

**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): October 14, 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
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 7.01 Regulation FD Disclosure.

On October 14, 2024, Treace Medical Concepts, Inc. (the “Company”) issued a press release announcing that it had filed a lawsuit against Stryker Corporation and its subsidiary Wright Medical Technology, Inc. alleging patent infringement and unfair competition. The Company also reaffirmed its previously-stated guidance on adjusted EBITDA for 2024 and expectation to reach Adjusted EBITDA breakeven in 2025. A copy of the press release is furnished as [Exhibit 99.1](#) to this Current Report on Form 8-K and is incorporated herein by reference.

The information furnished under this Item 7.01, including Exhibit 99.1 and any documents linked in that Exhibit, 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.

Forward-Looking Statements

This Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. All statements other than statements of historical fact are forward-looking statements, including, but not limited to, the Company’s guidance on Adjusted EBITDA for 2024 and its expectation of breakeven Adjusted EBITDA in 2025. 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 Form 8-K can be found in the Risk Factors section of the Company'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.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release of Treace Medical Concepts, Inc. issued on October 14, 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: October 15, 2024

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



Treace Files Patent Infringement and Unfair Competition Suit to Protect Lapiplasty® Bunion Technology

PONTE VEDRA, Fla., October 14, 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 announced that it filed a lawsuit against Stryker Corporation and its subsidiary Wright Medical Technology, Inc. (collectively, “Stryker”) (NYSE: SYK), alleging infringement of 9 patents related to Treace’s innovative Lapiplasty® 3D Bunion Correction® technologies and unfair competition. The suit was filed in the United States District Court for the District of New Jersey, and seeks injunctive relief and damages.

“Treace Medical was the first company to develop, patent, and introduce an instrumented 3D bunion correction system, which created an entirely new segment of the US bunion market and successfully built its market presence from zero to becoming a standard of care in bunion surgery over the past ten years,” said John T. Treace, CEO and Founder of Treace. “Our patented technologies have revolutionized the field of hallux valgus treatment, delivering a new paradigm of treatment in over 100,000 surgical procedures to date. Companies such as Stryker, unfortunately, have rushed to capitalize on Treace’s pioneering research and development by launching products that, as detailed in our Complaint, infringe on Treace’s intellectual property. Moreover, we believe Stryker has also commercialized those infringing products in ways that violate competition laws.”

Mr. Treace continued, “This suit not only sends a message to competitors in the marketplace, particularly those that infringe on our intellectual property, but also reassures our shareholders that we are committed to protecting our investments in our pioneering research and technology, which drives our ability to continue to innovate solutions that benefit patients.”

“Today’s action is consistent with what we stated publicly earlier this year, namely that our strategy all along has been to assert and enforce our IP rights,” Mr. Treace said. “We also continue to expect 2024 Adjusted EBITDA to improve approximately 50% compared to full-year 2023 and to reach Adjusted EBITDA breakeven in 2025.”

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 expected rate of Adjusted EBITDA improvement in 2024 and its expectation of breakeven Adjusted EBITDA in 2025. 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.

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 the midfoot as well as its Hammertoe PEEK Fixation System designed to address hammertoe, claw toe and mallet toe 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.

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