

**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 9, 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))
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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 9, 2022, Treace Medical Concepts, Inc. issued a press release regarding its financial results for the quarter ended June 30, 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 August 9, 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.

Date: August 9, 2022

By: /s/ Mark L. Hair

Mark L. Hair

Chief Financial Officer



Treace Medical Concepts Reports Second Quarter 2022 Financial Results

PONTE VEDRA, Fla. – August 9, 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 second quarter ended June 30, 2022.

Recent Highlights:

- Revenue of \$30.0 million in the second quarter 2022, a 45% increase over the same period last year. Blended average revenue per case increased 5% to over \$5,700 from the same period last year.
- Gross margin of 81.1% in the second quarter 2022, an increase of 20 basis points from the same period last year.
- Second quarter revenue contribution from direct sales channel, the industry’s only direct bunion-focused salesforce, was 68% of sales, an increase from 51% during the second quarter 2021.
- Full commercial release of several new technologies for bunion and related midfoot surgery previewed at the February 2022 American College of Foot and Ankle Surgeons Annual Scientific Conference.
- Cash and cash equivalents of \$101.5 million and a new five-year \$150 million loan arrangement are expected to provide sufficient cash to fund planned commercial, market and product development initiatives into profitability.
- Peer-reviewed publication of interim data from the landmark 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. This represents the 21st peer-reviewed article supporting the Company’s Lapiplasty® technology.
- Granted two additional U.S. patents in the second quarter on instrumented bunion correction techniques. Patent portfolio expands to 36 granted U.S. patents and over 40 pending U.S. patent applications as of the end of the second quarter.

“We are pleased to report annual revenue growth of 45% in the second quarter and 50% growth through the first half of 2022, with continued gains in key operating metrics, driven by the underlying strength of our business and solid execution of our commercial strategies,” said John T. Treace, CEO, Founder and Board Member of Treace. “We are confident our increased investments in our bunion-focused direct sales channel, focused R&D initiatives and direct-to-consumer programs are driving positive momentum in our business, with our operations poised to scale. Complemented by our differentiated body of positive clinical evidence and strong balance sheet, we believe we are well positioned for sustained growth and increased penetration into our \$5 billion market opportunity.”

Second Quarter 2022 Financial Results

Revenue for the second quarter of 2022 was \$30.0 million, representing an increase of 45% compared to \$20.7 million in the second 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, increased surgeon utilization and increased blended average selling prices due to increased adoption of our newer technologies and expanding product line.

Gross profit for the second quarter of 2022 was \$24.3 million, compared to a gross profit of \$16.7 million in the second quarter of 2021. Gross margin increased to 81.1% in the second quarter of 2022, compared to 80.9% in the second quarter of 2021. The increase in gross margin was primarily due to an increase in revenue and volume efficiencies.

Total operating expenses were \$36.2 million in the second quarter of 2022, including sales and marketing (S&M) expenses of \$26.2 million, research and development (R&D) expenses of \$3.0 million, and general and administrative (G&A) expenses of \$7.0 million. This compared to total operating expenses of \$20.7 million, including S&M expenses of \$14.0 million, R&D expenses of \$2.4 million, and G&A expenses of \$4.3 million in the second quarter of 2021. Expenses in the second quarter of 2022 reflect increased investments in our commercial initiatives as well as other G&A investments supporting our growing business.

Second quarter net loss attributable to common stockholders was (\$17.2) million, or (\$0.31) per share, compared to (\$5.1) million, or (\$0.10) per share, for the same period of 2021. Adjusted Net Loss, which is net loss attributable to common stockholders excluding the debt extinguishment loss of \$4.5 million, or (\$0.08) per share, was (\$12.8) million, or (\$0.23) per share. Adjusted EBITDA was a loss of (\$9.4) million in the second quarter, compared to a loss of (\$3.1) 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 \$101.5 million as of June 30, 2022. On May 2, 2022, the Company announced a refinancing of its existing debt for a 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. The Company believes its cash and the new debt facilities provide sufficient liquidity to fund planned commercial, market and product development initiatives into profitability.

Financial Outlook

Treace is raising its full-year 2022 revenue guidance to \$130 million to \$134 million, which represents approximately 38% to 42% growth over the Company's 2021 revenue. This compares to the prior revenue guidance of \$128 million to \$133 million.

Webcast and Conference Call Details

Treace will host a conference call today, August 9, 2022, at 4:30 p.m. ET to discuss its second quarter 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 positive momentum and market penetration; the Company's expectation that its cash and the new debt facilities provide sufficient liquidity to fund planned commercial, market and product development initiatives into profitability; 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 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 June 30, 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 deformities and related midfoot correction. 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 recently 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:

Treace Medical Concepts

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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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue	\$ 29,967	\$ 20,654	\$ 59,014	\$ 39,361
Cost of goods sold	5,651	3,944	11,157	7,271
Gross profit	24,316	16,710	47,857	32,090
Operating expenses				
Sales and marketing	26,250	14,010	48,173	26,158
Research and development	2,984	2,422	6,036	4,290
General and administrative	7,015	4,329	13,677	7,095
Total operating expenses	36,249	20,761	67,886	37,543
Loss from operations	(11,933)	(4,051)	(20,029)	(5,453)
Interest and other income, net	128	6	139	7
Interest expense	(946)	(1,038)	(1,897)	(2,069)
Debt extinguishment loss	(4,483)	—	(4,483)	—
Other expense, net	(5,301)	(1,032)	(6,241)	(2,062)
Net loss and comprehensive loss	(17,234)	(5,083)	(26,270)	(7,515)
Convertible preferred stock cumulative and undeclared dividends	—	(39)	—	(196)
Net loss attributable to common stockholders	\$ (17,234)	\$ (5,122)	\$ (26,270)	\$ (7,711)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.31)	\$ (0.10)	\$ (0.48)	\$ (0.18)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	55,308,273	49,187,285	55,071,368	43,556,107

