan agreements. The term loan and the revolving loan facility are accruing interest as of September 30, 2024 at the capped interest rates of 9% and 7%, respectively. The Company is obligated to pay interest only for the first 48 months and straight-line amortization for the remaining 12 months, subject to the Company's election to extend the initial interest-only period by 12 months to 60 months total if the Company's trailing twelve-month revenue is at or above certain levels. If the term loan is repaid before the maturity date or the revolving loan facility is terminated before the end of its term, the prepayment fees are 3.0% of the amount repaid in the first year, 2.0% in the second year and 1.0% in the third year and thereafter, and a final payment fee of 3.0% of the amount borrowed is due under the term loan. The revolving loan facility prepayment fees are based on the revolving loan commitment amount.

The loans are secured by substantially all of the Company's assets, including intellectual property. The loan agreements and other ancillary documents contain customary representations and warranties and affirmative and negative covenants. Under the loan agreements, the Company is not required to meet any minimum level of revenue if liquidity (defined as unrestricted cash plus undrawn availability under the revolving loan agreement) is greater than the outstanding balance under the term loan. If liquidity falls below such outstanding balance, then the Company is subject to a minimum trailing twelve-month revenue covenant. The Company is not subject to this covenant on September 30, 2024.

**7. Commitments and Contingencies**

***License and Royalty Commitments***

The Company has entered into product development and fee for service agreements with members of its Surgeon Advisory Board and other surgeon consultants that specify the terms under which the consultant is compensated for his or her consulting services and grants the Company rights to the intellectual property created by the consultant in the course of such services. As products are commercialized with the assistance of members of the Surgeon Advisory Board and other surgeon consultants, the Company may agree to enter into a royalty agreement if such consultant's contributions to the product are novel, significant and innovative. Each of the royalty agreements may be subsequently amended to add the license of additional intellectual property covering new products, and as a result, multiple royalty rates and duration of royalty payments may be included in one royalty agreement.

As of September 30, 2024 and 2023, the Company has royalty agreements with certain surgeon consultants. The Company recognized royalty expense of $1.4 million and $1.5 million for the three months ended September 30, 2024 and 2023, respectively, and $4.6 million and $4.7 million for the nine months ended September 30, 2024 and 2023, respectively. For the three months ended September 30, 2024 and 2023, the aggregate royalty rate was 3.2% and 3.8%, respectively. For the nine months ended September 30, 2024 and 2023, the aggregate royalty rate was 3.3% and 3.8%, 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, 2024 and December 31, 2023.

**8. Stockholders' Equity**

***Stock Options***

During the nine months ended September 30, 2024 and 2023, the Company granted stock options to employees to purchase 852,220 and 877,910 shares of the Company's common stock, respectively. The weighted-average grant-date fair value of the employee stock options granted during the nine months ended September 30, 2024 and 2023 was $4.96 and $10.42 per share, respectively.

***Restricted Stock Units***

During the nine months ended September 30, 2024 and 2023, the Company granted 3,370,462 and 870,326 restricted stock units ("RSUs"), respectively. The weighted average grant-date fair value of RSUs granted during the nine months ended September 30, 2024 and 2023 was $9.09 and $22.84, respectively.

***Performance Share Units***

The Company granted performance-based restricted stock unit ("PSU") awards in the first quarter of 2024 subject to market and service vesting conditions to certain executives under the Company's 2021 Incentive Award Plan. The actual number of PSUs that will vest at the end of the measurement period is determined based on the Company's total stockholder return ("TSR") ranking relative to the TSR of a published index of the Company's peers. The measurement period is three years. The grant date value of each target PSU award was determined using a Monte Carlo valuation model. Over the full three-year performance period, if the service vesting conditions are met, the actual number of PSUs earned may vary from zero, if performance thresholds are not met, to as much as 200% of target PSUs.

During the nine months ended September 30, 2024 and 2023, the Company granted performance stock units ("PSUs") for 453,375 and 509,600 shares, respectively, at target performance levels. The weighted average grant-date fair value of the PSUs granted during the nine months ended September 30, 2024 and 2023 was $18.89 and $30.90, respectively.

