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 5, 2022

TREACE MEDICAL CONCEPTS, INC.

(Exact name of registrant as specified in its charter)

Delaware

001-40355

47-1052611

(State or other jurisdiction of incorporation)

(Commission

, File Number)

(IRS Employer **Identification Number)**

203 Fort Wade Rd., Suite 150 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 \mathbf{X}

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. \Box

Item 2.02. Results of Operations and Financial Condition.

On May 5, 2022, Treace Medical Concepts, Inc. issued a press release regarding its financial results for the quarter ended March 31, 2022. 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 May 5, 2022
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.

By: /s/ Mark L. Hair

Mark L. Hair

Chief Financial Officer

Date: May 5, 2022



Treace Medical Concepts Reports First Quarter 2022 Financial Results

PONTE VEDRA, Fla. – May 5, 2022—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, 2022.

Recent Highlights:

- Revenue of \$29.0 million in the first quarter 2022, a 55% increase over the same period last year.
- Gross margin of 81.0% in the first quarter 2022.
- First quarter revenue contribution from our direct sales channel was 63% of sales, an increase from 44% of sales in the first quarter 2021.
- New five-year \$150 million loan arrangement, including up to a \$120 million term loan and a \$30 million revolving credit facility.
- Announced peer-reviewed publication of interim data from the ALIGN3D[™] clinical study in the *Journal of Foot & Ankle Surgery*. The data demonstrated continued positive radiographic and Patient-Reported Outcome (PRO) scores at 12- and 24- months following the Lapiplasty® procedure.
- Granted 2 additional US patents in the first quarter on instrumented bunion correction techniques. Patent portfolio expands to 34 granted US patents and over 40 pending US patent applications as of the end of the quarter.

"We are off to a solid start in 2022 led by strong execution of our commercial strategies," said John T. Treace, CEO, Founder and Board Member of Treace. "We remain confident that the increased investments we are making in our bunion-focused direct sales channel, direct-to-consumer programs, and focused R&D initiatives continue to drive positive momentum in our business. With additional financial flexibility from our new loan arrangement, these commercial strategies and investments, complemented by our growing body of clinical evidence, position us well for sustained growth and market share gains."

First Quarter 2022 Financial Results

Revenue for the first quarter of 2022 was \$29.0 million, representing an increase of 55% compared to \$18.7 million in the first quarter of 2021. The increase was driven by an increased number of Lapiplasty® procedure kits sold as a result of an expanded customer base and a slight increase in average selling prices.

Gross profit for the first quarter of 2022 was \$23.5 million, compared to a gross profit of \$15.4 million in the first quarter of 2021. Gross margin decreased to 81.0% in the first quarter of 2022, compared to 82.2% in the first quarter of 2021. The decline in gross margin was due to increase in royalty expense resulting from our increased sales and increase in depreciation expense from surgical instruments.

Total operating expenses were \$31.6 million in the first quarter of 2022, including sales and marketing (S&M) expenses of \$21.9 million, research and development (R&D) expenses of \$3.0 million, and general and administrative (G&A) expenses of \$6.7 million. This compared to total operating expenses of \$16.8 million, including S&M expenses of \$12.1 million, R&D expenses of \$1.9 million, and G&A expenses of \$2.8 million in the first quarter of 2021. Expenses in the first quarter of 2022 reflect increased investments in sales and marketing as well as other G&A investments supporting our growing business.

First quarter net loss attributable to common stockholders was (\$9.0) million, or (\$0.16) per share, compared to net loss of (\$2.6) million, or (\$0.07) per share, for the same period of 2021. Adjusted EBITDA was a loss of (\$6.4) million in the first quarter, compared to a loss of (\$0.9) million for the same period in 2021. See below for additional information and a reconciliation of non-GAAP financial information.

Cash and cash equivalents were \$98.5 million as of March 31, 2022. On May 2, 2022, The Company announced a refinancing of its existing debt for new, five-year \$150 million loan arrangement that includes up to a \$120 million

term loan and a \$30 million revolving credit facility. Upon the closing of the new loan agreements, the Company drew \$54 million and paid off its \$30 million in long term debt outstanding at the end of the first quarter.

Financial Outlook

Treace is raising its full year 2022 revenue guidance to \$128 million to \$133 million, which represents approximately 36% to 41% growth over the Company's 2021 revenue. This compares to the prior revenue guidance of \$125 million to \$130 million.

Webcast and Conference Call Details

Treace will host a conference call today, May 5, 2022, at 4:30 p.m. ET to discuss its first quarter 2022 financial results. The dial-in numbers are (888) 708-0264 for domestic callers or (720) 405-2122 for international callers, followed by Conference ID: 7287077. 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, stock-based compensation expense and interest income/expense. Adjusted EBITDA is presented in addition to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP. Management uses Adjusted EBITDA 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 expenses and other items that it excludes in Adjusted EBITDA. Accordingly, the Company believes Adjusted EBITDA provides 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 a key financial metric used by the Company's management in their financial and operational decision-making. The Company also presents Adjusted EBITDA because it believes investors, analysts and rating agencies consider it a useful metric 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 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 positive momentum and market share gains; and the Company's expected revenue and revenue growth rates for full year 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 in the final prospectus filed with the SEC on April 26, 2021 in connection with Treace's initial public offering and its Annual Report on Form 10-K for the year ended December 31, 2021, which was filed with the SEC on March 4, 2022. Because forward-looking statements are inherently subject to risks and uncertainties, you should not rely on these forward-looking statements are 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, 2022 are not necessarily indicative of our

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 deformities and related midfoot correction. Bunions are complex 3-dimensional

deformities that originate from an unstable joint in the middle of the foot. Treace has pioneered and patented the Lapiplasty® 3D Bunion CorrectionTM system – a combination of instruments, implants, and surgical methods designed to 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 recently expanded its offering with the AdductoplastyTM Midfoot Correction System, designed for reproducible correction of the midfoot to provide further support to hallux valgus patients. For more information, please visit www.treace.com.

