

**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 10, 2021**

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)

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 2.02. RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

On May 10, 2021, Pulse Biosciences, Inc. announced its financial results for the fiscal quarter ended March 31, 2021. A copy of the press release is attached hereto 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 May 10, 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: May 10, 2021

HAYWARD, Calif. [Business Wire] – May 10, 2021 – Pulse Biosciences, Inc. (Nasdaq: PLSE), a novel bioelectric medicine company progressing its Nano-Pulse Stimulation™ (NPS™) technology, today announced financial results for the first quarter of 2021.

Recent Highlights

- Commenced the CellFX® System Controlled Launch program and onboarded the first 15 participating U.S. and European aesthetic specialty practices in the first quarter, representing significant progress toward the program goal of onboarding 75 Key Opinion Leader (KOL) sites by the end of the third quarter
- Submitted anticipated final response to Health Canada regarding the CellFX System Medical Device License, expect completion of the review by the end of the second quarter
- Received FDA IDE approval for a feasibility study to assess the treatment of basal cell carcinoma using the CellFX System, enrollment of 30 patients is planned to begin in the second quarter and to be completed by the end of the third quarter
- Continued patient enrollment and treatments in an FDA IDE approved pivotal comparison study to assess the treatment of cutaneous non-genital warts using the CellFX System; 51 of 150 patients have been enrolled to date with completion expected as early as the end of the second quarter or early in the third quarter
- U.S. consumer research presented at the American Academy of Dermatology (AAD) virtual annual meeting rated aesthetic patients’ willingness to pay premium out-of-pocket fees and prioritize clearance of skin lesions with the CellFX procedure profile ahead of other popular aesthetic procedures
- Strengthened balance sheet through \$41 million term loan with a maturity of June 2022 and announced an at-the-market (ATM) equity offering program which could raise up to \$60 million in aggregate gross proceeds

“In the first quarter of 2021, we achieved two significant milestones in our business with regulatory clearances for our CellFX System in the U.S. and in Europe. With these regulatory clearances in hand, we immediately executed the rollout of our Controlled Launch program of the CellFX System integrated with CellFX CloudConnect services in both these important markets. We have already made meaningful progress onboarding the first group of KOL participants and over the next several months look forward to gaining insights and developing best practices on driving long term adoption and utilization as we move towards full commercial launch later this year,” said Darrin Uecker, President and CEO of Pulse Biosciences. “As we continue to execute on our commercial strategy, we plan to build upon these clearances, selectively adding new markets and pursuing additional applications of our CellFX System outside of aesthetic dermatology.”

First Quarter 2021 Results

Cash, cash equivalents and investments totaled \$59.9 million as of March 31, 2021, compared to \$20.5 million as of December 31, 2020. Cash used in the first quarter of 2021 totaled \$10.7 million excluding net proceeds received under the Company’s term loan, ATM program and the exercise of warrants. This compares with \$9.5 million used in the same period in the prior year and \$9.2 million used in the fourth quarter of 2020, excluding net proceeds received from the exercise of warrants.

GAAP operating expenses for the three months ended March 31, 2021 were \$18.5 million, compared to \$12.0 million for the prior year period. Non-GAAP operating expenses for the first quarter were \$11.3 million, compared to \$9.1 million for the same period in the prior year. The year-over-year increase in operating expenses was primarily driven by the expansion of commercial and operational infrastructure, including increased headcount, to support commercialization activities.

GAAP net loss for the three months ended March 31, 2021 was (\$18.6) million compared to (\$11.9) million for the three months ended March 31, 2020. Non-GAAP net loss for the three months ended March 31, 2021 was (\$11.4) million compared to (\$9.0) million for the three months ended March 31, 2020.

Reconciliations of GAAP to non-GAAP operating expenses and net loss have been provided in the tables following the financial statements in this press release. An explanation of these measures is also included below under the heading “Non-GAAP Financial Measures.”

Impact of COVID-19

The COVID-19 pandemic had minimal impact on the Company’s operations in the first quarter of 2021. Product development, execution of clinical trials, regulatory timelines and Controlled Launch have not been materially affected at this time but due to the uncertain scope and duration of the pandemic, future impact to the Company’s operations and financial results cannot be reasonably estimated.

Webcast and Conference Call Information

Pulse Biosciences’ management will host a conference call today, May 10, 2021 beginning at 1:30pm PT. Investors interested in listening to the conference call may do so by dialing 1-877-705-6003 for domestic callers or 1-201-493-6725 for international callers. A live and recorded webcast of the event will be available at <http://investors.pulsebiosciences.com/>.

