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)
June 9, 2021

Pulse Biosciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-37744**	**46-5696597**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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)

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 (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, par value $0.001 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 8.01 OTHER EVENTS.

On June 9, 2021, Pulse Biosciences, Inc. issued a press release announcing the approval of its proprietary CellFX® System by Health Canada for use in dermatological procedures requiring ablation and resurfacing of the skin for the reduction, removal, and/or clearance of cellular-based benign lesions. A copy of this press release is attached as Exhibit 99.1.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release issued by Pulse Biosciences, Inc. dated June 9, 2021.
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.

PULSE BIOSCIENCES, INC.

By: /s/ Sandra A. Gardiner
Sandra A. Gardiner
Chief Financial Officer, Executive Vice President of Finance and Administration, Secretary and Treasurer
(*Principal Financial and Accounting Officer*)

Date: June 9, 2021

Pulse Biosciences Announces Health Canada Approval for CellFX® System

- Company to Expand Global Controlled Launch Program with Clinical Aesthetic Experts in Canada

HAYWARD, Calif.--(BUSINESS WIRE)--Pulse Biosciences, Inc. (Nasdaq: PLSE) (“Pulse Biosciences” or the “Company”), a novel bioelectric medicine company progressing Nano-Pulse Stimulation™ (NPS™) technology, today announced the CellFX® System has been approved by Health Canada for a Medical Device License for use in dermatological procedures requiring ablation and resurfacing of the skin for the reduction, removal, and/or clearance of cellular-based benign lesions. Pulse Biosciences will now expand its controlled commercial launch of the CellFX System to select medical practices in Canada for the treatment of general dermatologic conditions, including sebaceous hyperplasia, seborrheic keratosis and cutaneous non-genital warts.

Renowned dermatologist Sheetal Sapra, MD of Toronto, Canada, is expected to begin participation in the CellFX System Controlled Launch program this month. “I am thrilled to be the first dermatologist in Canada to provide the clinical advantages of the CellFX System using NPS technology. I'm constantly seeking innovative ways to help my patients and I see an unmet need that the CellFX procedure can address in clearing challenging skin lesions like sebaceous hyperplasia, common warts and seborrheic keratosis," said Dr. Sapra, co-founder and director of the Institute of Cosmetic and Laser Surgery and Centre for Clinical Trials.

“Health Canada approval marks an important corporate milestone in our regulatory strategy and enables the planned expansion of our CellFX System Controlled Launch program in Canada this quarter. This third regulatory approval, following FDA clearance and CE mark approval earlier this year, further validates our NPS technology and we are excited to bring our novel CellFX procedure to patients in Canada,” said Darrin Uecker, President and Chief Executive Officer of Pulse Biosciences. “We look forward to initiating our controlled launch program with leading aesthetic dermatologists in Canada, expanding to an estimated 80 practices participating across the US, EU and Canada.”

The CellFX System is a multi-application platform that harnesses the Company’s proprietary NPS technology delivering nano-second pulses of electrical energy to non-thermally clear cells while sparing adjacent noncellular tissue. The distinct advantages of the NPS mechanism have the potential to improve clinical and aesthetic outcomes by clearing benign lesions where important treatment gaps exist.

About Pulse Biosciences®

Pulse Biosciences is a novel bioelectric medicine company committed to health innovation that has the potential to improve the quality of life for patients. The company’s proprietary Nano-Pulse Stimulation (NPS™) technology delivers nano-second pulses of electrical energy to non-thermally clear cells while sparing adjacent non-cellular tissue. The CellFX® System is the first commercial product to harness the distinctive advantages of NPS technology to treat a variety of applications for which an optimal solution remains unfulfilled. The initial commercial use of the CellFX System is to address a range of dermatologic conditions that share high demand among patients and practitioners for improved dermatologic outcomes. Designed as a multi-application platform, the CellFX System offers customer value with a utilization-based revenue model.
To stay informed about the CellFX System, please visit CellFX.com and sign-up for updates.

Forward-Looking Statements

All statements in this press release that are not historical are forward-looking statements, including, among other things, statements relating to Pulse Biosciences' expectations regarding its Controlled Launch program, such as the number of sites expected to participate in the program, statements relating to the Company's commercialization plan and prospects for the CellFX System, and statements regarding the potential benefits of NPS technology, including the effectiveness of such technology and the benefits of the CellFX System to clear challenging skin lesions like sebaceous hyperplasia, common warts and seborrheic keratosis. These statements are not historical facts but rather are based on Pulse Biosciences' current expectations, estimates, and projections regarding Pulse Biosciences' business, operations and other similar or related factors. Words such as "may," "will," "could," "would," "should," "anticipate," "predict," "potential," "continue," "expects," "intends," "plans," "projects," "believes," "estimates," and other similar or related expressions are used to identify these forward-looking statements, although not all forward-looking statements contain these words. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and assumptions that are difficult or impossible to predict and, in some cases, beyond Pulse Biosciences' control. Actual results may differ materially from those in the forward-looking statements as a result of a number of factors, including those described in Pulse Biosciences' filings with the Securities and Exchange Commission. Pulse Biosciences undertakes no obligation to revise or update information in this release to reflect events or circumstances in the future, even if new information becomes available.

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