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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**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 25, 2021**

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**TREACE MEDICAL CONCEPTS, INC.**

(Exact name of registrant as specified in its charter)

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**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**

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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.

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**Item 2.02. Results of Operations and Financial Condition.**

On May 25, 2021, Treace Medical Concepts, Inc. issued a press release regarding its financial results for the quarter ended March 31, 2021. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

This information, including the exhibit hereto, 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	<a href="#">Press Release of Treace Medical Concepts, Inc. dated May 25, 2021</a>

**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: May 25, 2021

By: /s/ Mark L. Hair

Mark L. Hair

Chief Financial Officer



### Treace Medical Concepts Reports First Quarter 2021 Financial Results

PONTE VEDRA, Fla. – May 25, 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 first quarter ended March 31, 2021.

#### Recent Highlights:

- Revenue of \$18.7 million, a 66% increase over the same period last year
- Gross margin of 82.2%, an increase of 340 basis points from the same period last year
- Completed initial public offering with \$107.1 million in proceeds, net of underwriting discounts, commissions and offering costs
- 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 report a solid start to 2021, with strength led by our expanding direct sales channel and surgeon and patient education initiatives, particularly as we exited the first quarter,” said John T. Treace, CEO, Founder and Board Member of Treace. “As we navigate toward a potential return to normalcy through 2021, we believe we are well positioned to drive continued market penetration of our Lapiplasty® system leveraging a comprehensive set of tools and capabilities that include a body of clinical evidence demonstrating consistent, reliable correction and low recurrence rates.”

#### First Quarter 2021 Financial Results

Revenue for the first quarter of 2021 was \$18.7 million, representing an increase of 66.2% compared to \$11.3 million in the first quarter of 2020. The increase was driven by an increased number of Lapiplasty Procedure Kits sold and an expanded customer base.

Gross profit for the first quarter of 2021 was \$15.4 million, compared to a gross profit of \$8.9 million in the first quarter of 2020. Gross margin increased to 82.2% in the first quarter of 2021, compared to 78.8% in the first quarter of 2020. Gross margin expansion was the result of increased number of Lapiplasty® Procedure Kits sold and a higher average blended ASP.

Total operating expenses were \$16.8 million in the first quarter of 2021, including sales and marketing (S&M) expenses of \$12.1 million, research and development (R&D) expenses of \$1.9 million, and general and administrative expenses (G&A) expenses of \$2.8 million. This compared to total operating expenses of \$10.1 million, including S&M expenses of \$7.3 million, R&D expenses of \$1.4 million, and G&A expenses of \$1.3 million in the first quarter of 2020.

First quarter net loss was (\$2.6) million, or (\$0.07) per share, compared to net loss of (\$1.8) million, or (\$0.05) per share, for the same period of 2020.

Cash and cash equivalents were \$16.2 million as of March 31, 2021. This excludes cash proceeds of \$118.3 million before underwriting discounts, commissions and offering costs from the Company’s initial public offering that closed in April 2021.

## **Financial Outlook**

Treace Medical Concepts projects revenue for the full year 2021 to range from \$87 million to \$92 million, which represents approximately 52% to 60% growth over the Company's fiscal year 2020 revenue.

## **Webcast and Conference Call Details**

Treace Medical Concepts will host a conference call today, May 25, 2021, at 4:30 p.m. ET to discuss its first quarter 2021 financial results. The dial-in numbers are (833) 730-3977 for domestic callers or (720) 405-2122 for international callers, followed by Conference ID: 1157038. 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 allows 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 that the market will continue to recover as 2021 unfolds; the Company's belief that it is well positioned to drive continued market penetration of the Lapiplasty system; and the Company's estimated revenue for the remainder of 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 March 31, 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.

To learn more about Lapiplasty® 3D Bunion Correction™, or find a Lapiplasty® surgeon in your area, please visit: [www.AlignMyToe.com](http://www.AlignMyToe.com) or [www.Lapiplasty.com](http://www.Lapiplasty.com).