***Share-Based Compensation Expense***

Share-based compensation expense is reflected in operating expenses in the Condensed Statements of Operations and Comprehensive Loss as follows (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| Cost of goods sold | $ 91 | $ 63 | $ 272 | $ 192 |
| Sales and marketing expense | 1,764 | 1,202 | 5,052 | 3,087 |
| Research and development expense | 1,152 | 642 | 3,174 | 1,274 |
| General and administrative expense | 4,893 | 3,285 | 13,550 | 6,927 |
| Total | $ 7,900 | $ 5,192 | $ 22,048 | $ 11,480 |

**9. 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, 2024 and 2023, 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, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| Numerator | | | | |
| Net loss | $ (15,360) | $ (17,521) | $ (55,242) | $ (43,246) |
| Denominator | | | | |
| Weighted-average common stock outstanding, basic and diluted | 62,229,463 | 61,562,494 | 62,035,293 | 60,566,655 |
| Net loss per share attributable to common stockholders, basic and diluted | $ (0.25) | $ (0.28) | $ (0.89) | $ (0.71) |

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:

| | As of September 30, | |
|---|---|---|
| | 2024 | 2023 |
| Common stock options issued and outstanding | 7,793,815 | 7,542,275 |
| Unvested full value awards | 4,157,460 | 1,250,478 |
| Total | 11,951,275 | 8,792,753 |

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

*You should read the following discussion and analysis of our financial condition and results of operations together with our condensed financial statements and related notes thereto included in this Quarterly Report on Form 10-Q (this "Quarterly Report") and our audited financial statements and related notes thereto for the year ended December 31, 2023, included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC") on February 27, 2024 (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," and in the section titled "Risk Factors" and elsewhere in this Quarterly Report. Please also see the section of this Quarterly Report titled "Special Note Regarding Forward-Looking Statements."*

**Overview**

We are a medical technology company with the goal of advancing the standard of care for the surgical management of bunion and related midfoot deformities. We have pioneered our proprietary Lapiplasty 3D Bunion Correction System—a combination of instruments, implants and surgical methods designed to surgically correct all three planes of the bunion deformity and secure the unstable joint, addressing the root cause of the bunion and helping patients get back to their active lifestyles. Although bunions are deformities typically caused by an unstable joint in the middle of the foot that leads to a three-dimensional ("3D") misalignment in the foot's anatomical structure, the majority of traditional surgical approaches focus on correcting the deformity from a two-dimensional ("2D") perspective and therefore fail to address the root cause of the disorder. To effectively restore the normal anatomy of bunion patients and improve clinical outcomes, we believe addressing the root cause of the bunion is critical and have developed the Lapiplasty System to correct the deformity across all three anatomic dimensions. Our other products often used in conjunction with bunion surgery include the Adductoplasty System, the Hammertoe PEEK Fixation System, the SpeedPlate™ Rapid Compression Implant System, and specialized osteotomes and release instruments. In addition, we recently announced our entrance into the metatarsal osteotomy segment with the Nanoplasty™ Procedure, which allows for a 3D correction of the bunion through a cosmetically appealing, hidden incision on the side of the foot. With the Lapiplasty and Nanoplasty Procedures and other new products, we are continuing to execute our strategy of becoming a comprehensive bunion solutions company and supporting further penetration into the bunion market opportunity. See the Innovation and Growth section below for more information on our new products.

We were formed in 2013, and since receiving 510(k) clearance for the Lapiplasty System in March 2015, we have sold more than 100,000 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 and other products through a combination of a direct employee sales force and independent sales agencies across the United States.

As of September 30, 2024, we had cash and cash equivalents of $12.1 million and marketable securities of $70.7 million available for sale to fund operations, an accumulated deficit of $189.5 million and $54.0 million of principal outstanding under our term loan and revolving loan agreements.

**Economic Environment**

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

**Factors Affecting Our Business**

We believe that our financial performance has been and in the foreseeable future, will continue to depend on many factors, including the macro-economic conditions as described above, those noted in our Annual Report, in the section titled "Special

Note Regarding Forward-Looking Statements" and in the section titled "Risk Factors" and elsewhere in this Quarterly Report.

