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 5, 2024

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)

100 Palmetto Park Place

	(Address o	Ponte Vedra, Florida 32081 of principal executive offices, including Zip Co	ode)					
	Registrant's teleph	none number, including area code: (9	004) 373-5940					
Check the a following p	appropriate box below if the Form 8-K filing is interovisions:	ended to simultaneously satisfy the fili	ng obligation of the registrant under any of the					
	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 A	Act (17 CFR 240.13e-4(c))					
	Securities reg	gistered pursuant to Section 12(b) of	the Act:					
	Title of each class	Trading Symbol(s)	Name of each exchange on which registered					
Commo	on Stock, \$0.001 par value per share	TMCI	The Nasdaq Global Select Market					
-	check mark whether the registrant is an emerging Rule 12b-2 of the Securities Exchange Act of 193		05 of the Securities Act of 1933 (§230.405 of this					
			Emerging growth company \Box					
	ing growth company, indicate by check mark if th inancial accounting standards provided pursuant to		extended transition period for complying with any new					

Item 2.02 Results of Operations and Financial Condition.

On November 5, 2024, Treace Medical Concepts, Inc. (the "Company") issued a press release regarding its financial results for the quarter ended September 30, 2024. A copy of the press release is furnished as <u>Exhibit 99.1</u> to this Current Report on Form 8-K and is incorporated by reference herein.

This information furnished under this Item 2.02, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release of Treace Medical Concepts, Inc. issued on November 5, 2024
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: November 5, 2024 By: /s/ Mark L. Hair

Mark L. Hair

Chief Financial Officer



Treace Medical Concepts Reports Third Quarter 2024 Financial Results

PONTE VEDRA, Fla. – November 5, 2024 – Treace Medical Concepts, Inc. ("Treace" or the "Company") (NasdaqGS: TMCI), a medical technology company driving a fundamental shift in the surgical treatment of bunions and related midfoot deformities through its flagship Lapiplasty® and Adductoplasty® Procedures, today reported financial results for the third quarter ended September 30, 2024.

Recent Highlights

- Revenue of \$45.1 million in third quarter 2024 increased 11% over same period in 2023
- Third quarter 2024 net loss was (\$15.4) million compared to (\$17.5) million for same period in 2023. Adjusted EBITDA loss improved 45% to (\$5.1) million in the third quarter 2024 compared to (\$9.2) million for the same period in 2023
- Announces first entry into high volume osteotomy market with Nanoplasty[™] 3D Minimally Invasive Bunion Correction[™] Procedure
 and reaffirms plan to release second minimally invasive technology platform later in the fourth quarter
- Focused R&D innovation pipeline is now poised to significantly expand technology and procedure offerings through 2025 and beyond
- Files patent infringement and unfair competition suit to protect Lapiplasty® bunion technology. Expanded patent portfolio now includes 67 granted U.S. patents, 24 granted patents outside of the U.S. and 85 pending U.S. patent applications

"Our third quarter results reflect our focused execution to drive growth in the business while steadily improving our operating leverage. In addition, we are excited to announce the market release of Nanoplasty™ 3D MIS System, our first entry into the osteotomy market," said John T. Treace, CEO and Founder of Treace. "We believe this innovative new system, combined with our market leading Lapiplasty®, Adductoplasty® and robust pipeline of future technology and procedure offerings, will further drive penetration into the overall bunion market and continue to expand our surgeon customer base through 2025 and beyond."

Third Quarter 2024 Financial Results

Revenue for the third quarter of 2024 was \$45.1 million, representing an increase of 11% compared to \$40.8 million in the third quarter of 2023. The increase was driven by product mix shift that resulted from increased adoption of newer technologies and increased sales of ancillary products used in bunion cases and an increase in active surgeons.

Gross profit for the third quarter of 2024 was \$36.1 million compared to a gross profit of \$32.8 million in the third quarter of 2023. Gross margin totaled 80.1% in the third quarter of 2024, compared to 80.4% in the third quarter of 2023, primarily due to an increase in inventory provisions and a shift in product mix, partially offset by lower royalty rates.