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 CellFX® System is the first commercial product to harness the distinctive advantages of the Company’s proprietary Nano-Pulse Stimulation™ (NPS™) technology, such as the ability to non-thermally clear cells while sparing non-cellular tissue, to treat a variety of applications for which an optimal solution remains unfulfilled. Nano-Pulse Stimulation technology delivers nano-second pulses of electrical energy. 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 learn more, please visit pulsebiosciences.com.

To stay informed about the CellFX System, please visit CellFX.com and sign up for updates.

Pulse Biosciences, CellFX, Nano-Pulse Stimulation, NPS and the stylized logos are among the trademarks and/or registered trademarks of Pulse Biosciences, Inc. in the United States and other countries.

Non-GAAP Financial Measures

In this press release, in order to supplement the Company's condensed consolidated financial statements presented in accordance with Generally Accepted Accounting Principles, or GAAP, management has disclosed certain non-GAAP financial measures for the statement of operations. The Company believes that an evaluation of its ongoing operations (and comparisons of its current operations with historical and future operations) would be difficult if the disclosure of its financial results were limited to financial measures prepared in accordance with GAAP. As a result, the Company is disclosing certain non-GAAP results in order to supplement investors' and other readers' understanding and assessment of the Company's financial performance because Company management uses these measurements as aids in monitoring the Company's ongoing financial performance from quarter to quarter, and year to year, on a regular basis and for financial and operational decision-making. Non-GAAP adjustments include stock-based compensation, depreciation and amortization. From time to time in the future, there may be other items that the Company may exclude if the Company believes that doing so is consistent with the goal of providing useful information to investors and management. The Company has provided a reconciliation of each non-GAAP financial measure used in this earnings release to the most directly comparable GAAP financial measure. Investors are cautioned that there are a number of limitations associated with the use of non-GAAP financial measures as analytical tools. Investors are encouraged to review these reconciliations, and not to rely on any single financial measure to evaluate the Company's business.

Non-GAAP financial measures used by the Company may be calculated differently from, and therefore may not be comparable to, similarly titled measures used by other companies, which could reduce the usefulness of the Company's non-GAAP financial measures as tools for comparison. Investors and other readers are encouraged to review the related GAAP financial measures and the reconciliation of non-GAAP measures to their most directly comparable GAAP measures set forth below and should consider non-GAAP measures only as a supplement to, not as a substitute for or as a superior measure to, measures of financial performance prepared in accordance with GAAP. Non-GAAP financial measures in this earnings release exclude the following:

Non-cash expenses for stock-based compensation. The Company has excluded the effect of stock-based compensation expenses in calculating the Company's non-GAAP operating expenses and net loss measures. Although stock-based compensation is a key incentive offered to employees, the Company continues to evaluate its business performance excluding stock-based compensation expenses. The Company records stock-based compensation expense related to grants of performance and time-based options. Depending upon the size, timing and terms of the grants, as well as the probability of achievement of performance-based awards, this expense may vary significantly but will recur in future periods. The Company believes that excluding stock-based compensation better allows for comparisons from period to period.

Depreciation and amortization. The Company has excluded depreciation and amortization expense in calculating its non-GAAP operating expenses and net loss measures. Depreciation and amortization are non-cash charges to current operations.

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 the benefits of the Company's Controlled Launch program and commercialization of the CellFX System, including the timing for onboarding KOLs, regulatory clearance and the timing of FDA, Health Canada and other regulatory filings or approvals, including the ability of the Company to successfully complete a 510(k) submission for the CellFX System for other dermatologic indications, NPS technology including the effectiveness of such technology, the CellFX System including the benefits of the CellFX System, current and planned

future clinical studies, the timing for completion of such studies, and the ability of the Company to execute such studies and the results of any such studies, other matters related to its pipeline of product candidates, the Company's market opportunity and commercial launch plans, including the market for aesthetic dermatologic procedures and the willingness of consumers to pay premium out-of-pocket fees for treatments, and expectations regarding adoption of the CellFX System, additional applications of the CellFX System outside of aesthetic dermatology, future financial performance, the impact of COVID-19 and other future events. 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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PULSE BIOSCIENCES, INC.
Condensed Consolidated Balance Sheets
(In thousands, except par value)
(Unaudited)