***Increased Competition***

Before we launched our flagship Lapiplasty system, there were no other products in the market that provided a 3D solution and specialized procedural instrumentation for these traditionally freehand, difficult Lapidus surgeries, which allowed us to capitalize on our pioneering technology and grow our market share quickly. We are experiencing increased competition from the accelerating adoption of minimally invasive osteotomy solutions and from new Lapidus products, which has, and may continue to, negatively impact our growth rates and market share.

***Innovation and Growth***

We expect to continue to focus on long-term revenue growth through investments in our business and new products. In sales and marketing, we have dedicated meaningful resources and believe that we have built a sales force and management team that can support our future growth as well as our patient focused outreach and education campaigns.

In research and development, our team and surgeon consultants are continually working on next-generation innovations for the surgical correction of bunions and other conditions that often present with bunions. In 2023, in addition to the acquisition of the assets of RPM-3D, we began the market release of (1) the SpeedPlate fixation platform, which can be used in the Lapiplasty and Adductoplasty Procedures, as well as other common bone fusion procedures of the foot, (2) the Hammertoe PEEK Fixation System designed to address hammertoe, claw toe and mallet toe deformities, which often present concomitantly with bunions, and (3) LapiTome and RazorTome Osteotomes, which are sterile, single-use instruments that are designed to facilitate more efficient removal and release of bone slices and soft tissue in Lapiplasty and Adductoplasty cases.

We expect to introduce new products on a steady cadence through 2025, including launching the limited market releases of the following new products during the fourth quarter of 2024 or soon thereafter: (1) the Nanoplasty™ system, a minimally invasive 3D osteotomy system, (2) IntelliGuide™ PSI Cut Guides for Lapiplasty and Adductoplasty procedures, which are cut guides created specifically for an individual patient’s foot anatomy, (3) expanded SpeedPlate configurations designed to address additional fusion procedures throughout the foot, (4) the Micro-Lapiplasty system, which is designed to allow the Lapiplasty Procedure to be performed through a minimally-invasive 2cm incision; and (5) the Mini-Adductoplasty System, which is designed to allow the Adductoplasty midfoot correction procedure to be performed through an approximately 50% smaller incision.

***Intellectual Property Strategy***

We actively seek to protect the technology, inventions, and improvements that we consider important to our business using patents, trade secrets, trademarks and copyrights in the United States and foreign markets. As of September 30. 2024, our patent portfolio included 65 granted U.S. patents, with an additional 24 granted patents worldwide and over 100 pending patent applications. In keeping with our strategy of protecting our intellectual property rights, on October 14, 2024, we filed a lawsuit against Stryker Corporation ("Stryker") and its subsidiary Wright Medical Technology, Inc. alleging infringement of 9 patents related to our innovative Lapiplasty® 3D Bunion Correction® technologies and unfair competition. The suit was filed in the United States District Court for the District of New Jersey, and seeks injunctive relief and damages.

***Adoption of the Lapiplasty System and other products***

The growth of our business depends on our ability to gain broader acceptance of the Lapiplasty System as well as our other existing products and the new systems that we intend to introduce by successfully marketing and distributing these products. While surgeon adoption of the Lapiplasty Procedure and our other products and procedures remains critical to supporting procedure growth, hospital and ambulatory surgery center facility approvals are necessary for both existing and future surgeon customers to access our products. To facilitate greater access to our products and support future sales growth, we intend to continue educating hospitals and facility administrators on the differentiated benefits associated with the Lapiplasty System as well as new systems we plan to introduce, supported by our robust portfolio of clinical data on our existing procedures and additional clinical data we expect to develop on our new products. If we are unable to successfully continue to commercialize our Lapiplasty System and to successfully introduce new products, we may not be able to generate sufficient revenue to achieve or sustain profitability. In the near term, we expect we will continue to operate at a loss, and we anticipate we will finance our operations principally through the use of our cash and cash equivalents, marketable securities, and expected revenues. We may also raise funds by incurring debt and through offerings of our capital stock.

