

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): November 4, 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.

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

On November 4, 2021, Treace Medical Concepts, Inc. issued a press release regarding its financial results for the quarter ended September 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.**

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release of Treace Medical Concepts, Inc. issued on November 4, 2021</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

**SIGNATURES**

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**TREACE MEDICAL CONCEPTS, INC.**

Date: November 4, 2021

By: /s/ Mark L. Hair  
Mark L. Hair  
Chief Financial Officer

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

PONTE VEDRA, Fla. – November 4, 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 third quarter ended September 30, 2021.

#### Recent Highlights:

- Revenue of \$21.6 million, a 52% increase over the same period last year and a 4.7% increase sequentially
- Gross margin of 80.4%, an increase of 80 basis points from the same period last year
- Commercial launch of Adductoplasty™ System, a comprehensive set of implants and instrumentation designed for reproducible midfoot correction
- Additional U.S. patent grant on instrumented bunion correction, directed generally to methods of performing a bunion surgery to correct a first metatarsal alignment
- New interim data from ALIGN3D™ clinical study, presented at 2021 American Orthopaedic Foot & Ankle Society annual meeting, demonstrating continued positive radiographic and patient-reported outcomes starting at 6 weeks and maintained at 24 months following the Lapiplasty® procedure. Low recurrence rate also maintained, with 0.9% (1 out of 104 patients) observed at 12 months post surgery
- First patient treated in Mini3D™ Lapiplasty® clinical study evaluating patient outcomes using the Lapiplasty® Mini-Incision™ System
- Appointed two new members to the Board of Directors

“In the third quarter we saw steady and encouraging progress across multiple initiatives. Despite pandemic-related headwinds, we posted a 52% revenue increase compared to year ago levels, launched a new and complementary midfoot correction Adductoplasty™ System, and treated our first patient in our Mini3D™ clinical study using our Lapiplasty® Mini-Incision™ System. Further, key business metrics, including surgeon utilization, customer engagement, and direct sales channel contributions, continue to trend favorably,” said John T. Treace, CEO, Founder and Board Member of Treace. “We are focused on our execution and believe we are well-positioned to drive market penetration of our Lapiplasty® System, supported by a comprehensive set of strategies and offerings, including a growing body of clinical evidence demonstrating reproducible outcomes with low recurrence rates.”

#### Third Quarter 2021 Financial Results

Revenue for the third quarter of 2021 was \$21.6 million, representing an increase of 52% compared to \$14.3 million in the third 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 third quarter of 2021 was \$17.4 million, compared to a gross profit of \$11.4 million in the third quarter of 2020. Gross margin increased to 80.4% in the third quarter of 2021, compared to 79.6% in the third quarter of 2020. Gross margin expansion was the result of improved absorption on an increased number of Lapiplasty® procedure kits sold and a higher blended average selling price.

Total operating expenses were \$22.8 million in the third quarter of 2021, including sales and marketing (S&M) expenses of \$16.0 million, research and development (R&D) expenses of \$2.5 million, and general and administrative (G&A) expenses of \$4.3 million. This compared to total operating expenses of \$11.4 million, including S&M expenses of \$8.1 million, R&D expenses of \$1.5 million, and G&A expenses of

\$1.8 million in the third quarter of 2020. Expenses in the third quarter of 2021 reflect increased spending on marketing initiatives, patient outreach and additions to our sales organization. Third quarter net loss was (\$6.4) million, or (\$0.12) per share, compared to net loss of (\$2.8) million, or (\$0.08) per share, for the same period of 2020.

Cash and cash equivalents were \$109.5 million as of September 30, 2021.

#### **Financial Outlook**

For the full year 2021, Treace is reaffirming revenue guidance to be in the range of \$90 million to \$95 million, which represents approximately 57% to 65% growth over the Company's 2020 revenue.

#### **Webcast and Conference Call Details**

Treace will host a conference call today, November 4, 2021, at 4:30 p.m. ET to discuss its third quarter 2021 financial results. The dial-in numbers are (800) 447-0521 for domestic callers or (847) 413-3238 for international callers, followed by Conference ID: 50243277. 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 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

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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 September 30, 2021 are not necessarily indicative of our operating results for any future periods.

**About Treace Medical Concepts**

Treace Medical Concepts, Inc. is a commercial-stage orthopaedic medical device 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 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 helping patients get back to their active lifestyles. Treace recently expanded its offering with the Adductoplasty™ Midfoot Correction System, designed for reproducible correction of the midfoot which could provide further support to hallux valgus patients.

