

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 9, 2023

TREACE MEDICAL CONCEPTS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40355
(Commission
File Number)

47-1052611
(IRS Employer
Identification Number)

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

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

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

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	TMCI	The Nasdaq Global Select Market

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

Emerging growth company

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

Item 2.02. Results of Operations and Financial Condition.

On November 9, 2023, Treace Medical Concepts, Inc. issued a press release regarding its financial results for the quarter ended September 30, 2023. A copy of the press release is furnished as [Exhibit 99.1](#) to this Form 8-K.

This information is intended to be furnished under Item 2.02 of Form 8-K and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Treace Medical Concepts, Inc. issued on November 9, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

TREACE MEDICAL CONCEPTS, INC.

Date: November 9, 2023

By: /s/ Mark L. Hair

Mark L. Hair

Chief Financial Officer



Treace Medical Concepts Reports Third Quarter 2023 Financial Results

PONTE VEDRA, Fla. – November 9, 2023 – Treace Medical Concepts, Inc. (“Treace” or the “Company”) (NasdaqGS: TMCI), a medical technology company driving a fundamental shift in the surgical treatment of hallux valgus (commonly known as bunions) through its Lapiplasty® 3D Bunion Correction® Procedure, today reported financial results for the third quarter ended September 30, 2023.

Recent Highlights:

- Revenue of \$40.8 million in the third quarter, a 23% increase over same period last year and a 36% increase year to date over prior year
- Blended average revenue per Lapiplasty® procedure kit sold was record high \$6,311, a 9% increase over same period last year
- Gross margin of 80.4% in the third quarter 2023 and 81.0% year to date
- Third quarter 2023 revenue contribution from direct sales channel, the industry’s only direct bunion-focused salesforce, increased to 81% of sales compared to 74% during third quarter 2022
- Initiated commercialization of several new technologies, including the 2nd generation SpeedPlate™ fixation platform, the Micro-Lapiplasty™ System, Hammertoe PEEK Fixation System, and LapiTome™ and RazorTome™ sterile instruments
- Patent portfolio expands to 52 granted U.S. patents, with an additional 12 patents worldwide and 78 pending U.S. patent applications

“We’re pleased to report substantial gains in our key performance metrics during the third quarter, including 36% year-to-date revenue growth and a significant increase in our surgeon base, which now totals 2,691, a 21% increase over the prior year,” said John T. Treace, CEO, Founder and Board Member of Treace. “We also achieved a record blended average selling price of \$6,311, driven by the early impact of our new technologies, and we are particularly excited about the opportunity for our SpeedPlate™ fixation platform.”

Mr. Treace stated, “Our updated guidance reflects our year-to-date surgeon count, which was impacted by prioritized travel and vacations for our patient demographic that started in the second quarter and continued through most of the third quarter. We also made the strategic decision to further refine our SpeedPlate™ platform, extending our timeline to achieve full commercial supply until the first quarter of 2024. This decision has enabled us to make our Gen 2 SpeedPlate™ technology more broadly applicable across a greater range of clinical applications, which we believe will expand our footprint in the foot and ankle market.”

Mr. Treace continued, “With accelerating additions to our surgeon base, increasing productivity of our direct sales channel and several new technologies that are already starting to make a positive impact on customer demand, I’m confident that we have the right strategy in place to outpace our competitors, drive continued market penetration and deliver strong growth for the remainder of this year and beyond.”

Third Quarter 2023 Financial Results

Revenue for the second quarter of 2023 was \$40.8 million, representing an increase of 23% compared to \$33.1 million in the third quarter of 2022. The increase was driven by an increased number of Lapiplasty[®] procedure kits sold as a result of an expanded surgeon customer base, increased utilization and increased blended average selling prices due to increased adoption of the Company's newer technologies and expanding portfolio of complementary products.

Gross profit for the third quarter of 2023 was \$32.8 million, representing an increase of 21% compared to a gross profit of \$27.0 million in the third quarter of 2022. Gross margin totaled 80.4% in the third quarter of 2023, compared to 81.6% in third quarter of 2022, primarily due to changes in product mix, an increase in inventory provisions, and an increase in overhead costs due to headcount to support the growing business, partially offset by lower royalty rates.

Total operating expenses were \$50.6 million in the third quarter of 2023, compared to total operating expenses of \$38.3 million in the third quarter of 2022. Increased operating expenses in the third quarter of 2023 reflect strategic investments in its expanding direct sales channel, investments in product innovation, increased capacity requirements, as well as support for other commercial initiatives.