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

	June 30, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	\$ 101,533	\$ 105,833
Accounts receivable, net of allowance for doubtful accounts of \$430 and \$414 as of June 30, 2022 and December 31, 2021, respectively	16,501	18,568
Inventories	13,168	10,561
Prepaid expenses and other current assets	3,995	3,010
Total current assets	135,197	137,972
Property and equipment, net	8,741	2,849
Operating lease right-of-use assets	14,650	—
Other non-current assets	134	—
Total assets	\$ 158,722	\$ 140,821
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 3,099	\$ 4,056
Accrued liabilities	4,809	4,518
Accrued commissions	4,308	5,181
Accrued compensation	4,038	4,455
Operating lease liabilities	383	—
Total current liabilities	16,637	18,210
Derivative liability on term loan	—	173
Long-term debt, net of discount of \$1,438 and \$635 as of June 30, 2022 and December 31, 2021, respectively	52,562	29,365
Operating lease liabilities, net of current portion	17,811	—
Total liabilities	87,010	47,748
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized as of June 30, 2022 and December 31, 2021; 0 shares issued and outstanding as of June 30, 2022 and December 31, 2021	—	—
Common stock, \$0.001 par value, 300,000,000 shares authorized; 55,391,309 issued and outstanding as of June 30, 2022; 300,000,000 shares authorized; 54,181,082 issued and outstanding as of December 31, 2021	46	45
Additional paid-in capital	139,841	134,933
Accumulated deficit	(68,175)	(41,905)
Total stockholders' equity	71,712	93,073
Total liabilities and stockholders' equity	\$ 158,722	\$ 140,821

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

	Six Months Ended June 30,	
	2022	2021
Cash flows from operating activities		
Net loss	\$ (26,270)	\$ (7,515)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization expense	757	220
(Recovery) for allowance for doubtful accounts	(45)	(72)
Share-based compensation expense	3,372	1,277
Non-cash lease expense	1,165	—
Amortization of debt issuance costs	95	88
(Recovery) Provision of inventory obsolescence	(197)	88
Gain on fair value adjustment to derivative liability	(173)	—
Debt extinguishment loss	4,483	—
Net changes in operating assets and liabilities:		
Accounts Receivable	2,112	4,511
Inventory	(2,410)	89
Prepaid expenses and other assets	(1,039)	(2,919)
Other non-current assets	(134)	—
Operating lease liabilities	2,392	—
Accounts payable	(957)	656
Accrued liabilities	(958)	(600)
Net cash used in operating activities	<u>(17,807)</u>	<u>(4,177)</u>
Cash flows from investing activities		
Purchases of property and equipment	(6,649)	(866)
Net cash used in investing activities	<u>(6,649)</u>	<u>(866)</u>
Cash flows from financing activities		
Repayment of PPP loan	—	(1,788)
Proceeds from interest bearing term debt	49,651	—
Proceeds from interest bearing revolving debt	3,850	—
Debt issuance costs paid to third parties	(989)	—
Repayment of term loan	(33,893)	—
Proceeds from issuance of common stock upon initial public offering, net of issuance costs and underwriting fees of \$10.6 million	—	107,610
Proceeds from exercise of employee stock options	1,537	763
Net cash provided by financing activities	<u>20,156</u>	<u>106,585</u>
Net (decrease) increase in cash and cash equivalents	<u>(4,300)</u>	<u>101,542</u>
Cash and cash equivalents at beginning of period	105,833	18,079
Cash and cash equivalents at end of period	<u>\$ 101,533</u>	<u>\$ 119,621</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 1,897	\$ 2,917
Operating lease right-of-use assets obtained in exchange for new lease liabilities	\$ 15,300	\$ —
Supplemental disclosure of noncash investing activities:		
Property and equipment received in exchange for lease liability	\$ 4,115	\$ —
Supplemental disclosure of 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 June 30, 2022	
	Per Basic and Diluted Share	
Net loss	\$ (17,234)	\$ (0.31)
Adjustment:		
Debt extinguishment loss	4,483	0.08
Adjusted net loss	\$ (12,751)	\$ (0.23)
Weighted average common shares outstanding per share attributable to common stockholders, basic and diluted	55,308,273	

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net loss	\$ (17,234)	\$ (5,083)	\$ (26,270)	\$ (7,515)
Adjustments:				
Interest Expense	946	1,038	1,897	2,069
Taxes	—	—	—	—
Depreciation & Amortization	423	103	757	220
EBITDA	\$ (15,865)	\$ (3,942)	\$ (23,616)	\$ (5,226)
Share-based compensation expense	1,963	875	3,372	1,277
Debt extinguishment loss	4,483	—	4,483	—
Adjusted EBITDA	\$ (9,419)	\$ (3,067)	\$ (15,761)	\$ (3,949)

