

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): June 15, 2023

STEREOTAXIS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation)

001-36159

(Commission File Number)

94-3120386

(IRS Employer Identification No.)

710 North Tucker Boulevard, Suite 110, St. Louis, Missouri

(Address of Principal Executive Offices)

63101

(Zip Code)

(314) 678-6100

(Registrant's Telephone Number, Including Area Code)

(Former Name or Former Address, if Changed Since Last Report)

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))

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.

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, par value \$0.001 per share	STXS	NYSE American LLC

Item 8.01 Other Events

On June 15, 2023, Stereotaxis, Inc. (the “Company”) issued a press release providing an update regarding the status of the Company’s July 2022 CE Mark submission for its MAGiC catheter, a robotically-navigated magnetic ablation catheter designed to perform minimally invasive cardiac ablation procedures. A copy of the Press Release is being filed as Exhibit 99.1 hereto and is incorporated by reference herein.

Forward-Looking Statements and Additional Information

Statements are made herein or incorporated herein that are “forward-looking statements” as defined by the Securities and Exchange Commission (the “SEC”). All statements, other than statements of historical fact, included or incorporated herein that address activities, events or developments that the Company expects, believes or anticipates will or may occur in the future are forward-looking statements. These statements are not guarantees of future events or the Company’s future performance and are subject to risks, uncertainties and other important factors that could cause events or the Company’s actual performance or achievements to be materially different than those projected by the Company. For a full discussion of these risks, uncertainties and factors, the Company encourages you to read its documents on file with the SEC. Except as required by law, the Company does not intend to update or revise its forward-looking statements, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

99.1 [Stereotaxis, Inc. Press Release dated June 15, 2023.](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

STEREOTAXIS, INC.

Date: June 15, 2023

By: /s/ Kimberly R. Peery

Name: Kimberly R. Peery

Title: Chief Financial Officer



Stereotaxis to Initiate First-in-Human Trial to Support CE Mark Application of MAGiC Catheter

St. Louis, June 15, 2023 (GLOBE NEWSWIRE) – Stereotaxis (NYSE: STXS), a pioneer and global leader in surgical robotics for minimally invasive endovascular intervention, today announced that it intends to initiate a first-in-human trial to support the CE Mark submission for its MAGiC™ catheter.

Stereotaxis' MAGiC catheter is a robotically-navigated magnetic ablation catheter designed to perform minimally invasive cardiac ablation procedures. The catheter's CE Mark submission was made in July 2022 and included substantial in vivo preclinical, lab and bench data. The submission strategy was in-line with multiple historical precedents for similar ablation catheters as well as verbal feedback provided by the European Notified Body. Given evolving interpretation of recent EU Medical Device Regulation, the Notified Body has now requested clinical data to support the submission. Stereotaxis intends to complete a first-in-human study to support the MAGiC submission before the end of this year.

"We look forward to advancing the MAGiC catheter into clinical use and are working expeditiously to ensure the technology becomes available to patients and the electrophysiology community as soon as possible," said David Fischel, Stereotaxis Chairman and CEO.

"Stereotaxis continues to experience demand for its Genesis robotic system, and reiterates its expectation of double-digit revenue growth in 2023. Our strong financial position allows us to advance a robust innovation strategy through commercialization without the need for additional financing. This innovation strategy, including a highly-accessible robot with proprietary interventional catheters for use in electrophysiology and broadly across endovascular interventions, serves as the foundational product ecosystem to transform endovascular surgery with robotics."

About Stereotaxis

Stereotaxis (NYSE: STXS) is a pioneer and global leader in innovative surgical robotics for minimally invasive endovascular intervention. Its mission is the discovery, development and delivery of robotic systems, instruments, and information solutions for the interventional laboratory. These innovations help physicians provide unsurpassed patient care with robotic precision and safety, expand access to minimally invasive therapy, and enhance the productivity, connectivity, and intelligence in the operating room. Stereotaxis technology has been used to treat over 100,000 patients across the United States, Europe, Asia, and elsewhere. For more information, please visit www.stereotaxis.com

This press release includes statements that may constitute "forward-looking" statements, usually containing the words "believe", "estimate", "project", "expect" or similar expressions. Forward-looking statements inherently involve risks and uncertainties that could cause actual results to differ materially. Factors that would cause or contribute to such differences include, but are not limited to, the Company's ability to manage expenses at sustainable levels, acceptance of the Company's products in the marketplace, the effect of global economic conditions on the ability and willingness of customers to purchase its technology, competitive factors, changes resulting from healthcare policy, dependence upon third-party vendors, timing of regulatory approvals, the impact of pandemics or other disasters, and other risks discussed in the Company's periodic and other filings with the Securities and Exchange Commission. By making these forward-looking statements, the Company undertakes no obligation to update these statements for revisions or changes after the date of this release. There can be no assurance that the Company will recognize revenue related to its purchase orders and other commitments because some of these purchase orders and other commitments are subject to contingencies that are outside of the Company's control and may be revised, modified, delayed, or canceled.

Stereotaxis Contacts:

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