Total operating expenses were \$51.3 million in the third quarter of 2024, compared to total operating expenses of \$50.6 million in the third quarter of 2023. Increased operating expenses in the third quarter of 2024 reflect increased share-based compensation expense, investments in product innovation, and support for other corporate initiatives.

Third quarter 2024 net loss was (\$15.4) million, or (\$0.25) per share, compared to (\$17.5) million, or (\$0.28) per share, for the same period in 2023. Adjusted EBITDA loss was (\$5.1) million in the third quarter of 2024 compared to a loss of (\$9.2) million for the same period in 2023. See below for additional information and a reconciliation of non-GAAP financial information.

Cash, cash equivalents, and marketable securities totaled \$82.8 million as of September 30, 2024. The Company believes it has sufficient balance sheet strength and flexibility to continue effectively executing on its strategic investments and growth initiatives for the foreseeable future.

Financial Outlook

The Company is revising full-year 2024 revenue guidance to \$204 million to \$211 million, representing growth of 9% to 13%, compared to full-year 2023. This compares to previous guidance of \$201 million to \$211 million.

The Company continues to expect our Adjusted EBITDA loss to decrease by approximately 50% compared to full-year 2023.*

* A reconciliation of Adjusted EBITDA to GAAP net loss on a forward-looking basis is not available without unreasonable efforts due to the high variability, complexity and low visibility with respect to the items excluded from this non-GAAP measure.

Webcast and Conference Call Details

Treace will host a conference call today, November 5, 2024, at 4:30 p.m. ET to discuss its third quarter 2024 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 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, interest income, interest expense, taxes, share-based compensation expense, acquisition-related costs, restructuring costs, customer credit loss, and debt extinguishment loss. Non-GAAP financial measures such as Adjusted EBITDA are presented in addition to, and not as a substitute for, or superior to, financial measures calculated in accordance with GAAP. Management uses 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 helps to identify underlying trends in the Company's business that may otherwise be masked by the effect of the income and expenses and other items that it excludes in its calculation of Adjusted EBITDA. Accordingly, the Company believes this non-GAAP financial measure 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 key financial metrics used by the Company's management in their financial and operational decision-making. The Company also presents this non-GAAP financial measure because it believes investors, analysts and rating agencies consider it to be 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 income and 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. A reconciliation between GAAP and non-GAAP results is presented below.

Forward-Looking Statements

This press release and statements made during the Company's earnings call contain 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: revenue guidance and estimated revenue growth rates for full-year 2024; estimated quarterly revenue growth rates; sufficient balance sheet strength and flexibility to continue effectively executing on its strategic investments and growth initiatives for the foreseeable future; anticipated liquidity; expected rate of Adjusted EBITDA improvement; ability to effectively respond to and mitigate the impact of challenges in the current market environment, including in response to increased competition and accelerating adoption of MIS osteotomy solutions; anticipated future product launches and the timing of such product launches, including its planned 3D MIS osteotomy platforms and the number and pace of new product innovations through 2025; ability to increase its procedure volumes, expand its surgeon customer base, provide a suite of technologies to address the evolving needs of bunion surgeons and patients, and increase penetration into the overall bunion market; strategic investments supporting its market position and long-term outlook; ability to protect and enforce its intellectual property rights, including through its recently filed patent infringement and unfair competition suit; success in defending against infringement of its intellectual property by third parties, including its competitors; expected seasonality; and anticipated pace of growth in the foot and ankle market . 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 its Annual Report on Form 10-K for the year ended December 31, 2023, which was filed with the SEC on February 27, 2024, and its subsequent SEC filings. 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 guarter ended September 30, 2024 are not necessarily indicative of its operating results for any future periods.

Internet Posting of Information

Treace routinely posts information that may be important to investors in the "Investor Relations" section of its website at www.treace.com. The Company encourages investors and potential investors to consult the Treace website regularly for important information about Treace.

