

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 5, 2021

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)

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

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 5, 2021, Treace Medical Concepts, Inc. issued a press release regarding its financial results for the quarter ended June 30, 2021. 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.

Exhibit No.	Description
99.1	Press Release of Treace Medical Concepts, Inc. issued on August 5, 2021
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 5, 2021

By: /s/ Mark L. Hair

Mark L. Hair
Chief Financial Officer



Treace Medical Concepts Reports Second Quarter 2021 Financial Results

PONTE VEDRA, Fla. – August 5, 2021—Treace Medical Concepts, Inc. (“Treace” or the “Company”) (NasdaqGS: TMCI), a commercial-stage orthopaedic medical device company driving a paradigm shift in the surgical treatment of *Hallux Valgus* (commonly known as bunions), today reported financial results for the second quarter ended June 30, 2021.

Recent Highlights:

- Revenue of \$20.7 million, a 167% increase over the same period last year
- Gross margin of 80.9%, an increase of 780 basis points from the same period last year
- Interim results from ALIGN3D™ clinical study demonstrating positive radiographic and patient-reported outcomes starting at 6 weeks and maintained at 12 months

“We are pleased to announce continued strength in our business, with growth in the second quarter led by increasing surgeon utilization and steady gains in our customer base supported by our expanding direct sales channel” said John T. Treace, CEO, Founder and Board Member of Treace. “While the return to pre-pandemic levels may not be linear, we continue to believe we are well-positioned to drive continued market penetration of our Lapiplasty® system, with comprehensive strategies and offerings that include a body of clinical evidence demonstrating consistent, reliable correction and low recurrence rates.”

Second Quarter 2021 Financial Results

Revenue for the second quarter of 2021 was \$20.7 million, representing an increase of 167% compared to \$7.7 million in the second quarter of 2020. The increase was driven by an increased number of Lapiplasty® procedure kits sold and an expanded customer base. Revenues during the 2020 second quarter were severely impacted by the COVID-19 pandemic, including the government-mandated restrictions on elective procedures.

Gross profit for the second quarter of 2021 was \$16.7 million, compared to a gross profit of \$5.7 million in the second quarter of 2020. Gross margin increased to 80.9% in the second quarter of 2021, compared to 73.1% in the second quarter of 2020. Gross margin expansion was the result of an increased number of Lapiplasty® procedure kits sold and a higher average blended ASP. Gross margin for the 2020 period also reflects pandemic-related disruptions.

Total operating expenses were \$20.8 million in the second quarter of 2021, including sales and marketing (S&M) expenses of \$14.0 million, research and development (R&D) expenses of \$2.4 million, and general and administrative (G&A) expenses of \$4.3 million. This compared to total operating expenses of \$7.2 million, including S&M expenses of \$4.8 million, R&D expenses of \$1.0 million, and G&A expenses of \$1.4 million in the second quarter of 2020. Expenses in the second quarter of 2020 reflect cost-reduction initiatives and the effect of shelter-in-place orders as a result of the COVID-19 pandemic.

Second quarter net loss was (\$5.1) million, or (\$0.10) per share, compared to net loss of (\$2.1) million, or (\$0.06) per share, for the same period of 2020.

Cash and cash equivalents were \$119.6 million as of June 30, 2021. This includes cash proceeds of \$107.6 million from the Company’s initial public offering that closed in April 2021.

Financial Outlook

Treace now expects revenue for the full year 2021 to range from \$90 million to \$95 million, which represents approximately 57% to 65% growth over the Company's fiscal year 2020 revenue. Previous revenue expectation was \$87 million to \$92 million.

Webcast and Conference Call Details

Treace will host a conference call today, August 5, 2021, at 4:30 p.m. ET to discuss its second quarter 2021 financial results. The dial-in numbers are (888) 708-0264 for domestic callers or (720) 405-2122 for international callers, followed by Conference ID: 9779815. 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 being 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 could 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 the key financial metrics 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 expectations regarding the recovery of the market to pre-pandemic levels; the Company's belief that it is well positioned to drive continued market penetration of the Lapiplasty® system; and the Company's expected revenue for full year 2021. 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. 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, 2021 are not necessarily indicative of our operating results for any future periods.

About Treace Medical Concepts

Treace Medical Concepts is a commercial-stage orthopaedic medical device company with the goal of advancing the standard of care for the surgical management of bunion deformities. 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 Correction™ 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 getting patients back to their active lives quickly.

