

**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): May 8, 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 May 8, 2023, Treace Medical Concepts, Inc. issued a press release regarding its financial results for the quarter ended March 31, 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	<a href="#">Press Release of Treace Medical Concepts, Inc. issued on May 8, 2023</a>
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: May 8, 2023

By: /s/ Mark L. Hair

Mark L. Hair

Chief Financial Officer

---



## Treace Medical Concepts Reports First Quarter 2023 Financial Results

PONTE VEDRA, Fla. – May 8, 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), today reported financial results for the first quarter ended March 31, 2023.

### Recent Highlights:

- Revenue of \$42.2 million in the first quarter of 2023, a 45% increase over the same period last year.
- Blended average revenue per Lapiplasty® procedure kit sold was \$6,244, a 13% increase over the same period last year and a 6% increase sequentially.
- Gross margin of 80.9% in the first quarter 2023.
- First quarter revenue contribution from direct sales channel, the industry’s only direct bunion-focused salesforce, increased to 79% of sales compared to 63% during the first quarter 2022.
- New interim data<sup>1</sup> from ALIGN3D™ clinical study highlighted at the 2023 American College of Foot and Ankle Surgeons (ACFAS) Annual Scientific Conference demonstrating 97.3% patient satisfaction rating at 36 months (n=37), with 92% and 90% improvement in walking/standing and social interaction scores, respectively, through 36 months (n=41); an 80.8% decrease in pain at 24 months (n=128); and a low recurrence rate of 0.9% (1 out of 114 patients) observed at 24 months post-surgery<sup>2</sup>.
- Granted seven additional U.S. patents year-to-date on innovative systems, devices, and methods for performing instrumented surgery for bunions and related deformities. Patent portfolio expands to 47 granted U.S. patents and 51 pending U.S. patent applications.

“First quarter revenue grew 45% with steady execution of our growth strategies and gains across our key operating metrics,” said John T. Treace, CEO, Founder and Board Member of Treace. “With increasing strategic investments into our direct sales channel, R&D initiatives, and direct-to-consumer programs, we continue to drive strong revenue growth and expand our market penetration. These proven commercial programs coupled with our differentiated technologies well-position us to advance our mission to improve surgical outcomes for bunion patients.”

### First Quarter 2023 Financial Results

Revenue for the first quarter of 2023 was \$42.2 million, representing an increase of 45% compared to \$29.0 million in the first 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 and increased blended average selling prices due to increased adoption of our newer technologies and expanding product line.

Gross profit for the first quarter of 2023 was \$34.2 million, representing an increase of 43% compared to a gross profit of \$23.9 million in the first quarter of 2022. Gross margin totaled 80.9% in the first quarter of 2023, compared to 82.3% in the first quarter of 2022. The decrease was primarily due to an increase in payroll costs and an increase in inventory and obsolescence provisions.

<sup>1</sup> The ACFAS Scientific Poster, which includes additional details such as patient demographics, inclusion/exclusion criteria, and complications reported in the study, will be accessible on Treace’s website at: <https://www.lapiplasty.com/surgeons/journal-publications/>.

<sup>2</sup> 0.9% of patients (1 out of 114 patients) demonstrated radiographic recurrence at the 24 month follow up timepoint. 1.4% of patients (2 out of 144 patients) demonstrated radiographic recurrence at the 12 month follow up timepoint.

Total operating expenses were \$47.9 million in the first quarter of 2023, including sales and marketing (S&M) expenses of \$33.7 million, research and development (R&D) expenses of \$3.4 million, and general and administrative (G&A) expenses of \$10.9 million. This compared to total operating expenses of \$32.0 million, including S&M expenses of \$22.3 million, R&D expenses of \$3.1 million, and G&A expenses of \$6.7 million in the first quarter of 2022. Increased operating expenses in the first quarter of 2023 reflect increased investments in our commercial initiatives as well as other G&A investments supporting our growing business.

First quarter net loss attributable to common stockholders was (\$13.5) million, or (\$0.23) per share, compared to a net loss of (\$9.0) million, or (\$0.16) per share, for the same period of 2022. Adjusted EBITDA was a loss of (\$10.0) million in the first quarter, compared to a loss of (\$6.4) million for the same period in 2022. See below for additional information and a reconciliation of non-GAAP financial information.

### **Financial Outlook**

Treace is raising its full year 2023 revenue guidance to \$190 million to \$196 million, which represents approximately 34% to 38% growth over the Company's 2022 revenue. This compares to the prior revenue guidance of \$187 million to \$193 million.

### **Webcast and Conference Call Details**

Treace will host a conference call today, May 8, 2023, at 4:30 p.m. ET to discuss its first 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, share-based compensation expense, interest income, interest expense, and taxes. As of March 31, 2023, in its calculation of Adjusted EBITDA, the Company is subtracting interest income from net loss as interest income is more significant this quarter and is expected to be significant for the full year 2023. Prior period results for Adjusted EBITDA have been updated to be consistent with the current quarter's presentation. Non-GAAP financial measures such as Adjusted EBITDA 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 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. 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 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 that it is well positioned to advance its mission to improve surgical outcomes for bunion patients; and the Company's expected revenue and revenue growth rates for full year 2023. 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, which was filed with the SEC on March 8, 2023 and its Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, expected to be filed with the SEC on May 9, 2023. 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 March 31, 2023 are not necessarily indicative of our operating results for any future periods.

#### **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. For more information, please visit [www.treace.com](http://www.treace.com).