Third quarter net loss attributable to common stockholders was (\$17.5) million, or (\$0.28) per share, compared to (\$12.1) million, or (\$0.22) per share, for the same period of 2022. Third quarter adjusted net loss was (\$17.5) million, or (\$0.28) per share, compared to (\$12.1) million, or (\$0.22) per share for the same period of 2022. Adjusted EBITDA was a loss of (\$9.2) million in the third quarter of 2023 compared to a loss of (\$8.6) million for the same period in 2022. See below for additional information and a reconciliation of non-GAAP financial information.

Cash, cash equivalents, marketable securities and investment receivable totaled \$128.2 million as of September 30, 2023. The Company believes it has sufficient balance sheet strength and flexibility to continue aggressively executing on its strategic investments and growth initiatives.

Financial Outlook

Treace is updating its full-year 2023 revenue guidance to \$182 million to \$186 million, which represents approximately 28% to 31% growth over the Company's 2022 revenue. This compares to the prior full-year 2023 revenue guidance of \$191 million to \$197 million.

The Company expects positive adjusted EBITDA in the fourth quarter of 2023 and continues to expect to show modest improvement in adjusted EBITDA for full-year 2023 compared to 2022.

An investor presentation for the Company's third quarter 2023 financial results is available in the "Investors" section of Treace's website at investors.treace.com.

Webcast and Conference Call Details

Treace will host a conference call today, November 9, 2023, at 4:30 p.m. ET to discuss its third quarter 2023 financial results. Investors interested in listening to the conference call may do so by registering. Once registered, participants will receive dial-in numbers and a unique pin to join the call and ask questions. The live webcast of the conference call will be available on the Investor Relations section of the Company's website at <https://investors.treace.com/>. The webcast will be archived on the website following the completion of the call.

Use of Non-GAAP Financial Measures

To supplement the financial results presented in accordance with GAAP, this earnings release presents Adjusted EBITDA, which the Company defines as net loss before depreciation and amortization expense, interest income, interest expense, taxes, share-based compensation expense, acquisition-related costs

and debt extinguishment loss. As of March 31, 2023, in its calculation of Adjusted EBITDA, the Company began subtracting interest income from net loss as interest income is expected to be significant for the full-year 2023. Prior period results for Adjusted EBITDA have been updated to be consistent with the updated presentation as described above. This earning release also presents net loss attributable to common stockholders excluding the debt extinguishment loss on an aggregate and per share basis (“Adjusted Net Loss”). Non-GAAP financial measures such as Adjusted EBITDA and Adjusted Net Loss are presented in addition to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP. Management uses these non-GAAP financial measures to evaluate the Company’s operating performance and trends, as well as for making planning decisions. The Company believes that Adjusted EBITDA and Adjusted Net Loss helps to identify underlying trends in the Company’s business that may otherwise be masked by the effect of the income and expenses and other items that it excludes in its calculation of Adjusted EBITDA and Adjusted Net Loss. Accordingly, the Company believes these non-GAAP financial measures provide useful information to investors and others in understanding and evaluating the Company’s operating results, enhancing the overall understanding of its past performance and future prospects, and allowing for greater transparency with respect to key financial metrics used by the Company’s management in their financial and operational decision-making. The Company also presents these non-GAAP financial measures because it believes investors, analysts and rating agencies consider them to be a useful metrics in measuring the Company’s performance against other companies and its ability to meet its debt service obligations.

There are limitations related to the use of non-GAAP financial measures such as Adjusted EBITDA and Adjusted Net Loss because they are not prepared in accordance with GAAP, may exclude significant income and expenses required by GAAP to be recognized in the Company’s financial statements, and may not be comparable to non-GAAP financial measures used by other companies. The Company encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP information and the reconciliation between these presentations, to more fully understand its business. Reconciliations between GAAP and non-GAAP results are presented below.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are forward-looking statements, including, but not limited to the Company’s expectations about the opportunity for its SpeedPlate™ fixation platform, including its expansion of the Company’s footprint in the foot and ankle market and the timeline to achieve full commercial supply of that product; the Company’s confidence that it has the right strategy in place to outpace its competitors, drive continued market penetration and deliver strong growth for the remainder of 2023 and beyond; the Company’s belief that it has sufficient balance sheet strength and flexibility to continue aggressively executing on its strategic investments and growth initiatives; the Company’s revenue guidance and revenue growth rates for full-year 2023; and the Company’s expectation of positive adjusted EBITDA in the fourth quarter of 2023 and modest improvement in adjusted EBITDA for full-year 2023 compared to 2022. Forward-looking statements are based on management’s current assumptions and expectations of future events and trends, which affect or may affect the Company’s business, strategy, operations or financial performance, and actual results and other events may differ materially from those expressed or implied in such statements due to numerous risks and uncertainties. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Factors that could cause actual results or other events to differ materially from those contemplated in this press release can be found in the Risk Factors section of Treace’s public filings with the Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K for the year ended December 31, 2022, and any subsequent Quarterly Report on Form 10-Q or Current Report on Form 8-K. Because forward-looking statements are inherently subject to risks and uncertainties, you should not rely on these forward-looking statements as predictions of future events. These forward-looking statements speak only as of their date and, except to the extent required by law, the Company undertakes no obligation to update these statements, whether as a result of any new information, future developments or otherwise.