***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 30% to 40% of full year revenues, and lower sales volumes in the subsequent first calendar quarter. Our sales volumes in the fourth quarter tend to be higher as many patients elect to have surgery after meeting their annual deductible and having time to recover over the winter holidays. Our sales volumes in subsequent first calendar quarters also tend to be lower versus the prior year fourth quarters as a result of adverse weather and by resetting annual patient healthcare insurance plan deductibles, both of which may cause patients to delay elective procedures; however, in some years the first quarter may benefit from additional sales volumes when high patient demand for surgeries in the fourth quarter cannot be fully accommodated and those surgical procedures are rolled over into the first quarter. Similar to the rest of the orthopaedic industry, we have experienced and expect to continue to experience lower sales volumes in the third quarter than throughout the rest of the year as elective procedures generally decline during the summer months.

***Coverage and Reimbursement***

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

Medicare payment rates to hospital outpatient departments are set under the Medicare hospital outpatient prospective payment system, which groups clinically similar hospital outpatient procedures and services with similar costs to ambulatory payment classifications ("APCs"). Each APC is assigned a single lump sum payment rate, which includes payment for the primary procedure as well as any integral, ancillary, and adjunctive services. The primary current procedure terminology ("CPT") codes for the Lapiplasty Procedure, CPT 28297 and CPT 28740, are grouped together under APC 5114. For Lapiplasty Procedures in which fusion is performed on multiple tarsometatarsal ("TMT") joints, CPT 28730 applies and is classified under APC 5115. For Adductoplasty Procedures in which fusion is performed on multiple TMT joints, either CPT 28730 or CPT 27835 applies and are classified under APC 5115.

**Components of Our Results of Operations**

***Revenue***

We currently generate revenue from the sale of our proprietary Lapiplasty System and the minimally invasive variations, Adductoplasty System, Hammertoe PEEK Fixation System, SpeedPlate Implant Fixation Platform, single use osteotomes and release instruments, and other ancillary products. These systems bring together single-use implant kits, reusable instrument trays, and surgical techniques. We sell the kits and single use instruments and other products to physicians, surgeons, hospitals and ambulatory surgery centers in the United States through a network of employee sales representatives and independent sales agencies.

No single customer accounted for 10% or more of our revenue during the nine months ended September 30, 2024. We expect our revenue to increase in absolute dollars in the foreseeable future as we expand our product offerings, sales territories, new accounts and trained physician base and as existing physician customers perform more Lapiplasty and other procedures using our products, though it may fluctuate from quarter to quarter due to a variety of factors, including seasonality, the macro-economic environment and competition.

***Cost of Goods Sold***

Cost of goods sold consists primarily of costs for the purchase of our products from third-party manufacturers. Direct costs from our third-party manufacturers include 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, certain direct costs such as those incurred for shipping our products, sterilization, packaging, and personnel costs. We expense all inventory provisions for excess, obsolete and field losses as cost of goods sold. We record adjustments to our inventory valuation for estimated excess, obsolete and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes and overall market conditions. We expect our cost of goods sold to increase in absolute dollars in the foreseeable future to the extent more of our products are sold, though it may fluctuate from quarter to quarter.

***Gross Profit and Gross Margin***

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

***Operating Expenses***

*Sales and Marketing*

Sales and marketing expenses consist primarily of compensation for personnel, including salaries, bonuses, benefits, sales commissions and share-based compensation, related to selling and marketing functions, surgical instrument expense, physician education programs, training, shipping costs related to sending products to our sales representatives, travel expenses, marketing initiatives including our direct-to-patient outreach program and advertising, market research and analysis and conferences and trade shows.

*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 other products, though it may fluctuate from quarter to quarter due to a variety of factors, including the level and timing of our new product development efforts, as well as our clinical development, clinical studies 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, legal and human resource functions, as well as professional services fees (including legal, audit and tax fees), insurance costs, general corporate expenses and allocated facilities-related expenses. We have the infrastructure and personnel in place to support the growth of our organization.

