

**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): March 7, 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 March 7, 2023, Treace Medical Concepts, Inc. issued a press release regarding its financial results for the year ended December 31, 2022. 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 March 7, 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: March 7, 2022

By: /s/ Mark L. Hair

Mark L. Hair

Chief Financial Officer



Treace Medical Concepts Reports Fourth Quarter and Full Year 2022 Financial Results

PONTE VEDRA, Fla. – March 7, 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 fourth quarter and full year ended December 31, 2022.

Recent Highlights:

- Revenue of \$49.8 million in the fourth quarter of 2022, a 49% increase over the same period last year and a 51% increase sequentially. Full year 2022 revenue of \$141.8 million increased 50% over 2021.
- Blended average revenue per Lapiplasty® procedure kit sold was \$5,907, a 10% increase over the same period last year and a 2% increase sequentially. Full year 2022 blended average revenue per Lapiplasty® procedure kit sold of \$5,753 increased 7% over 2021.
- Gross margin of 80.4% in the fourth quarter 2022. Full year 2022 gross margin of 80.6%.
- Fourth quarter revenue contribution from direct sales channel, the industry’s only direct bunion-focused salesforce, increased to 77% of sales compared to 58% during the fourth quarter 2021.
- New interim data¹ from ALIGN3D™ clinical study highlighted at the 2023 American College of Foot and Ankle Surgeons (ACFAS) Annual Scientific Conference demonstrating 97% 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; and a low recurrence rate of 0.9% (1 out of 114 patients) observed at 24 months post-surgery².
- Granted two additional U.S. patents in the fourth quarter on novel methods of performing bunion surgery utilizing a bone positioning device. Patent portfolio expands to 40 granted U.S. patents and 46 pending U.S. patent applications as of the end of the fourth quarter.
- Completed a follow-on offering of common stock which raised net proceeds of \$107.5 million.

“Our 2022 revenue growth was driven by strong execution and focused investments that fueled our commercial momentum. Early in the year, we increased strategic investments into our direct sales channel, direct-to-consumer programs, and R&D initiatives that led to accelerating revenue growth and market penetration in the back half of the year, with steady gains in key operating metrics,” said John T. Treace, CEO, Founder and Board Member of Treace.

“Nearly 1-in-4 of the estimated 10,000 U.S. surgeons who perform bunion surgery used Lapiplasty® in 2022, which demonstrates the growing adoption of our differentiated technologies. Supported by a strengthened balance sheet, we believe we have a well-defined, scalable, and proven commercial strategy to further advance our mission to improve surgical outcomes for bunion patients by establishing the Lapiplasty® Procedure as the standard of care.”

Fourth Quarter 2022 Financial Results

Revenue for the fourth quarter of 2022 was \$49.8 million, representing an increase of 49% compared to \$33.4 million in the fourth quarter of 2021. 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.

¹The 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 Medical’s website at: <https://www.lapiplasty.com/surgeons/journal-publications/>.

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

Gross profit for the fourth quarter of 2022 was \$40.0 million, representing an increase of 48% compared to a gross profit of \$27.1 million in the fourth quarter of 2021. Gross margin decreased to 80.4% in the fourth quarter of 2022, compared to 81.1% in the fourth quarter of 2021. The decrease in gross margin was primarily due to an increase in payroll costs and additional depreciation related to capitalized surgical instruments necessary to support our expanded salesforce.

Total operating expenses were \$43.5 million in the fourth quarter of 2022, including sales and marketing (S&M) expenses of \$29.4 million, research and development (R&D) expenses of \$3.7 million, and general and administrative (G&A) expenses of \$10.4 million. This compared to total operating expenses of \$32.7 million, including S&M expenses of \$22.3 million, R&D expenses of \$3.4 million, and G&A expenses of \$7.0 million in the fourth quarter of 2021. Increased operating expenses in the fourth quarter of 2022 reflect increased investments in our commercial initiatives as well as other G&A investments supporting our growing business.

Fourth quarter net loss attributable to common stockholders was (\$4.4) million, or (\$0.08) per share, compared to (\$6.6) million, or (\$0.12) per share, for the same period of 2021. Adjusted EBITDA was \$0.3 million in the fourth quarter, compared to a loss of (\$4.0) million for the same period in 2021. See below for additional information and a reconciliation of non-GAAP financial information.

Full Year 2022 Financial Results

Revenue for the year ended December 31, 2022 was \$141.8 million, representing an increase of 50% compared to \$94.4 million in 2021. 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 year ended December 31, 2022 was \$114.3 million, representing an increase of 49% compared to a gross profit of \$76.6 million in 2021. Gross margin decreased to 80.6% in 2022, compared to 81.1% in 2021. The decrease in gross margin was primarily due to an increase in payroll costs and additional depreciation related to capitalized surgical instruments necessary to support our expanded salesforce.