The Company's results for the quarter ended September 30, 2023 are not necessarily indicative of its operating results for any future periods.

Internet Posting of Information

Treace routinely posts information that may be important to investors in the "Investor Relations" section of its website at www.treace.com. The Company encourages investors and potential investors to consult the Treace website regularly for important information about Treace.

About Treace Medical Concepts

Treace Medical Concepts, Inc. is a medical technology company with the goal of advancing the standard of care for the surgical management of bunion and related midfoot deformities. Bunions are complex 3-dimensional deformities that originate from an unstable joint in the middle of the foot and affect approximately 65 million Americans, of which Treace estimates 1.1 million are annual surgical candidates. Treace has pioneered and patented the Lapiplasty[®]3D Bunion Correction[®] System – a combination of instruments, implants, and surgical methods designed to surgically correct all 3 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. Treace expanded its offering with the Adductoplasty[®] Midfoot Correction System, designed for reproducible surgical correction of the midfoot to provide further support to hallux valgus patients, and the Hammertoe PEEK Fixation System, designed to address hammertoe, claw toe and mallet toe deformities. For more information, please visit www.treace.com.

To learn more about Treace, connect with us on [LinkedIn](#), [Twitter](#), [Facebook](#), and [Instagram](#).

Contacts:

Treace Medical Concepts, Inc.

Julie Dewey, IRC

Chief Communications & Investor Relations Officer

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

Note: A change in presentation has been made within the Statement of Operations and Comprehensive Loss for the three months and nine months ended September 30, 2022, reclassifying \$0.5 million and \$1.3 million of surgical instrument expense from cost of goods sold to sales and marketing expense to conform with the current year's presentation. Please refer to supplemental materials related to quarterly 2022 results available on our investor relations website.

Treace Medical Concepts, Inc.
Balance Sheets
(in thousands, except share and per share amounts)
(unaudited)

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

Treace Medical Concepts, Inc.
Statements of Cash Flows
(in thousands)
(unaudited)

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

Treace Medical Concepts, Inc.
Reconciliation of GAAP Net Loss to Adjusted Net Loss
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss	\$ (17,521)	\$ (12,133)	\$ (43,246)	\$ (38,403)
Adjustment:				
Debt extinguishment loss	—	—	—	4,483
Adjusted net loss	<u>\$ (17,521)</u>	<u>\$ (12,133)</u>	<u>\$ (43,246)</u>	<u>\$ (33,920)</u>
Per share				
Net loss	\$ (0.28)	(0.22)	(0.71)	(0.70)
Adjustment:				
Debt extinguishment loss	—	—	—	0.08
Adjusted net loss	<u>\$ (0.28)</u>	<u>\$ (0.22)</u>	<u>\$ (0.71)</u>	<u>\$ (0.62)</u>
Weighted average common shares outstanding per share attributable to common stockholders, basic and diluted	61,562,494	55,429,211	60,566,655	55,190,587

Treace Medical Concepts, Inc.
Reconciliation of GAAP Net Loss to EBITDA & Adjusted EBITDA
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss	\$ (17,521)	\$ (12,133)	\$ (43,246)	\$ (38,403)
Adjustments:				
Interest income	(1,570)	(420)	(5,017)	(560)
Interest expense	1,296	1,190	3,863	3,087
Taxes	—	—	—	—
Depreciation & Amortization	1,564	459	3,583	1,216
EBITDA	<u>\$ (16,231)</u>	<u>\$ (10,904)</u>	<u>\$ (40,817)</u>	<u>\$ (34,660)</u>
Share-based compensation expense	5,192	2,269	11,480	5,641
Acquisition-related costs	1,802	—	2,322	—
Debt extinguishment loss	—	—	—	4,483
Adjusted EBITDA	<u>\$ (9,237)</u>	<u>\$ (8,635)</u>	<u>\$ (27,015)</u>	<u>\$ (24,536)</u>