***Interest Income***

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

***Interest Expense***

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

**Results of Operations**

***Comparison of the three and nine months ended September 30, 2024 and 2023***

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 | |
|---|---|---|---|---|---|---|---|---|
| | 2024 | 2023 | Amount | % | 2024 | 2023 | Amount | % |
| Revenue | $ 45,086 | $ 40,758 | $ 4,328 | 10.6% | $ 140,649 | $ 124,906 | $ 15,743 | 12.6% |
| Cost of goods sold | 8,954 | 7,998 | 956 | 12.0% | 27,862 | 23,712 | 4,150 | 17.5% |
| Gross profit | 36,132 | 32,760 | 3,372 | 10.3% | 112,787 | 101,194 | 11,593 | 11.5% |
| Operating expenses | | | | | | | | |
| Sales and marketing | 32,775 | 33,542 | (767) | (2.3%) | 110,784 | 100,970 | 9,814 | 9.7% |
| Research and development | 4,963 | 4,350 | 613 | 14.1% | 15,379 | 11,288 | 4,091 | 36.2% |
| General and administrative | 13,528 | 12,686 | 842 | 6.6% | 42,108 | 33,582 | 8,526 | 25.4% |
| Total operating expenses | 51,266 | 50,578 | 688 | 1.4% | 168,271 | 145,840 | 22,431 | 15.4% |
| Loss from operations | (15,134) | (17,818) | 2,684 | (15.1%) | (55,484) | (44,646) | (10,838) | 24.3% |
| Interest income | 1,067 | 1,570 | (503) | (32.0%) | 3,978 | 5,017 | (1,039) | (20.7%) |
| Interest expense | (1,313) | (1,296) | (17) | 1.3% | (3,942) | (3,863) | (79) | 2.0% |
| Other income, net | 20 | 23 | (3) | (13.0%) | 206 | 246 | (40) | (16.3%) |
| Other non-operating income (expense), net | (226) | 297 | (523) | (176.1%) | 242 | 1,400 | (1,158) | (82.7)% |
| Net loss | $ (15,360) | $ (17,521) | $ 2,161 | (12.3%) | $ (55,242) | $ (43,246) | $ (11,996) | 27.7% |

*Comparison of the three months ended September 30, 2024 and 2023*

*Revenue.* Revenue increased by $4.3 million, or 10.6%, for the three months ended September 30, 2024 as compared to the same period in 2023. The increase was driven primarily by a product mix shift that resulted from increased adoption of newer technologies and increased sales of ancillary products used in bunion cases and an increase in active surgeons.

*Cost of Goods Sold, Gross Profit and Gross Margin.* Cost of goods sold increased by $1.0 million, or 12.0%, for the three months ended September 30, 2024 as compared to the same period in 2023. The increase in cost of goods sold was primarily due to a $0.6 million increase in direct costs of goods sold resulting from increased sales, a $0.3 million increase in inventory provisions, and a $0.2 million increase in allocations of payroll and related costs. During the three months ended September 30, 2024, gross profit increased by $3.4 million, or 10.3%, as compared to the same period in 2023, due to increased revenue from a product mix shift. Gross profit margin for the three months ended September 30, 2024 decreased from 80.4% to 80.1%, as compared to the same period in 2023, primarily due to increases in inventory provisions, a product mix shift to newer products, and allocations of payroll and related costs, partially offset by lower royalty rates.

*Sales and Marketing Expenses.* Sales and marketing expenses decreased by $0.8 million, or 2.3%, for the three months ended September 30, 2024 as compared to the same period in 2023. Sales and marketing expenses decreased due to $0.9 million lower advertising fees for direct to consumer campaigns, a $0.5 million decrease in surgeon training and clinical-related expenses, a $0.3 million decrease in professional services related to marketing, and a decrease of $0.3 million due to lower costs for conferences and events, partially offset by an increase of $0.6 million in commissions due to higher sales, an increase of $0.4 million in surgical instrument expense due to an increase in volume of surgical instruments, and $0.3 million in higher payroll and related expenses primarily from increased headcount of sales and marketing personnel, including stock compensation expense.

*Research and Development Expenses.* R&D expenses increased by $0.6 million, or 14.1%, for the three months ended September 30, 2024 as compared to the same period in 2023. The increase in R&D expenses was primarily due to a $1.1 million increase in payroll and related costs resulting from increased headcount of research and development personnel, including stock compensation expense, partially offset by a $0.4 million decrease in healthcare professional costs for R&D activities.