Contacts:

Treace Medical Concepts

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

Investors:

Gilmartin Group Lynn Lewis or Vivian Cervantes IR@treace.net

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

(unautieu)				
	 Three Months E 2022	Ended March 31, 2021		
Revenue	\$ 29,047	\$	18,707	
Cost of goods sold	 5,506		3,327	
Gross profit	23,541		15,380	
Operating expenses				
Sales and marketing	21,923		12,148	
Research and development	3,052		1,868	
General and administrative	 6,662		2,766	
Total operating expenses	 31,637		16,782	
Loss from operations	(8,096)		(1,402)	
Interest and other income, net	11		1	
Interest expense	 (951)		(1,031)	
Other expense, net	(940)		(1,030)	
Net loss and comprehensive loss	(9,036)		(2,432)	
Convertible preferred stock cumulative and undeclared dividends	 —		(158)	
Net loss attributable to common stockholders	\$ (9,036)	\$	(2,590)	
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.16)	\$	(0.07)	
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	 54,827,665		37,854,687	

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

		March 31, 2022		December 31, 2021	
Assets					
Current assets					
Cash and cash equivalents	\$	98,483	\$	105,833	
Accounts receivable, net of allowance for doubtful accounts of \$509 and \$414 as of March 31, 2022 and December 31, 2021, respectively		15,995		18,568	
Inventories		11,112		10,561	
Prepaid expenses and other current assets		1,723		3,010	
Total current assets		127,313		137,972	
Property and equipment, net		3,996		2,849	
Operating lease right-of-use assets		15,069		_	
Other non-current assets		134			
Total assets	\$	146,512	\$	140,821	
Liabilities and Stockholders' Equity		· · · · ·			
Current liabilities					
Accounts payable	\$	3,448	\$	4,056	
Accrued liabilities		3,552		4,518	
Accrued commissions		3,882		5,181	
Accrued compensation		4,060		4,455	
Operating lease liabilities		435			
Total current liabilities		15,377		18,210	
Derivative liability on term loan		83		173	
Long-term debt, net of discount of \$590 and \$635 as of March 31, 2022 and December 31, 2021, respectively		29,410		29,365	
Operating lease liabilities, net of current portion		14,824			
Total liabilities		59,694		47,748	
Commitments and contingencies (Note 7)		· · · ·		, <u>,</u>	
Stockholders' equity					
Preferred stock, \$0.001 par value, 5,000,000 shares authorized as of March 31, 2022 and December 31, 2021; 0 shares issued and outstanding as of March 31, 2022 and December 31, 2021		_		_	
Common stock, \$0.001 par value, 300,000,000 shares authorized; 55,278,942 issued and outstanding as of March 31, 2022; 300,000,000 shares authorized; 54,181,082 issued and		10		45	
outstanding as of December 31, 2021		46		45	
Additional paid-in capital		137,713		134,933	
Accumulated deficit		(50,941)		(41,905)	
Total stockholders' equity	<i>ф</i>	86,818	<i>.</i>	93,073	
Total liabilities and stockholders' equity	\$	146,512	\$	140,821	

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

	7	Three Months Ended March 31,			
		2022		2021	
Cash flows from operating activities					
Net loss	\$	(9,036)	\$	(2,432)	
Adjustments to reconcile net loss to net cash used in operating					
activities					
Depreciation and amortization expense		334		117	
Provision (Recovery) for allowance for doubtful accounts		30		(77)	
Share-based compensation expense		1,409		402	
Non-cash lease expense		336		—	
Amortization of debt issuance costs		45		43	
Recovery of inventory obsolescence		(3)		(27)	
Gain on fair value adjustment to derivative liability		(90)		—	
Net changes in operating assets and liabilities:					
Accounts Receivable		2,542		3,769	
Inventory		(548)		478	
Prepaid expenses and other assets		1,233		(379)	
Other non-current assets		(134)		—	
Operating lease liabilities		(133)		—	
Accounts payable		(607)		(1,173)	
Accrued liabilities		(2,619)		(1,167)	
Net cash used in operating activities		(7,241)		(446)	
Cash flows from investing activities					
Purchases of property and equipment		(1,481)		(196)	
Net cash used in investing activities		(1,481)		(196)	
Cash flows from financing activities					
Repayment of PPP Loan		_		(1,788)	
Proceeds from exercise of employee stock options		1,372		569	
Net cash provided by (used in) financing activities		1,372		(1,219)	
Net decrease in cash and cash equivalents		(7,350)		(1,861)	
Cash and cash equivalents at beginning of period		105,833		18,079	
Cash and cash equivalents at end of period	\$	98,483	\$	16,218	
Supplemental disclosure of cash flow information:	<u>+</u>		<u> </u>		
Cash paid for interest	\$	951	\$	1,945	
Operating lease right-of-use assets obtained in exchange for new lease liabilities	\$	15,300	ֆ \$	1,945	
Supplemental disclosure of noncash financing activities:	φ	15,500	φ		
Unpaid offering costs included in accounts payable and accrued liabilities	\$		\$	1,118	
onpaid onering costs included in accounts payable and accrued nabilities	Φ		Φ	1,110	

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

	 Three Months Ended March 31,				
	2022		2021		
Net loss	\$ (9,036)	\$	(2,432)		
Adjustments:					
Interest	940		1,030		
Taxes	-		-		
Depreciation & Amortization	334		117		
EBITDA	\$ (7,762)	\$	(1,285)		
Share-based compensation expense	1,409		402		
Adjusted EBITDA	\$ (6,353)	\$	(883)		