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.
Condensed Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended June 30,		2021	Six Mo Je
	2021	2020		
Revenue	\$	20,654	\$ 7,739	\$ 39,361
Cost of goods sold		3,944	2,085	7,271
Gross profit		16,710	5,654	32,090
Operating expenses				
Sales and marketing		14,010	4,789	26,158
Research and development		2,422	982	4,290
General and administrative		4,329	1,401	7,095
Total operating expenses		20,761	7,172	37,543
Loss from operations		(4,051)	(1,518)	(5,453)
Interest and other income, net		6	3	7
Interest expense		(1,038)	(458)	(2,069)
Other expense, net		(1,032)	(455)	(2,062)
Net loss and comprehensive loss		(5,083)	(1,973)	(7,515)
Convertible preferred stock cumulative and undeclared dividends		(39)	(159)	(196)
Net loss attributable to common stockholders	\$	(5,122)	\$ (2,132)	\$ (7,711)
Net loss per share attributable to common stockholders, basic and diluted	\$	(0.10)	\$ (0.06)	\$ (0.18)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted		49,187,285	37,068,288	43,556,107

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

	June 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	\$ 119,621	\$ 18,079
Accounts receivable, net of allowance for doubtful accounts of \$271 and \$446 as of June 30, 2021 and December 31, 2020, respectively	10,047	14,486
Inventories	7,643	7,820
Prepaid expenses and other current assets	3,512	593
Total current assets	140,823	40,978
Property and equipment, net	1,475	829
Total assets	\$ 142,298	\$ 41,807
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 2,921	\$ 2,265
Accrued liabilities	1,957	1,848
Accrued commissions	2,553	3,513
Accrued compensation	2,434	2,183
Short-term debt	-	1,788
Total current liabilities	9,865	11,597
Derivative liability on term loan	245	245
Long-term debt, net of discount of \$723 and \$811 as of June 30, 2021 and December 31, 2020, respectively	29,277	29,189
Total liabilities	39,387	41,031
Commitments and contingencies (Note 7)		
Stockholders' equity		
Series A convertible preferred stock, \$0.001 par value, 0 shares authorized and 0 shares issued and outstanding as of June 30, 2021; 6,687,500 shares authorized and 6,687,475 shares issued and outstanding as of December 31, 2020, respectively; liquidation value of \$0 and \$8,000 as of June 30, 2021 and December 31, 2020, respectively	—	7,935
Preferred stock, \$0.001 par value, 5,000,000 shares authorized; 0 shares issued and outstanding as of June 30, 2021; 0 shares authorized, issued and outstanding as of December 31, 2020	—	—
Common stock, \$0.001 par value, 300,000,000 shares authorized; 52,755,981 issued and outstanding as of June 30, 2021; 66,875,000 shares authorized, 37,366,865 issued and outstanding as of December 31, 2020	45	28
Common stock Class B, \$0.001 par value, 0 shares authorized, issued and outstanding as of June 30, 2021; 1,000,000 shares authorized and 0 shares issued and outstanding as of December 31, 2020	—	—
Additional paid-in capital	131,734	14,166
Accumulated deficit	(28,868)	(21,353)
Total stockholders' equity	102,911	776
Total liabilities and stockholders' equity	\$ 142,298	\$ 41,807

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

	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020
Cash flows from operating activities		
Net loss	\$ (7,515)	\$ (3,580)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization expense	220	667
(Recovery) Provision for allowance for doubtful accounts	(72)	228
Share-based compensation expense	1,277	457
Amortization of debt issuance costs	88	118
Provision for inventory obsolescence	88	412
Net changes in operating assets and liabilities:		
Accounts Receivable	4,511	3,532
Inventory	89	(2,590)
Prepaid expenses and other assets	(2,919)	178
Accounts payable	656	1,071
Accrued liabilities	(600)	(3,233)
Net cash used in operating activities	(4,177)	(2,740)
Cash flows from investing activities		
Purchases of property and equipment	(866)	(923)
Net cash used in investing activities	(866)	(923)
Cash flows from financing activities		
Proceeds from SBA Loan	—	1,788
Repayments on SBA 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	—
Proceeds from exercise of employee stock options	763	41
Net cash provided by financing activities	106,585	1,829
Net increase (decrease) in cash and cash equivalents	101,542	(1,834)
Cash and cash equivalents at beginning of period	18,079	12,139
Cash and cash equivalents at end of period	\$ 119,621	\$ 10,305
Supplemental disclosure of cash flow information:		
Cash paid for interest	2,917	—
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 EBITDA

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net loss	\$ (5,083)	\$ (1,973)	\$ (7,515)	\$ (
Adjustments:				
Interest	1,032	455	2,062	
Taxes	-	-	-	-
Depreciation & Amortization	124	364	220	
Non-cash compensation expense	875	248	1,277	
Adjusted EBITDA	<u>\$ (3,052)</u>	<u>\$ (906)</u>	<u>\$ (3,956)</u>	<u>\$ (</u>