*General and Administrative Expenses.* General and administrative expenses increased by $0.8 million, or 6.6%, for the three months ended September 30, 2024 as compared to the same period in 2023. The increase in general and administrative expenses was due to $1.5 million in higher payroll and related cost, due to higher stock compensation expense, a $0.6 million increase in professional services primarily related to legal fees, and a $0.2 million increase in the provision for allowance for

credit losses partially offset by a decrease of $1.5 million in compensation expense related to the milestone obligations for our acquisition of RPM-3D that were fully expensed in the second quarter of 2024.

*Interest Income.* Interest income decreased $0.5 million, or 32.0%, during the three months ended September 30, 2024. The decrease in interest income was primarily due to lower balances invested in marketable securities during the current year period and slightly lower interest rates.

*Comparison of the nine months ended September 30, 2024 and 2023*

*Revenue.* Revenue increased by $15.7 million, or 12.6%, for the nine months ended September 30, 2024 as compared to the same period in 2023. The increase was driven primarily by a product mix shift that resulted from increased adoption of newer technologies and increased sales of ancillary products used in bunion cases and an increase in active surgeons.

*Cost of Goods Sold, Gross Profit and Gross Margin.* Cost of goods sold increased by $4.2 million, or 17.5%, for the nine months ended September 30, 2024 as compared to the same period in 2023. The increase in cost of goods sold was primarily due to a $3.0 million increase in direct costs of goods sold resulting from increased sales, a $0.7 million increase in allocations of payroll and related costs, and a $0.5 million increase in inventory provisions. During the nine months ended September 30, 2024, gross profit increased by $11.6 million, or 11.5%, as compared to the same period in 2023, due to increased sales. Gross profit margin for the nine months ended September 30, 2024 decreased from 81.0% to 80.2%, as compared to the same period in 2023, primarily due to a product mix shift to newer products, an increase in inventory provisions, and an increase in allocations of payroll and related costs, partially offset by lower royalty rates.

*Sales and Marketing Expenses.* Sales and marketing expenses increased by $9.8 million, or 9.7%, for the nine months ended September 30, 2024 as compared to the same period in 2023. Sales and marketing expenses increased due to $8.6 million in higher payroll and related expenses primarily from increased headcount of sales and marketing personnel, including stock compensation expense, an increase of $1.4 million in surgical instrument expense due to an increase in the volume of surgical instruments, a $1.1 million increase in commissions due to higher sales, and an increase of $0.5 million due to higher costs for conferences and events from an expanding sales force and surgeon base, partially offset by a decrease of $1.0 million in surgeon training and clinical-related costs and a decrease of $0.8 million in advertising fees for direct to consumer campaigns. Of the $8.6 million increase in payroll and related expenses, $0.9 million was related to a non-recurring restructuring charge that includes severance and other post-employment benefits.

*Research and Development Expenses.* R&D expenses increased by $4.1 million, or 36.2%, for the nine months ended September 30, 2024 as compared to the same period in 2023. The increase in R&D expenses was primarily due to a $3.8 million increase in payroll and related costs resulting from increased headcount of research and development personnel, including stock compensation expense, and a $0.4 million increase related to the technological advancements milestone obligation from our acquisition of RPM-3D.

*General and Administrative Expenses.* General and administrative expenses increased by $8.5 million, or 25.4%, for the nine months ended September 30, 2024 as compared to the same period in 2023. The increase in general and administrative expenses was primarily related to $6.2 million in higher payroll and related costs, due to higher stock compensation expense, a $2.3 million increase in the provision for allowance for credit losses that includes a $2.1 million write-off of receivables due from a customer that filed bankruptcy in the second quarter, and a $0.5 million increase in amortization of finite-lived intangible assets from our acquisition of RPM-3D, partially offset by a $0.5 million decrease in compensation expense related to the milestone obligations for our acquisition of RPM-3D that was fully expensed in the second quarter of 2024.

*Interest Income.* Interest income decreased $1.0 million, or 20.7%, during the nine months ended September 30, 2024. The decrease in interest income was primarily due to lower balances invested in marketable securities during the current year period and slightly lower interest rates.

**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. On February 10, 2023, we received net proceeds of $107.5 million from a follow-on public offering of our common stock.