**Contacts:**

**Treace Medical Concepts**

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**Investors:**

**Gilmartin Group**

Lynn Lewis or Vivian Cervantes  
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**Treace Medical Concepts, Inc.**  
**Condensed Statements of Operations and Comprehensive Loss**  
**(in thousands, except share and per share amounts)**  
**(unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue	\$ 21,619	\$ 14,266	\$ 60,980	\$ 33,260
Cost of goods sold	4,248	2,911	11,519	7,386
Gross profit	17,371	11,355	49,461	25,874
Operating expenses				
Sales and marketing	15,984	8,103	42,142	20,229
Research and development	2,537	1,511	6,827	3,925
General and administrative	4,310	1,804	11,405	4,500
Total operating expenses	22,831	11,418	60,374	28,654
Loss from operations	(5,460)	(63)	(10,913)	(2,780)
Interest and other income (expense), net	5	(1,784)	12	(1,748)
Interest expense	(963)	(808)	(3,032)	(1,707)
Other expense, net	(958)	(2,592)	(3,020)	(3,455)
Net loss and comprehensive loss	(6,418)	(2,655)	(13,933)	(6,235)
Convertible preferred stock cumulative and undeclared dividends	—	(161)	(196)	(479)
Net loss attributable to common stockholders	\$ (6,418)	\$ (2,816)	\$ (14,129)	\$ (6,714)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.12)	\$ (0.08)	\$ (0.30)	\$ (0.18)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	52,766,150	37,069,294	46,603,487	37,063,446



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

	September 30, 2021	December 2020
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 109,459	\$
Accounts receivable, net of allowance for doubtful accounts of \$282 and \$446 as of September 30, 2021 and December 31, 2020, respectively	11,795	
Inventories	10,351	
Prepaid expenses and other current assets	3,760	
<b>Total current assets</b>	<b>135,365</b>	
Property and equipment, net	2,225	
<b>Total assets</b>	<b>\$ 137,590</b>	<b>\$</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accounts payable	\$ 2,442	\$
Accrued liabilities	2,824	
Accrued commissions	3,021	
Accrued compensation	2,436	
Short-term debt	-	
<b>Total current liabilities</b>	<b>10,723</b>	
Derivative liability on term loan	173	
Long-term debt, net of discount of \$679 and \$811 as of September 30, 2021 and December 31, 2020, respectively	29,321	
<b>Total liabilities</b>	<b>40,217</b>	
Commitments and contingencies		
Stockholders' equity		
Series A convertible preferred stock, \$0.001 par value, 0 shares authorized and 0 shares issued and outstanding as of September 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 September 30, 2021 and December 31, 2020, respectively	—	
Preferred stock, \$0.001 par value, 5,000,000 shares authorized; 0 shares issued and outstanding as of September 30, 2021; 0 shares authorized, issued and outstanding as of December 31, 2020	—	
Common stock, \$0.001 par value, 300,000,000 shares authorized; 52,772,969 issued and outstanding as of September 30, 2021; 66,875,000 shares authorized, 37,366,865 issued and outstanding as of December 31, 2020	45	
Common stock Class B, \$0.001 par value, 0 shares authorized, issued and outstanding as of September 30, 2021; 1,000,000 shares authorized and 0 shares issued and outstanding as of December 31, 2020	—	
Additional paid-in capital	132,614	
Accumulated deficit	(35,286)	
<b>Total stockholders' equity</b>	<b>97,373</b>	
<b>Total liabilities and stockholders' equity</b>	<b>\$ 137,590</b>	<b>\$</b>

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

	Nine Months Ended September 30, 2021	Nine Months Ended S 2020
<b>Cash flows from operating activities</b>		
Net loss	\$ (13,933)	\$
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization expense	409	
(Recovery) Provision for allowance for doubtful accounts	(56)	
Share-based compensation expense	2,116	
Amortization of debt issuance costs	133	
Gain on fair value adjustment to derivative liability	(72)	
Provision for inventory obsolescence	179	
Loss on early settlement of debt	—	
<b>Net changes in operating assets and liabilities:</b>		
Accounts Receivable	2,747	
Inventory	(2,710)	
Prepaid expenses and other assets	(3,168)	
Accounts payable	177	
Accrued liabilities	737	
Net cash used in operating activities	<u>(13,441)</u>	
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	<u>(1,805)</u>	
Net cash used in investing activities	<u>(1,805)</u>	
<b>Cash flows from financing activities</b>		
Proceeds from interest bearing debt	—	
Payments on interest bearing debt	—	
Proceeds from SBA Loan	—	
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	
Debt issuance costs	—	
Proceeds from exercise of employee stock options	804	
Net cash provided by financing activities	<u>106,626</u>	
Net increase in cash and cash equivalents	<u>91,380</u>	
Cash and cash equivalents at beginning of period	18,079	
Cash and cash equivalents at end of period	<u>\$ 109,459</u>	<u>\$</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	2,917	
<b>NONCASH FINANCING ACTIVITIES:</b>		
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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss	\$ (6,418)	\$ (2,655)	\$ (13,933)	\$ (6,418)
Adjustments:				
Interest	\$ 958	\$ 2,592	\$ 3,020	\$ 3,020
Taxes	\$ -	\$ -	\$ -	\$ -
Depreciation & Amortization	\$ 189	\$ 335	\$ 409	\$ 1,116
Non-cash compensation expense	\$ 839	\$ 125	\$ 2,116	\$ -
Adjusted EBITDA	\$ (4,432)	\$ 397	\$ (8,388)	\$ (1,282)