

**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 27, 2023**

Pulse Biosciences, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-37744
(Commission
File Number)

46-5696597
(IRS Employer
Identification No.)

3957 Point Eden Way
Hayward, California 94545
(Address of Principal Executive Offices) (Zip Code)

510-906-4600
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(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 (*see* General Instruction A.2. below):

- 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 | PLSE | The Nasdaq Stock 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 November 27, 2023, Pulse Biosciences, Inc. (the “Company”) provided the following programmatic updates with respect to its proprietary CellFX nsPFA cardiac catheter and cardiac clamp:

CellFX nsPFA Cardiac Catheter

- As of today, the Company has received all regulatory approvals and it has substantially completed all required activities to commence its planned catheter ablation feasibility study. The first study procedures in this clinical trial are scheduled for mid-December 2023.
- The Company expects to provide updates from these first procedures by the end of January 2024.

CellFX nsPFA Cardiac Clamp

- The Company anticipate filing a 510(k) submission with the U.S. Food and Drug Administration (the “FDA”) for its cardiac surgery ablation clamp by the end of January 2024, and possibly by the end of December 2023.
- Pursuant to Section 510(k), once the application has been accepted, the FDA will conduct its substantive review and may request additional information from the Company based on that review. FDA guidance suggests the goal is to complete the 510(k) review within 90 calendar days, not including time required by the Company to respond to additional information requests. The time required to respond to any such requests will depend on the nature of the request.

Other Updates

- The Company’s controlling stockholder and Executive Chairman, Robert W. Duggan, has informed management that he is evaluating one or more potential market purchases of Company common stock, and the Company has cleared these pursuant to its Insider Trading Policy, giving Mr. Duggan through the end of December 11, 2023 to purchase, in his sole discretion, up to one million shares of Company common stock.

The information furnished under Item 7.01 of this Current Report on Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liabilities under that Section, nor shall it be deemed incorporated by reference into any registration statement or other filings of the Company made under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing. The furnishing of this programmatic update is not intended to constitute a representation that such furnishing is required by Regulation FD or that this Current Report includes material investor information that is not otherwise publicly available.

Caution About Forward-Looking Statements

This Current Report contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements concerning the Company’s expected product development efforts, such as the possible initiation of a first-in-human safety feasibility study of its nsPFA endocardial ablation catheter system in December 2023, statements concerning the Company’s future regulatory strategies and possible government clearances and approvals, such as the timing and appropriateness of any 510(k) regulatory submissions by the Company, and Pulse Biosciences’ expectations, whether stated or implied, regarding whether the Company’s nsPFA technology will become a disruptive treatment option for treating cardiac arrhythmias, benign thyroid nodules or any other medical condition. These statements are based on management's current expectations and beliefs and are subject to uncertainty and changes in circumstances. Actual results may vary materially from those expressed or implied by such statements due to, among other factors, the risks, uncertainties and other factors described in the Company's filings with the Securities and Exchange Commission. The “forward-looking statements” included in such information are made only as of the date of this Current Report. The Company does not have, and does not undertake, any obligation to publicly update any “forward-looking statements” to reflect subsequent events or circumstances, and it expressly disclaims any such obligation, except as required by law or regulation.

SIGNATURE

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, thereunto duly authorized.

PULSE BIOSCIENCES, INC.

Date: November 27, 2023

By: /s/ Kevin P. Danahy
Kevin P. Danahy
President and Chief Executive Officer
(Principal Executive and Principal Financial Officer)