As of September 30, 2024, we had cash and cash equivalents of $12.1 million and marketable securities of $70.7 million available for sale, an accumulated deficit of $189.5 million and $54.0 million principal outstanding under the term and revolving loans with MidCap. We believe that our existing cash and cash equivalents, marketable securities and available debt borrowings and expected revenues will be sufficient to meet our capital requirements and fund our operations for at least twelve months from the issuance of our condensed financial statements. We may be required or decide to raise additional debt or equity financing to support further growth of our operations.

***Funding Requirements***

We use our cash, marketable securities, and revenues to fund our operations, which primarily include the costs of manufacturing our Lapiplasty, Adductoplasty, SpeedPlate, and other products, as well as our sales and marketing, R&D, and general and administrative expenses. We expect R&D expenses to increase as we continue to hire personnel and invest in next-generation innovations of our existing products and new products. The timing and amount of our operating and capital expenditures will depend on many factors, including:

- the scope and timing of our investment in our commercial infrastructure and sales force;
- the costs of our ongoing commercialization activities including product sales, marketing, manufacturing, and distribution;
- the scope of our marketing efforts, including the degree to which we utilize direct to consumer campaigns;
- the degree and rate of market acceptance of the Lapiplasty System and our other products;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, including enforcing our intellectual property rights against infringing products or technologies or enforcing contractual rights against parties breaching agreements with us, including the litigation proceeding we initiated against Stryker;
- 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 other products, to commercialize PSI technologies, to gain share in the minimally invasive osteotomy market, 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;
- the effect of inflation, interest rate changes, and other general economic conditions on our operations and business;
- 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 any infectious disease outbreak or natural or other disaster or event beyond our control on our business or on the healthcare industry, particularly elective surgeries where our products are used.

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

insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets.

**Cash Flows**

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2024 | 2023 |
| Net cash (used in) provided by: | | |
| Operating activities | $ (32,960) | $ (35,107) |
| Investing activities | 31,954 | (86,306) |
| Financing activities | 134 | 109,218 |
| Net increase (decrease) in cash and cash equivalents | $ (872) | $ (12,195) |

***Cash Flows from Operating Activities***

Net cash used in operating activities for the nine months ended September 30, 2024 was $33.0 million, consisting primarily of a net loss of $55.2 million, adjusted for non-cash charges of $30.6 million and an increase in net operating assets. The non-cash charges consist primarily of share-based compensation expense of $22.0 million, depreciation and amortization expense of $6.2 million, and provision for allowance for credit losses of $2.4 million primarily due to a significant customer that filed for bankruptcy. The increase in net operating assets was primarily due to an increase of $14.4 million in inventories to meet demand for new products and a decrease of $12.8 million in accrued liabilities due to timing of payments, and an increase of $0.3 million in other non-current assets, partially offset by a $11.5 million decrease in accounts receivable from higher sales in the fourth quarter of 2023, an increase of $6.8 million in accounts payable due to timing of payments, and a $0.8 million decrease in prepaid expenses and other current assets.

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

***Cash Flows from Investing Activities***

Net cash provided by investing activities was $32.0 million for the nine months ended September 30, 2024, consisting primarily of $93.4 million in sales and maturities of available for sale marketable securities, partially offset by $52.9 million in purchases of available for sale marketable securities and $8.5 million in purchases of property and equipment. The net of marketable securities sales and maturities and purchases of $40.5 million were primarily used to fund our current operations. The purchases in property and equipment included $6.7 million in capitalized surgical instruments for the reusable instrument trays related to new products, and $1.8 million for equipment and leasehold improvements to support the growth of our business.

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

***Cash Flows from Financing Activities***

Net cash provided by financing activities was $0.1 million for the nine months ended September 30, 2024, consisting primarily of $0.4 million in proceeds from stock option exercises, partially offset by $0.2 million of shares repurchased for tax withholding on vested RSUs.

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

***Royalty Agreements***

We recognized royalty expense of $1.4 million and $1.5 million for the three months ended September 30, 2024 and 2023, respectively, and $4.6 million and $4.7 million for the nine months ended September 30, 2024 and 2023, respectively. For the three months ended September 30, 2024 and 2023, the aggregate royalty rate was 3.2% and 3.8%, respectively. For the nine months ended September 30, 2024 and 2023, the aggregate royalty rate was 3.3% and 3.8%, respectively. Each of the royalty agreements with our surgeon consultants 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 corporate headquarters office located in Ponte Vedra, Florida. We entered into a 10-year lease in February 2022 for our headquarters which expires in July 2032. Lease payments comprise the base rent plus operating costs which includes taxes, insurance, and common area maintenance. We also have commitments for future payments related to our former headquarters which expire in April 2026. We have obtained subleases for this space. The remaining lease obligations are $24.3 million under these leases as of September 30, 2024.

