
**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)
April 30, 2019

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, including zip code)

(510) 906-4600
(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 (see General Instruction A.2):

- 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.

ITEM 2.02. RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

On April 30, 2019, Pulse Biosciences, Inc. announced its financial results for the fiscal quarter ended March 31, 2019. A copy of the press release containing the announcement is included as Exhibit 99.1 and is incorporated herein by reference.

This information, as well as Exhibit 99.1, is intended to be furnished under Item 2.02 of Form 8-K, "Results of Operations and Financial Condition" and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS

(d) Exhibits.

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 99.1 | Press Release issued by Pulse Biosciences, Inc. dated April 30, 2019 |

PULSE BIOSCIENCES QUARTERLY INVESTOR CONFERENCE CALL

Conference call today at 1:30 p.m. PDT / 4:30 p.m. EDT

HAYWARD, Calif. - (BUSINESS WIRE) – April 30, 2019 – Pulse Biosciences, Inc. (Nasdaq: PLSE) (the “Company”), a novel bioelectric medicine company bringing to market its proprietary CellFX™ System, today reported recent corporate developments and financial results for the quarter ended March 31, 2019.

Recent Corporate Developments

- Pre-market Notification (510(k)) submitted to the U.S. Food and Drug Administration (FDA) for its proprietary CellFX System seeking clearance for commercial use in common dermatologic procedures to remove general benign lesions including Sebaceous Hyperplasia, a common but difficult-to-treat facial lesion and Seborrheic Keratosis, a common benign pigmented lesion. This afternoon we received an additional information (“AI”) letter request from FDA, and the FDA among other things is questioning the adequacy of the predicate device provided in the 510(k). Responding to this request will add time and require additional testing, inclusive of clinical trials. In consideration of the above we are presently evaluating an alternative approach, the De Novo process approach, which would also likely require additional time, testing and clinical studies. At the end of the day the De Novo approach may be in the best interest of Pulse Biosciences. We will update on this important matter no later than the upcoming Annual Meeting of Stockholders scheduled for May 16, 2019.
- Mitchell Levinson, a well-seasoned entrepreneur and executive in the aesthetic procedure market, appointed to the Board of Directors.
- Podium presentations by key opinion leaders in aesthetic dermatology speaking to the novel mechanism of action of the CellFX System and the positive results from our clinical studies in Sebaceous Hyperplasia and Common Warts at the American Academy of Dermatology Annual Meeting and the American Society for Laser Medicine and Surgery Annual Conference.
- Continued progress in active feasibility studies including Common Warts, Back Acne and Basal Cell Carcinoma.

“At Pulse Biosciences we remain focused on commercializing our CellFX System in aesthetic dermatology and we are pleased with our progress towards this goal in Q1,” said Darrin Uecker, Pulse Biosciences’ President and Chief Executive Officer.

Financial Highlights

Cash, cash equivalents, and investments totaled \$52.8 million at March 31, 2019, compared to \$59.6 million at December 31, 2018. Cash use totaled \$6.8 million for the first quarter of 2019 compared to cash use of \$6.4 million for the fourth quarter of 2018, and \$4.7 million for the first quarter of 2018.

Operating expenses for the three-month period ended March 31, 2019 was \$10.4 million, compared to \$8.7 million for the three-month period ended March 31, 2018. The operating expenses for the three-month period ended March 31, 2019 included non-cash stock-based compensation of \$2.4 million, compared to non-cash stock-based compensation of \$3.4 million for the three-month period ended March 31, 2018.

Net Loss for the three-month period ended March 31, 2019 totaled \$10.1 million, compared to \$8.7 million for the three-month period ended March 31, 2018.

Conference Call Details

Pulse Biosciences will host an investor call on April 30, 2019, at 1:30 p.m. PDT / 4:30 p.m. EDT. The telephone dial-in number for the call is (844) 494-0190 (U.S. toll-free) or (508) 637-5580 (international) using Conference ID 3466369. Listeners will also be able to access the call via webcast available on the Investors section of the Company's website at www.PulseBiosciences.com.

About Pulse Biosciences

Pulse Biosciences is a novel bioelectric medicine company committed to health innovation that improves and extends the lives of patients. The Company utilizes its patented groundbreaking Nano-Pulse Stimulation™ (NPS™) technology to treat a variety of applications for which an optimal solution remains unfulfilled. NPS is a proprietary technology that delivers nano-second pulses of high amplitude electrical energy to non-thermally clear targeted cells while sparing adjacent non-cellular tissue. The cell-specific effects of NPS technology have been validated in a series of ongoing clinical trials. In addition, early pre-clinical evidence suggests that the NPS technology holds a promising future in immuno-oncology by demonstrating an ability to induce immunogenic cell death. The CellFX System, the first planned commercial product to harness the distinctive advantages of NPS technology, is preparing to launch in 2019 as a multi-application platform designed to address a broad range of dermatologic conditions. As part of the customer experience, the Company is offering an utilization-based revenue model and easy-access customer portal offering a suite of services. CellFX procedures offer customer value across an expanding spectrum of clinical applications. The initial commercial use will be the clearance of common skin lesions, including sebaceous hyperplasia (SH) and seborrheic keratosis (SK) – two prevalent and difficult-to-treat benign skin conditions that share high demand among patients and practitioners for improved and durable aesthetic outcomes that lead to greater overall satisfaction. For more information about Pulse Biosciences, proprietary NPS technology, or CellFX, please visit us at PulseBiosciences.com