#### **Contacts:**

##### **Treace Medical Concepts**

Mark L. Hair  
Chief Financial Officer  
[mhair@treace.net](mailto:mhair@treace.net)  
(904) 373-5940

#### **Investors:**

##### **Gilmartin Group**

Lynn Lewis or Vivian Cervantes  
[IR@treace.net](mailto:IR@treace.net)

**Treace Medical Concepts, Inc.**  
**Statements of Operations and Comprehensive Loss**  
**(in thousands, except share and per share amounts)**  
**(unaudited)**

	Three Months Ended March 31,	
	2023	2022
Revenue	\$ 42,195	\$ 29,047
Cost of goods sold	8,039	5,130
Gross profit	34,156	23,917
Operating expenses		
Sales and marketing	33,655	22,299
Research and development	3,412	3,052
General and administrative	10,865	6,662
Total operating expenses	47,932	32,013
Income (loss) from operations	(13,776)	(8,096)
Interest income	1,479	9
Interest expense	(1,285)	(951)
Other income, net	128	2
Other non-operating income (expense), net	322	(940)
Net loss	\$ (13,454)	\$ (9,036)
Other comprehensive income (loss):		
Unrealized loss on marketable securities	\$ (29)	\$ —
Comprehensive income (loss)	\$ (13,483)	\$ (9,036)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.23)	\$ (0.16)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	58,723,760	54,827,665

Note: A change in presentation has been made within the Statement of Operations and Comprehensive Loss for the three months ended March 31, 2022, reclassifying \$0.4 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)

	March 31, 2023	December 31, 2022
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 29,613	\$ 19,473
Marketable securities, short-term	141,049	61,779
Accounts receivable, net of allowance for doubtful accounts of \$677 and \$735 as of March 31, 2023 and December 31, 2022, respectively	25,365	29,196
Inventories	22,519	19,330
Prepaid expenses and other current assets	4,587	3,624
Total current assets	223,133	133,402
Property and equipment, net	15,915	15,338
Operating lease right-of-use assets	9,907	10,138
Other non-current assets	215	146
Total assets	\$ 249,170	\$ 159,024
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accounts payable	\$ 5,076	\$ 8,668
Accrued liabilities	7,971	6,216
Accrued commissions	5,891	7,356
Accrued compensation	3,300	7,666
Operating lease and other liabilities	1,058	339
Total current liabilities	23,296	30,245
Long-term debt, net of discount of \$1,215 and \$1,289 as of March 31, 2023 and December 31, 2022, respectively	52,785	52,711
Operating lease liabilities, net of current portion	15,447	15,539
Other long-term liabilities	25	—
Total liabilities	91,553	98,495
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized as of March 31, 2023 and December 31, 2022; 0 shares issued and outstanding as of March 31, 2023 and December 31, 2022	—	—
Common stock, \$0.001 par value, 300,000,000 shares authorized; 61,280,703 issued and outstanding as of March 31, 2023; 300,000,000 shares authorized; 55,628,208 issued and outstanding as of December 31, 2022	61	55
Additional paid-in capital	255,786	145,221
Accumulated deficit	(98,174)	(84,720)
Accumulated other comprehensive (loss) income	(56)	(27)
Total stockholders' equity	157,617	60,529
Total liabilities and stockholders' equity	\$ 249,170	\$ 159,024



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

	<b>Three Months Ended March 31,</b>	
	<b>2023</b>	<b>2022</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (13,454)	\$ (9,036)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization expense	924	334
Provision for allowance for doubtful accounts	38	30
Share-based compensation expense	2,692	1,409
Non-cash lease expense	626	336
Amortization of debt issuance costs	74	45
Recovery of loss reserve for surgical instruments	(23)	—
Gain on fair value adjustment to derivative liability	—	(90)
Accretion (amortization) of discount (premium) on marketable securities, net	(297)	—
Net changes in operating assets and liabilities:		
Accounts Receivable	3,793	2,542
Inventory	(3,189)	(551)
Prepaid expenses and other assets	(963)	1,233
Other non-current assets	(69)	(134)
Payable to broker for unsettled marketable security purchases	710	—
Operating lease liabilities	(478)	(133)
Accounts payable	(3,592)	(607)
Accrued liabilities	(4,076)	(2,619)
Other, net	25	—
Net cash used in operating activities	<u>(17,259)</u>	<u>(7,241)</u>
<b>Cash flows from investing activities</b>		
Purchases of available-for-sale marketable securities	(99,550)	—
Maturities of available-for-sale marketable securities	20,548	—
Purchases of property and equipment	(1,478)	(1,481)
Net cash used in investing activities	<u>(80,480)</u>	<u>(1,481)</u>
<b>Cash flows from financing activities</b>		
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	352	1,372
Net cash provided by financing activities	<u>107,879</u>	<u>1,372</u>
Net increase (decrease) in cash and cash equivalents	10,140	(7,350)
Cash and cash equivalents at beginning of period	19,473	105,833
Cash and cash equivalents at end of period	<u>\$ 29,613</u>	<u>\$ 98,483</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	\$ 1,285	\$ 951
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	\$ (35)	\$ —
Unrealized losses on marketable securities	\$ 29	\$ —

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

	Three Months Ended March 31,	
	2023	2022
Net loss	\$ (13,454)	\$ (9,036)
Adjustments:		
Interest income	(1,479)	(9)
Interest expense	1,285	951
Taxes	—	—
Depreciation & Amortization	924	334
EBITDA	\$ (12,724)	\$ (7,760)
Share-based compensation expense	2,692	1,409
Adjusted EBITDA	\$ (10,032)	\$ (6,351)