Total operating expenses were \$149.2 million in 2022, including S&M expenses of \$102.6 million, R&D expenses of \$13.6 million, and G&A expenses of \$33.0 million. This compared to total operating expenses of \$93.1 million, including S&M expenses of \$64.5 million, R&D expenses of \$10.2 million, and G&A expenses of \$18.4 million in 2021. Increased operating expenses in 2022 reflect increased investments in our commercial initiatives as well as other G&A investments supporting our growing business.

Net loss attributable to common stockholders for the year ended December 31, 2022 was (\$42.8) million, or (\$0.77) per share, compared to (\$20.7) million, or (\$0.43) per share, in 2021. Adjusted EBITDA was a loss of (\$23.7) million in 2022, compared to a loss of (\$12.4) million in 2021. See below for additional information and a reconciliation of non-GAAP financial information.

Cash, cash equivalents, and marketable securities were \$81.3 million as of December 31, 2022. On February 10, Treace completed a follow-on offering of 5,476,190 shares of common stock which raised net proceeds of \$107.5 million.

Financial Outlook

Treace expects revenue for the full year 2023 to range from \$187 million to \$193 million, which represents approximately 32% to 36% growth over the Company's 2022 revenue.

Webcast and Conference Call Details

Treace will host a conference call today, March 7, 2023, at 4:30 p.m. ET to discuss its fourth quarter and full year 2022 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 expense, taxes and debt extinguishment loss. This earnings 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 help to identify underlying trends in the Company’s business that may otherwise be masked by the effect of the expenses and other items that it excludes in 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 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 belief that it is well positioned for sustained growth; the Company’s expectations regarding establishing the Lapiplasty® Procedure as the standard of care; 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, 2021, which was filed with the SEC on March 4, 2022 and its Annual Report on Form 10-K for the year ended December 31, 2022, which is expected to be filed with the SEC on March 8, 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 and year ended December 31, 2022 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.

Contacts:

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
Revenue	\$ 49,769	\$ 33,439	\$ 141,838	\$ 94,419
Cost of goods sold	9,742	6,307	27,523	17,826
Gross profit	40,027	27,132	114,315	76,593
Operating expenses				
Sales and marketing	29,369	22,325	102,576	64,467
Research and development	3,749	3,377	13,584	10,204
General and administrative	10,406	7,027	32,999	18,432
Total operating expenses	43,524	32,729	149,159	93,103
Income (loss) from operations	(3,497)	(5,597)	(34,844)	(16,510)
Interest and other income (expense), net	396	6	910	18
Interest expense	(1,311)	(1,028)	(4,398)	(4,060)
Debt extinguishment loss	—	—	(4,483)	—
Other expense, net	(915)	(1,022)	(7,971)	(4,042)
Net loss	(4,412)	(6,619)	(42,815)	(20,552)
Convertible preferred stock cumulative and undeclared dividends	—	—	—	(196)
Net loss attributable to common stockholders	\$ (4,412)	\$ (6,619)	\$ (42,815)	\$ (20,748)
Other comprehensive income (loss):				
Unrealized loss on marketable securities	\$ (27)	\$ —	\$ (27)	\$ —
Comprehensive income (loss)	\$ (4,439)	\$ (6,619)	\$ (42,842)	\$ (20,748)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.08)	\$ (0.12)	\$ (0.77)	\$ (0.43)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	55,558,364	53,618,371	55,276,834	48,415,679

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

	December 31,	
	2022	2021
Assets		
Current assets		
Cash and cash equivalents	\$ 19,473	\$ 105,833
Marketable securities, short-term	61,779	-
Accounts receivable, net of allowance for doubtful accounts of \$735 and \$414 as of December 31, 2022 and 2021, respectively	29,196	18,568
Inventories	19,330	10,561
Prepaid expenses and other current assets	3,624	3,010
Total current assets	133,402	137,972
Property and equipment, net	15,338	2,849
Operating lease right-of-use assets	10,138	—
Other non-current assets	146	—
Total assets	\$ 159,024	\$ 140,821
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 8,668	\$ 4,056
Accrued liabilities	6,216	4,518
Accrued commissions	7,356	5,181
Accrued compensation	7,666	4,455
Operating lease liabilities	339	—
Total current liabilities	30,245	18,210
Derivative liability on term loan	—	173
Long-term debt, net of discount of \$1,289 and \$635 as of December 31, 2022 and 2021, respectively	52,711	29,365
Operating lease liabilities, net of current portion	15,539	—
Total liabilities	98,495	47,748
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized as of December 31, 2022 and December 31, 2021; 0 shares issued and outstanding as of December 31, 2022 and December 31, 2021	—	—
Common stock, \$0.001 par value, 300,000,000 shares authorized; 55,628,208 issued and outstanding as of December 31, 2022; 300,000,000 shares authorized; 54,181,082 issued and outstanding as of December 31, 2021	55	45
Additional paid-in capital	145,221	134,933
Accumulated deficit	(84,720)	(41,905)
Accumulated other comprehensive (loss) income	(27)	—
Total stockholders' equity	60,529	93,073
Total liabilities and stockholders' equity	\$ 159,024	\$ 140,821