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding our CellFX System and the Company's commercialization of our CellFX System including the progress and timing of such commercialization and the results of clinical study plans. These forward-looking statements are based on current expectations and estimates and involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested or implied by the forward-looking statements. These forward-looking statements should, therefore, be considered in light of various important factors, including, but not limited to, the following: the impact of governmental regulatory agencies, including the U.S. FDA, and regulatory approvals, clearances and restrictions or any dispute that may occur with any regulatory body; risks inherent to the planning, design and execution of clinical studies; domestic and regional economic conditions on aesthetic healthcare spending; the timing and success of product development and market acceptance of developed and approved products, including, but not limited to, the CellFX System; intellectual property positions and litigation; competition in the medical device industry and in the specific markets of aesthetics and dermatology in which the Company operates; unanticipated manufacturing disruptions or the inability to meet demand for products; the results of legal proceedings to which the Company is or may become a party; product liability and other litigation claims; adverse

publicity regarding the company and the safety of the Company's products and adequacy of training; the impact of changes to tax legislation, guidance, and interpretations; and other risk factors under the heading "Risk Factors" in the Company's annual report on Form 10-K for the year ended December 31, 2018, as periodically updated by the Company's subsequent filings with the Securities and Exchange Commission. Statements using words such as "estimates," "projects," "believes," "anticipates," "plans," "expects," "intends," "may," "will," "could," "should," "would," "targeted" and similar words and expressions are intended to identify forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release, April 30, 2019. Pulse Biosciences, Inc. undertakes no obligation to publicly update or release any revisions to these forward-looking statements, except as required by law.

Caution: Pulse Biosciences' CellFX System and Nano-Pulse Stimulation (NPS) technology are for investigational use only.

Investor Relations:

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PULSE BIOSCIENCES, INC.
Condensed Consolidated Balance Sheets
(Unaudited)

| (in thousands) | March 31, 2019 | December 31, 2018 |
|---|---------------------------|------------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash, cash equivalents and investments | \$ 52,801 | \$ 59,583 |
| Prepaid expenses and other current assets | 550 | 779 |
| Total current assets | <u>53,351</u> | <u>60,362</u> |
| Property and equipment, net | 2,056 | 2,173 |
| Intangible assets, net | 5,046 | 5,213 |
| Goodwill | 2,791 | 2,791 |
| Other assets | 208 | 101 |
| Total assets | <u>\$ 63,452</u> | <u>\$ 70,640</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 1,200 | \$ 1,272 |
| Accrued expenses | 1,519 | 1,421 |
| Deferred rent, current | — | 415 |
| Lease liability, current | 396 | — |
| Total current liabilities | <u>3,115</u> | <u>3,108</u> |
| Long term liabilities: | | |
| Deferred rent, less current | — | 1,198 |
| Lease liability, less current | 1,223 | — |
| Total liabilities | <u>4,338</u> | <u>4,306</u> |
| Stockholders' equity: | | |
| Common stock and additional paid-in capital | 144,908 | 142,053 |
| Accumulated other comprehensive loss | 2 | (1) |
| Accumulated deficit | (85,796) | (75,718) |
| Total stockholders' equity | <u>59,114</u> | <u>66,334</u> |
| Total liabilities and stockholders' equity | <u>\$ 63,452</u> | <u>\$ 70,640</u> |

PULSE BIOSCIENCES, INC.
Condensed Consolidated Statements of Operations
(Unaudited)

| (in thousands, except per share amounts) | Three-Month Periods Ended | |
|---|----------------------------------|---------------------------|
| | March 31, 2019 | March 31, 2018 |
| Revenue | \$ — | \$ — |
| Operating expenses: | | |
| General and administrative | 4,401 | 5,383 |
| Research and development | 5,842 | 3,175 |
| Amortization of intangible assets | 167 | 166 |
| Total operating expenses | 10,410 | 8,724 |
| Other income: | | |
| Interest income | 332 | 56 |
| Total other income | 332 | 56 |
| Net loss | \$ (10,078) | (8,668) |
| Net loss per share: | | |
| Basic and diluted net loss per share | \$ (0.49) | (0.51) |
| Weighted average shares used to compute net loss per common share — basic and diluted | 20,679 | 16,842 |