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): August 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 August 8, 2023, Treace Medical Concepts, Inc. issued a press release regarding its financial results for the quarter ended June 30, 2023. A copy of the press release is furnished as <u>Exhibit 99.1</u> 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.

Exhibit No.	Description
99.1	Press Release of Treace Medical Concepts, Inc. issued on August 8, 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: August 8, 2023

By: /s/ Mark L. Hair

Mark L. Hair Chief Financial Officer



Treace Medical Concepts Reports Second Quarter 2023 Financial Results

PONTE VEDRA, Fla. – August 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) through its Lapiplasty[®] 3D Bunion Correction[™] Procedure, today reported financial results for the second quarter ended June 30, 2023.

Recent Highlights:

- Revenue of \$42.0 million in the second quarter of 2023, a 40% increase over same period last year
- Blended average revenue per Lapiplasty® procedure kit sold was \$6,176, an 8% increase over same period last year
- Gross margin of 81.7% in the second quarter 2023
- Second quarter revenue contribution from direct sales channel, the industry's only direct bunion-focused salesforce, increased to 79% of sales compared to 68% during the second quarter 2022
- Completed acquisition of certain assets from RedPoint Medical3D (RPM-3D) to enable patient specific instrumentation for bunion and related mid-foot surgical procedures
- Granted nine additional U.S. patents year-to-date; Patent portfolio expands to 49 granted U.S. patents and 72 pending U.S. patent applications
- · Announced appointment of Julie Dewey as Chief Communications and Investor Relations Officer

"Second quarter revenue grew 40% with solid execution of our growth strategies, encouraging adjusted EBITDA progress and continued gains across our key operating metrics," said John T. Treace, CEO, Founder and Board Member of Treace. "I'm especially pleased that we reached our stated year-end target of 200 quota carrying direct sales reps by the end of the second quarter. We expect this expansion, along with our proven commercial programs and differentiated technologies, will drive continued market penetration and position us well for the remainder of 2023 and beyond."

Second Quarter 2023 Financial Results

Revenue for the second quarter of 2023 was \$42.0 million, representing an increase of 40% compared to \$30.0 million in the second 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 second quarter of 2023 was \$34.3 million, representing an increase of 39% compared to a gross profit of \$24.7 million in the second quarter of 2022. Gross margin totaled 81.7% in the second quarter of 2023, compared to 82.3% in second quarter of 2022, primarily due to changes in product mix and an increase in inventory provisions, partially offset by lower royalty rates.

Total operating expenses were \$47.3 million in the second quarter of 2023, including sales and marketing (S&M) expenses of \$33.8 million, research and development (R&D) expenses of \$3.5 million, and general and administrative (G&A) expenses of \$10.0 million. This compared to total operating expenses of \$36.6 million, including S&M expenses of \$26.6 million, R&D expenses of \$3.0 million, and G&A expenses of \$7.0

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million, in the second quarter of 2022. Increased operating expenses in the second 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.

Second quarter net loss attributable to common stockholders was (\$12.3) million, or (\$0.20) per share, compared to (\$17.2) million, or (\$0.31) per share, for the same period of 2022. Second quarter adjusted net loss was (\$12.3) million, or (\$0.20) per share, compared to (\$12.8) million, or (\$0.23) per share for the same period of 2022. Adjusted EBITDA was a loss of (\$7.7) million in the second quarter of 2023 compared to a loss of (\$9.6) 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 \$191 million to \$197 million, which represents approximately 35% to 39% growth over the Company's 2022 revenue. This compares to the prior full-year 2023 revenue guidance of \$190 million to \$196 million.

Webcast and Conference Call Details

Treace will host a conference call today, August 8, 2023, at 4:30 p.m. ET to discuss its second 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 that the expansion of the number of its quota carrying direct sales reps, along with its commercial programs and technologies, will drive continued market penetration and position the Company well for the remainder of 2023 and beyond; and the Company's revenue guidance 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, 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 guarter ended June 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. 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 Julie Dewey, IRC Chief Communications & IR Officer jddewey@treace.com (209) 613-6945

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

	Three Months Ended June 30,			Six Mont June		
		2023		2022	 2023	 2022
Revenue	\$	41,953	\$	29,967	\$ 84,148	\$ 59,014
Cost of goods sold		7,675		5,291	15,714	10,421
Gross profit		34,278		24,676	68,434	 48,593
Operating expenses						
Sales and marketing		33,773		26,610	67,428	48,909
Research and development		3,526		2,984	6,938	6,036
General and administrative		10,031		7,015	20,896	13,677
Total operating expenses		47,330		36,609	95,262	 68,622
Loss from operations		(13,052)		(11,933)	(26,828)	 (20,029)
Interest income		1,968		131	3,447	140
Interest expense		(1,282)		(946)	(2,567)	(1,897)
Debt extinguishment loss		—		(4,483)		(4,483)
Other income, net		95		(3)	 223	 (1)
Other non-operating income (expense), net		781		(5,301)	 1,103	 (6,241)
Net loss	\$	(12,271)	\$	(17,234)	\$ (25,725)	\$ (26,270)
Other comprehensive income (loss):						
Unrealized loss on marketable securities	\$	(163)	\$		\$ (192)	\$
Comprehensive loss	\$	(12,434)	\$	(17,234)	\$ (25,917)	\$ (26,270)
Net loss per share attributable to common stockholders, basic and diluted	\$	(0.20)	\$	(0.31)	\$ (0.43)	\$ (0.48)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted		61,382,514		55,308,273	 60,060,483	 55,071,368

Note: A change in presentation has been made within the Statement of Operations and Comprehensive Loss for the three months and six months ended June 30, 2022, reclassifying \$0.4 million and \$0.7 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.