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

	Year Ended December 31,	
	2022	2021
Cash flows from operating activities		
Net loss	\$ (42,815)	\$ (20,552)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization expense	2,133	685
Provision for allowance for doubtful accounts	411	144
Share-based compensation expense	8,111	3,409
Non-cash lease expense	2,522	—
Amortization of debt issuance costs	244	176
Gain on fair value adjustment to derivative liability	(173)	(72)
Debt extinguishment loss	4,483	—
Loss on impairment of long-lived assets	346	—
Accretion (amortization) of discount (premium) on marketable securities, net	(126)	—
Other, net	25	—
Net changes in operating assets and liabilities:		
Accounts Receivable	(11,039)	(4,226)
Inventory	(8,769)	(2,741)
Prepaid expenses and other assets	(668)	(2,417)
Other non-current assets	(146)	—
Operating lease liabilities	3,076	—
Accounts payable	4,612	1,791
Accrued liabilities	7,125	6,610
Net cash used in operating activities	<u>(30,648)</u>	<u>(17,193)</u>
Cash flows from investing activities		
Purchases of available-for-sale marketable securities	(63,409)	—
Maturities of available-for-sale marketable securities	1,729	—
Purchases of property and equipment	(14,838)	(2,705)
Net cash used in investing activities	<u>(76,518)</u>	<u>(2,705)</u>
Cash flows from financing activities		
Proceeds from interest bearing term debt	49,651	—
Proceeds from interest bearing revolving debt	3,850	—
Payments on interest bearing debt	(33,893)	—
Payments on PPP Loan	—	(1,788)
Proceeds from issuance of common stock upon initial public offering, net of issuance costs and underwriting fees of \$10.6 million	—	107,610
Debt issuance costs	(989)	—
Proceeds from exercise of employee stock options	2,187	1,830
Net cash provided by financing activities	<u>20,806</u>	<u>107,652</u>
Net increase (decrease) in cash and cash equivalents	<u>(86,360)</u>	<u>87,754</u>
Cash and cash equivalents at beginning of period	105,833	18,079
Cash and cash equivalents at end of period	<u>\$ 19,473</u>	<u>\$ 105,833</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 4,398	\$ 3,900
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	\$ 3,615	\$ —
Unrealized losses on marketable securities	\$ 27	\$ —
Noncash financing activities:		
Issuance of common stock upon exercise of warrants	\$ —	\$ 1
Conversion of convertible preferred stock and accrued dividends on convertible preferred stock into common stock	\$ —	\$ 7,935

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
Net loss	\$ (4,412)	\$ (6,619)	\$ (42,815)	\$ (20,552)
Adjustment:				
Debt extinguishment loss	—	—	4,483	—
Adjusted net loss	<u>\$ (4,412)</u>	<u>\$ (6,619)</u>	<u>\$ (38,332)</u>	<u>\$ (20,552)</u>
Per share				
Net loss	\$ (0.08)	(0.12)	(0.77)	(0.42)
Adjustment:				
Debt extinguishment loss	—	—	0.08	—
Adjusted net loss	<u>\$ (0.08)</u>	<u>\$ (0.12)</u>	<u>\$ (0.69)</u>	<u>\$ (0.42)</u>
Weighted average common shares outstanding per share attributable to common stockholders, basic and diluted	55,558,364	53,618,371	55,276,834	48,415,679

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
Net loss	(4,412)	(6,619)	\$ (42,815)	\$ (20,552)
Adjustments:				
Interest Expense	1,311	1,028	4,398	4,060
Taxes	—	—	—	—
Depreciation & Amortization	917	276	2,133	685
EBITDA	\$ (2,184)	\$ (5,315)	\$ (36,284)	\$ (15,807)
Share-based compensation expense	2,470	1,293	8,111	3,409
Debt extinguishment loss	—	—	4,483	—
Adjusted EBITDA	<u>\$ 286</u>	<u>\$ (4,022)</u>	<u>\$ (23,690)</u>	<u>\$ (12,398)</u>

