

**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): May 25, 2023

iRhythm Technologies, Inc.

(Exact name of Registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-37918
(Commission
File Number)

20-8149544
(I.R.S. Employer
Identification Number)

**699 8th Street, Suite 600
San Francisco, California 94103**
(Address of principal executive office) (Zip Code)

(415) 632-5700
(Registrant's telephone number, including area code)

N/A
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, Par Value \$0.001 Per Share	IRTC	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 8.01. Other Events.

On May 25, 2023, iRhythm Technologies, Inc. (the “Company”) received a warning letter from the U.S. Food and Drug Administration (the “FDA”), which resulted from the inspection of the Company’s facility located in Cypress, California that concluded in August 2022. The warning letter alleges non-conformities to regulations for medical devices, including medical device reporting requirements, relating to the Company’s Zio AT System and medical device quality system requirements.

The Company takes these matters very seriously. The Company intends to respond within the specified time period and work diligently to address the FDA’s concerns.

As part of the Company’s response to the FDA Form 483 that it received on August 12, 2022 (“483 observations”), the Company has already taken measures intended to address certain items identified by the FDA. The Company intends to continue to undertake certain corrections and corrective actions and provide regular updates to the FDA in response to the 483 observations. With the Company’s receipt of the warning letter, it intends to take appropriate action to further address the 483 observations and other items identified in the warning letter with respect to the Zio AT System.

The warning letter does not directly restrict the manufacture, production or shipment of any of the Company’s products in the United States or require the withdrawal of any product from the U.S. marketplace. At this time, the Company believes that its receipt of this warning letter, without further adverse action initiated by the FDA, will not have a material impact to the Company’s financial results.

Although the Company intends to diligently respond to the concerns raised in the FDA’s warning letter, the Company cannot give any assurances that the FDA will be satisfied with its response, the actions taken to resolve the concerns raised in the warning letter, or the expected date for the resolution of such matters. Until the issues identified in the warning letter are resolved to the FDA’s satisfaction, additional legal or regulatory action may be taken with or without further notice. Any further adverse action initiated by the FDA, depending on its magnitude, may impact or restrict us from effectively manufacturing, producing, marketing or selling the Zio AT System, which is the focus of the warning letter, and could have a material adverse effect on our business, financial condition and results of operations.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K 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, that are intended to be covered by the “safe harbor” created by those sections. These forward-looking statements include the Company’s intent to respond to the warning letter in the timeframe required by the FDA, and the Company’s belief that its receipt of the warning letter will not have a material impact on its financial results, absent further adverse action initiated by the FDA. Forward-looking statements, which describe future plans, strategies, expectations and events, can otherwise generally be identified by the use of forward-looking terms such as “believe,” “expect,” “may,” “will,” “should,” “would,” “could,” “seek,” “intend,” “plan,” “goal,” “project,” “estimate,” “anticipate” or other similar or comparable terms. These forward-looking statements are based on current beliefs, expectations and assumptions that are subject to significant risks, uncertainties and changes in circumstances that could cause actual results to differ materially from the forward-looking statements. These and other risks are described in more detail in Part I, Item 1A “Risk Factors” of the Company’s most recent Annual Report on Form 10-K and the subsequently filed Company’s Quarterly Report on Form 10-Q. You should not rely upon forward-looking statements as predictions of future events. The forward-looking statements included in this Current Report on Form 8-K speak only as of the date hereof, and except as required by law, the Company expressly disclaims any intent, obligation or undertaking to release publicly any updates or revisions to any forward-looking statements to reflect any change in the Company’s expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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.

IRHYTHM TECHNOLOGIES, INC.

Date: May 30, 2023

By:

/s/ Brice Bobzien

Brice Bobzien

Chief Financial Officer