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

	June 30, 2023	December 31, 2022		
Assets				
Current assets				
Cash and cash equivalents	\$ 12,035	\$	19,473	
Marketable securities, short-term	127,444		61,779	
Accounts receivable, net of allowance for doubtful accounts of \$707 and \$735 as of June 30, 2023				
and December 31, 2022, respectively	27,232		29,196	
Inventories	26,101		19,330	
Prepaid expenses and other current assets	 5,284		3,624	
Total current assets	198,096		133,402	
Property and equipment, net	19,435		15,338	
Intangible assets, net	9,500			
Goodwill	12,815		—	
Operating lease right-of-use assets	9,651		10,138	
Other non-current assets	 146		146	
Total assets	\$ 249,643	\$	159,024	
Liabilities and Stockholders' Equity				
Current liabilities				
Accounts payable	\$ 8,146	\$	8,668	
Accrued liabilities	7,072		6,216	
Accrued commissions	5,661		7,356	
Accrued compensation	5,368		7,666	
Other liabilities	3,775		339	
Total current liabilities	30,022		30,245	
Long-term debt, net of discount of \$1,141 and \$1,289 as of June 30, 2023 and December 31, 2022,				
respectively	52,859		52,711	
Operating lease liabilities, net of current portion	16,766		15,539	
Other long-term liabilities	 37			
Total liabilities	 99,684		98,495	
Commitments and contingencies (Note 8)				
Stockholders' equity				
Common stock, \$0.001 par value, 300,000,000 shares authorized; 61,528,409 issued and outstanding as of June 30, 2023; 300,000,000 shares authorized; 55,628,208 issued and outstanding				
as of December 31, 2022	62		55	
Additional paid-in capital	260,561		145,221	
Accumulated deficit	(110,445)		(84,720)	
Accumulated other comprehensive (loss) income	(219)		(27)	
Total stockholders' equity	149,959		60,529	
	 	\$	159,024	

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

		Six Months E	nded June			
		2023	2022			
Cash flows from operating activities		··	*	(
Net loss	\$	(25,725)	\$	(26,270		
Adjustments to reconcile net loss to net cash used in operating activities						
Depreciation and amortization expense		2,019		757		
Provision (recovery) for allowance for doubtful accounts		78		(45		
Share-based compensation expense		6,288		3,372		
Non-cash lease expense		1,264		1,165		
Amortization of debt issuance costs		148		95		
Recovery of inventory obsolescence		—		(197		
Gain on fair value adjustment to derivative liability		—		(173		
Debt extinguishment loss		—		4,483		
Accretion (amortization) of discount						
(premium) on marketable securities, net		(663)		—		
Other, net		5		—		
Net changes in operating assets and liabilities, net of acquisitions:						
Accounts Receivable		1,886		2,112		
Inventory		(6,704)		(2,410		
Prepaid expenses and other assets		(1,641)		(1,039		
Other non-current assets		_		(134		
Other liabilities		1,072		2,392		
Accounts payable		(522)		(957		
Accrued liabilities		(3,137)		(958		
Other, net		38		_		
Net cash used in operating activities		(25,594)		(17,807		
Cash flows from investing activities						
Purchases of available-for-sale marketable securities		(120,957)				
Sales and maturities of available-for-sale marketable securities		55,763				
Purchases of property and equipment		(5,709)		(6,649		
Acquisition, net of cash acquired		(20,000)		(0,015		
Net cash used in investing activities		(90,903)		(6,649		
Cash flaves from financing activities						
Cash flows from financing activities				49.651		
Proceeds from interest bearing term debt				-)		
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		1,532		1,537		
Net cash provided by financing activities		109,059		20,156		
Net decrease in cash and cash equivalents		(7,438)		(4,300		
Cash and cash equivalents at beginning of period		19,473		105,833		
Cash and cash equivalents at end of period	\$	12,035	\$	101,533		
Supplemental disclosure of each flow information						
Supplemental disclosure of cash flow information:	¢	0.505	¢	4.007		
Cash paid for interest	\$	2,567	\$	1,897		
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	\$	(13)	\$	_		
Noncash investing activities: Unrealized losses on marketable securities	\$	192	\$	_		
	4	102	4			

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

	Three Months Ended June 30,			Six Months June 30				
		2023		2022		2023		2022
Net loss	\$	(12,271)	\$	(17,234)	\$	(25,725)	\$	(26,270)
Adjustment:								
Debt extinguishment loss		_		4,483				4,483
Adjusted net loss	\$	(12,271)	\$	(12,751)	\$	(25,725)	\$	(21,787)
Per share								
Net loss	\$	(0.20)		(0.31)		(0.43)		(0.48)
Adjustment:								
Debt extinguishment loss		—		0.08		_		0.08
Adjusted net loss	\$	(0.20)	\$	(0.23)	\$	(0.43)	\$	(0.40)
Weighted average common shares outstanding per share attributable to common stockholders, basic and diluted		61,382,514		55,308,273		60,060,483		55,071,368

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

		Three Months Ended June 30,				Six Montl June	ed	
		2023	23 2022			2023		2022
Net loss	\$	(12,271)	\$	(17,234)	\$	(25,725)	\$	(26,270)
Adjustments:								
Interest income		(1,968)		(131)		(3,447)		(140)
Interest expense		1,282		946		2,567		1,897
Taxes				—		—		_
Depreciation & Amortization		1,095		423		2,019		757
EBITDA	\$	(11,862)	\$	(15,996)	\$	(24,586)	\$	(23,756)
Share-based compensation expense		3,596		1,963		6,288		3,372
Acquisition-related costs		520				520		
Debt extinguishment loss		—		4,483		—		4,483
Adjusted EBITDA	\$	(7,746)	\$	(9,550)	\$	(17,778)	\$	(15,901)
	7							