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 and related midfoot deformities. Bunions are complex 3-dimensional deformities that originate from an unstable joint in the middle of the foot and affect approximately 67 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 three 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. To further support the needs of bunion patients, Treace has introduced its Adductoplasty[®] Midfoot Correction System, designed for reproducible surgical correction of midfoot deformities. The Company continues to expand its footprint in the foot and ankle market with the introduction of its SpeedPlate[™] Rapid Compression Implants, an innovative fixation platform with broad versatility across Lapiplasty[®] and Adductoplasty[®] procedures, as well as other common bone fusion procedures of the foot. For more information, please visit www.treace.com.

To learn more about Treace, connect with us on LinkedIn, X, Facebook and Instagram.

Contacts:

Treace Medical Concepts Mark L. Hair

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

Investors: Gilmartin Group Vivian Cervantes IR@treace.net

Treace Medical Concepts, Inc. 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,				
		2024		2023		2024		2023
Revenue	\$	45,086	\$	40,758	\$	140,649	\$	124,906
Cost of goods sold		8,954		7,998		27,862		23,712
Gross profit		36,132		32,760		112,787		101,194
Operating expenses								
Sales and marketing		32,775		33,542		110,784		100,970
Research and development		4,963		4,350		15,379		11,288
General and administrative		13,528		12,686		42,108		33,582
Total operating expenses		51,266		50,578		168,271		145,840
Loss from operations		(15,134)		(17,818)		(55,484)		(44,646)
Interest income		1,067		1,570		3,978		5,017
Interest expense		(1,313)		(1,296)		(3,942)		(3,863)
Other income, net		20		23		206		246
Other non-operating income (expense), net		(226)		297		242		1,400
Net loss	\$	(15,360)	\$	(17,521)	\$	(55,242)	\$	(43,246)
Other comprehensive income (loss)								
Unrealized gain (loss) on marketable securities	\$	217	\$	71	\$	28	\$	(121)
Comprehensive loss	\$	(15,143)	\$	(17,450)	\$	(55,214)	\$	(43,367)
Net loss per share, basic and diluted	\$	(0.25)	\$	(0.28)	\$	(0.89)	\$	(0.71)
Weighted-average shares used in computing net loss per share, basic and diluted		62,229,463		61,562,494		62,035,293		60,566,655

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

	Se	eptember 30, 2024		December 31, 2023
Assets				
Current assets				
Cash and cash equivalents	\$	12,110	\$	12,982
Marketable securities, short-term		70,689		110,216
Accounts receivable, net of allowance for credit losses of \$743 and \$980 as of September 30, 2024 and December 31, 2023, respectively		24,177		38,063
Inventories		43,611		29,245
Prepaid expenses and other current assets		7,015		7,853
Total current assets		157,602		198,359
Property and equipment, net		25,168		22,298
Intangible assets, net of accumulated amortization of \$1,188 and \$475 as of September 30, 2024 and December 31, 2023, respectively		8,312		9,025
Goodwill		12,815		12,815
Operating lease right-of-use assets		8,569		9,264
Other non-current assets		458		146
Total assets	\$	212,924	\$	251,907
Liabilities and Stockholders' Equity		,	÷	- ,
Current liabilities				
Accounts payable	\$	18,649	\$	11,835
Accrued liabilities		8,098		10,458
Accrued commissions		5,347		10,759
Accrued compensation		5,598		7,549
Other liabilities		571		4,432
Total current liabilities		38,263		45,033
Long-term debt, net of discount of \$769 and \$992 as of September 30, 2024 and December 31, 2023, respectively		53,231		53,008
Operating lease liabilities, net of current portion		16,487		15,891
Other long-term liabilities		37		37
Total liabilities		108,018		113,969
Commitments and contingencies (Note 7)				
Stockholders' equity				
Preferred stock, \$0.001 par value, 5,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 0 shares issued and outstanding as of September 30, 2024 and December 31, 2023		_		_
Common stock, \$0.001 par value, 300,000,000 shares authorized; 62,294,975 and 61,749,654 issued, and 62,275,371 and 61,749,654 outstanding as of September 30, 2024 and December 31, 2023,				
respectively		62		62
Additional paid-in capital		294,392		271,973
Accumulated deficit		(189,489)		(134,247)
Accumulated other comprehensive (loss) income		191		163
Treasury stock, at cost; 19,604 and 1,218 shares as of September 30, 2024 and December 31, 2023, respectively		(250)		(13)
Total stockholders' equity		104,906		137,938
Total liabilities and stockholders' equity	\$	212,924	\$	251,907