	March 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 59,883	\$ 12,463
Investments	—	8,012
Inventory	1,135	—
Prepaid expenses and other current assets	958	1,864
Total current assets	61,976	22,339
Property and equipment, net	2,430	2,478
Intangible assets, net	3,715	3,882
Goodwill	2,791	2,791
Right-of-use assets	9,280	9,438
Other assets	365	365
Total assets	\$ 80,557	\$ 41,293
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,164	\$ 1,717
Accrued expenses	5,617	5,326
Lease liability, current	629	542
Related party note payable, current	118	—
Total current liabilities	8,528	7,585
Lease liability, less current	10,632	10,814
Related party note payable, less current	41,000	—
Total liabilities	60,160	18,399
Stockholders' equity:		
Preferred stock, \$0.001 par value; authorized – 50,000 shares; no shares issued and outstanding	—	—
Common stock, \$0.001 par value; authorized – 500,000 shares; issued and outstanding – 26,401 shares and 25,550 shares at March 31, 2021 and December 31, 2020, respectively	26	25
Additional paid-in capital	211,550	195,410
Accumulated other comprehensive income (loss)	—	(1)
Accumulated deficit	(191,179)	(172,540)
Total stockholders' equity	20,397	22,894
Total liabilities and stockholders' equity	\$ 80,557	\$ 41,293

PULSE BIOSCIENCES, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except per share data)
(Unaudited)

	Three-Month Periods Ended	
	March 31,	
	2021	2020*
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	9,063	6,181
Sales and marketing	4,146	1,695
General and administrative	5,316	4,074
Total operating expenses	18,525	11,950
Other income (expense):		
Interest income (expense), net	(114)	78
Total other income (expense)	(114)	78
Net loss	(18,639)	(11,872)
Other comprehensive loss:		
Unrealized gain on available-for-sale securities	1	13
Comprehensive loss	\$ (18,638)	\$ (11,859)
Net loss per share:		
Basic and diluted net loss per share	\$ (0.71)	\$ (0.57)
Weighted average shares used to compute net loss per common share — basic and diluted	26,072	20,838

*Certain 2020 amounts have been reclassified to conform to the current period presentation. Sales and marketing expenses have been reclassified out of general and administrative and presented as a separate line item. Amortization of intangible assets have been reclassified to general and administrative expenses.

	Three-Month Periods Ended	
	March 31,	
	2021	2020
Stock Based Compensation Expense:		
Research and development	\$ 3,166	\$ 877
Sales and marketing	1,761	310
General and administrative	2,038	1,439
Total stock-based compensation expense	\$ 6,965	\$ 2,626

Reconciliation of GAAP to Non-GAAP Financial Measures

The following table presents the reconciliation of non-GAAP financial measures to the most directly comparable GAAP financial measures:

(In thousands)
(Unaudited)

	Three-Month Periods Ended March 31,	
	2021	2020
Reconciliation of GAAP to non-GAAP Research and development:		
GAAP Research and development	\$ 9,063	\$ 6,181
Less: Stock-based compensation expense	(3,166)	(877)
Less: Depreciation and amortization	(39)	(41)
Non-GAAP Research and development	<u>\$ 5,858</u>	<u>\$ 5,263</u>
Reconciliation of GAAP to non-GAAP Sales and marketing:		
GAAP Sales and Marketing	\$ 4,146	\$ 1,695
Less: Stock-based compensation expense	(1,761)	(310)
Non-GAAP Sales and marketing	<u>\$ 2,385</u>	<u>\$ 1,385</u>
Reconciliation of GAAP to non-GAAP General and administrative:		
GAAP General and administrative	\$ 5,316	\$ 4,074
Less: Stock-based compensation expense	(2,038)	(1,439)
Less: Depreciation and amortization	(240)	(229)
Non-GAAP General and administrative	<u>\$ 3,038</u>	<u>\$ 2,406</u>
Reconciliation of GAAP to non-GAAP Operating expenses:		
GAAP Operating expenses	\$ 18,525	\$ 11,950
Less: Stock-based compensation expense	(6,965)	(2,626)
Less: Depreciation and amortization	(279)	(270)
Non-GAAP Operating expenses	<u>\$ 11,281</u>	<u>\$ 9,054</u>
Reconciliation of GAAP to non-GAAP Net loss:		
GAAP Net loss	\$ (18,639)	\$ (11,872)
Add: Stock-based compensation expense	6,965	2,626
Add: Depreciation and amortization	279	270
Non-GAAP Net loss	<u>\$ (11,395)</u>	<u>\$ (8,976)</u>