

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 and Exchange Act of 1934

Date of Report (Date of earliest event reported): November 20, 2025

HEARTBEAM, INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-41060
(Commission File Number)

47-4881450
(IRS Employer
Identification No.)

2118 Walsh Avenue, Suite 210
Santa Clara, CA 95050
(Address of principal executive offices, including zip code)

(408) 899-4443
(Registrant's telephone number, including area code)

Check the appropriate box below if the 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

- ☐ Written communication 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	BEAT	NASDAQ
Warrant	BEATW	NASDAQ

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 8.01: Other Events

On November 20, 2025, HeartBeam, Inc. (the "Company") received a Not Substantially Equivalent (NSE) letter from the U.S. Food and Drug Administration (FDA) related to the Company's 510(k) application for its 12-Lead Electrocardiogram (ECG) Synthesis Software.

The Company stands behind its clinical data and will be working with the FDA to come to a resolution.

In addition, the Company is evaluating launching its novel 3D ECG system, which received FDA 510(k) clearance in December 2024.

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.

HeartBeam, Inc.

Date: November 21, 2025

By: /s/ Timothy Cruickshank
Name: Timothy Cruickshank