#### **Contacts:**

##### **Treace Medical Concepts**

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Chief Financial Officer  
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(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 March 31,	
	2021	2020
Revenue	\$ 18,707	\$ 11,256
Cost of goods sold	3,327	2,389
Gross profit	15,380	8,867
Operating expenses		
Sales and marketing	12,148	7,338
Research and development	1,868	1,433
General and administrative	2,766	1,295
Total operating expenses	16,782	10,066
Loss from operations	(1,402)	(1,199)
Interest and other income, net	1	33
Interest expense	(1,031)	(441)
Other income (expense), net	(1,030)	(408)
Net loss and comprehensive loss	(2,432)	(1,607)
Convertible preferred stock cumulative and undeclared dividends	(158)	(158)
Net loss attributable to common stockholders	\$ (2,590)	\$ (1,765)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.07)	\$ (0.05)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	37,854,687	37,052,294

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

	<u>March 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 16,218	\$ 18,079
Accounts receivable, net of allowance for doubtful accounts of \$329 and \$446 as of March 31, 2021 and December 31, 2020, respectively	10,793	14,486
Inventories	7,370	7,820
Prepaid expenses and other current assets	2,072	593
<b>Total current assets</b>	<u>36,453</u>	<u>40,978</u>
Property and equipment, net	929	829
<b>Total assets</b>	<u>\$ 37,382</u>	<u>\$ 41,807</u>
<b>Liabilities, and Stockholders' Equity</b>		
Current liabilities		
Accounts payable	\$ 1,269	\$ 2,265
Accrued liabilities	2,821	1,848
Accrued commissions	2,716	3,513
Accrued compensation	1,782	2,183
Short-term debt	—	1,788
<b>Total current liabilities</b>	<u>8,588</u>	<u>11,598</u>
Derivative liability on term loan	245	245
Long-term debt, net of discount of \$767 and \$811 as of March 31, 2021 and December 31, 2020, respectively	29,233	29,189
<b>Total liabilities</b>	<u>38,066</u>	<u>41,031</u>
Commitments and contingencies (Note 7)		
Stockholders' (deficit) equity		
Series A preferred stock, \$0.001 par value, 6,687,500 shares authorized; 6,687,475 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively; liquidation value of \$8,000 as of March 31, 2021 and December 31, 2020, respectively	7,935	7,935
Common stock Class A, \$0.001 par value, 66,875,000 shares authorized as of March 31, 2021 and December 31, 2020, respectively; 38,057,416 shares and 37,366,865 issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	30	28
Common stock Class B, \$0.001 par value, 1,000,000 shares authorized as of March 31, 2021 and December 31, 2020, respectively; no shares issued and outstanding as of March 31, 2021 and December 31, 2020	—	—
Additional paid-in capital	15,136	14,166
Accumulated deficit	(23,785)	(21,353)
<b>Total stockholders' (deficit) equity</b>	<u>(684)</u>	<u>776</u>
<b>Total liabilities, and stockholders' (deficit) equity</b>	<u>\$ 37,382</u>	<u>\$ 41,807</u>



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

	<b>Three Months Ended March 31,</b>	
	<b>2021</b>	<b>2020</b>
<b>Cash flows from operating activities</b>		
Net loss	\$ (2,432)	\$ (1,607)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization expense	117	304
(Recovery) Provision for allowance for doubtful accounts	(77)	73
Share-based compensation expense	402	209
Amortization of debt issuance costs	43	65
(Recovery) Provision for inventory obsolescence	(27)	53
Net changes in operating assets and liabilities:		
Accounts Receivable	3,769	3,807
Inventory	478	(1,360)
Prepaid expenses and other assets	(379)	147
Accounts payable	(1,173)	1,465
Accrued liabilities	(1,167)	(4,051)
Net cash used in operating activities	<u>(446)</u>	<u>(895)</u>
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(196)	(674)
Net cash used in investing activities	<u>(196)</u>	<u>(674)</u>
<b>Cash flows from financing activities</b>		
Repayment on SBA Loan	(1,788)	—
Debt issuance costs	—	(8)
Proceeds from exercise of employee stock options	569	41
Net cash (used in) provided by financing activities	<u>(1,219)</u>	<u>33</u>
Net decrease in cash and cash equivalents	<u>(1,861)</u>	<u>(1,536)</u>
Cash and cash equivalents at beginning of year	18,079	12,139
Cash and cash equivalents at end of year	<u>\$ 16,218</u>	<u>\$ 10,603</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	\$ 1,945	—
<b>NONCASH FINANCING ACTIVITIES:</b>		
Unpaid offering costs included in accounts payable and accrued liabilities	\$ 1,118	—

**Treace Medical Concepts, Inc.**  
**Reconciliation of GAAP Net Loss to Adjusted EBITDA**

	<u>Three Months Ended March 31, 2021</u>	<u>Three Months Ended March 31, 2020</u>
<b>Net Loss</b>	<b>\$ (2,432)</b>	<b>\$ (1,607)</b>
Depreciation & Amortization expense	96	303
Stock based compensation expense	402	209
Interest income/expense	1,030	408
<b>Adjusted EBITDA</b>	<b>\$ (903)</b>	<b>\$ (687)</b>