**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.

**Goodwill**

Our annual impairment testing date is July 1, 2024. We determined after performing the qualitative analysis that there was no evidence that it is more likely than not that the fair value of goodwill was less than the carrying amount. Therefore, it was not necessary to perform a quantitative impairment test. As of September 30, 2024 and December 31, 2023 goodwill was $12.8 million.

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, 2024.

**Recently Issued Accounting Pronouncements**

Refer to Note 3, "Recent Accounting Pronouncements" of the Notes to Condensed Financial Statements for new accounting pronouncements not yet adopted as of this Quarterly Report.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

**Market Risk**

Our primary market risk exposures are interest rate and credit risk.

*Interest Rate Risk*

The primary objectives of our investment activities are to preserve principal and provide liquidity. Since our investments may be used to fund operations, we performed sensitivity testing which measures the impact on the fair market value of the investments if a hypothetical 50 basis points increase and decrease in interest rates occurred. The interest rate risk analysis assumes using an immediate and parallel shift in interest rates.

The following table presents our estimate of the impact on fair value based on the scenario discussed above (in thousands):

| | September 30, 2024 | |
|---|---|---|
| | Change in fair value | |
| Fair value of marketable securities | Down 50 bps | Up 50 bps |
| $78,464 | $162 | ($165) |

Under our current outstanding debt terms, we do not have a risk to rising interest rates as the interest rates are capped at 9% for the term debt and 7% for the revolving loan facility. If a 194-basis point decrease in the 30-day forward looking secured overnight financing rate occurred, we would start to experience a reduction in our interest rate expense from current levels.

*Credit Risk*

We manage our credit risk within the available-for-sale securities portfolio by maintaining a well-diversified investment portfolio that limits the investments to certain types of investments, such as U.S. Treasury and agency securities, money market funds, commercial paper, Yankee CDs, and high credit quality asset-backed securities and corporate debt securities. In addition, the overall portfolio requires a maximum portfolio duration of one year.

**Item 4. Controls and Procedures.**

***Evaluation of disclosure controls and procedures***

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

***Changes in internal control over financial reporting***

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

***Inherent limitation on the effectiveness of internal control***

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur

because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings.

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

On October 14, 2024, we filed a lawsuit against Stryker Corporation and its subsidiary Wright Medical Technology, Inc. alleging infringement of 9 patents related to our innovative Lapiplasty® 3D Bunion Correction® technologies and unfair competition. The suit was filed in the United States District Court for the District of New Jersey, and seeks injunctive relief and damages.

### Item 1A. Risk Factors.

There have been no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K under "Part I, Item 1A—Risk Factors" for the year ended December 31, 2023, filed with the SEC on February 27, 2024.

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

None.

### Item 3. Defaults Upon Senior Securities.

None.

### Item 4. Mine Safety Disclosures.

Not applicable.

### Item 5. Other Information.

None.

### Item 6. Exhibits.

| Exhibit Number | Description |
|---|---|
| 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 With Embedded Linkbase Documents |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

* Filed herewith.

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

**SIGNATURES**

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

**Treace Medical Concepts, Inc.**

Date: November 5, 2024

By: /s/ John T. Treace

Name: John T. Treace

Title: Chief Executive Officer (Principal Executive Officer)

Date: November 5, 2024

By: /s/ Mark L. Hair

Name: Mark L. Hair

Title: Chief Financial Officer (Principal Financial Officer)

**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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 5, 2024

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 5, 2024

By: /s/ Mark L. Hair

Mark L. Hair
Chief Financial Officer
(Principal Financial 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, 2024 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 results of operations of the Company.

Date: November 5, 2024

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, 2024 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 results of operations of the Company.

Date: November 5, 2024

By: /s/ Mark L. Hair
Mark L. Hair
Chief Financial Officer
(Principal Financial Officer)