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

	Nine Months Ended September 30,		aber 30,	
		2024		2023
Cash flows from operating activities				
Net loss	\$	(55,242)	\$	(43,246)
Adjustments to reconcile net loss to net cash used in operating activities				
Depreciation and amortization expense		6,182		3,583
Provision for allowance for credit losses		2,381		79
Share-based compensation expense		22,048		11,480
Non-cash lease expense		607		1,868
Amortization of debt issuance costs		223		223
Accretion (amortization) of discount (premium) on marketable securities, net		(918)		(1,031)
Other, net		180		164
Net changes in operating assets and liabilities, net of acquisitions				
Accounts receivable		11,505		4,121
Inventory		(14,366)		(9,915)
Prepaid expenses and other assets		838		(1,028)
Other non-current assets		(312)		_
Operating lease liabilities		(147)		497
Accounts payable		6,814		12
Accrued liabilities		(12,753)		(1,954)
Other, net		_		40
Net cash provided by (used in) operating activities		(32,960)		(35,107)
Cash flows from investing activities				
Purchases of available-for-sale marketable securities		(52,890)		(140,075)
Sales and maturities of available-for-sale marketable securities		93,363		82,979
Purchases of property and equipment		(8,519)		(9,210)
Acquisition, net of cash acquired		_		(20,000)
Net cash provided by (used in) investing activities		31,954		(86,306)
Cash flows from financing activities				
Proceeds from issuance of common stock from public offering, net of issuance costs and underwriting discount of \$7.5 million		_		107,527
Proceeds from exercise of employee stock options		371		1,691
Taxes from withheld shares		(237)		1,071
		134		109,218
Net cash provided by (used in) financing activities	_	(872)		(12,195)
Net increase (decrease) in cash and cash equivalents				
Cash and cash equivalents at beginning of period	Φ.	12,982	ф	19,473
Cash and cash equivalents at end of period	\$	12,110	\$	7,278
Supplemental disclosure of cash flow information				
Cash paid for interest	\$	3,732	\$	3,863
Operating lease right-of-use asset and lease liability adjustment due to lease incentive	\$	88	\$	(22)
Noncash investing activities				
Unrealized (gains) losses, net on marketable securities	\$	(28)	\$	121
Unsettled marketable security purchase and payable to broker	\$		\$	(1,100)
Unsettled matured marketable security and receivable from broker	\$	_	\$	6,000

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

	Three Months Ended September 30,				 Nine Months Ended September 30,			
		2024		2023	2024		2023	
Net loss	\$	(15,360)	\$	(17,521)	\$ (55,242)	\$	(43,246)	
Adjustments:								
Interest income		(1,067)		(1,570)	(3,978)		(5,017)	
Interest expense		1,313		1,296	3,942		3,863	
Taxes		_		_	_		_	
Depreciation & Amortization		2,157		1,564	6,182		3,583	
EBITDA	\$	(12,957)	\$	(16,231)	\$ (49,096)	\$	(40,817)	
Share-based compensation expense		7,900		5,192	22,048		11,480	
Acquisition-related costs		_		1,802	1,873		2,322	
Restructuring costs ¹		_		_	964		_	
Customer credit loss ²		_		_	2,147		_	
Adjusted EBITDA	\$	(5,057)	\$	(9,237)	\$ (22,064)	\$	(27,015)	

¹ Restructuring charges primarily relate to severance payments and other post-employment benefits from a restructuring in June 2024. ² Customer credit loss consists of the write-off of accounts receivable due from a customer that filed for bankruptcy during the second quarter of 2024.