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 9, 2020

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 2.02. RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

On November 9, 2020, Pulse Biosciences, Inc. announced its financial results for the three- and nine-months ended September 30, 2020. 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.

Exhibit No.	Description
99.1	Press Release issued by Pulse Biosciences, Inc. dated November 9, 2020.

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: November 9, 2020

Pulse Biosciences Reports Third Quarter 2020 Financial Results

HAYWARD, Calif. [Business Wire] – November 9, 2020 – Pulse Biosciences, Inc. (Nasdaq: PLSE), a novel bioelectric medicine company developing its Nano-Pulse Stimulation™ (NPS™) technology, today announced financial results for the third quarter ended September 30, 2020.

Recent Highlights

- Submitted a 510(k) Premarket Notification application to the U.S. Food and Drug Administration (FDA) for the CellFX® System seeking to obtain initial clearance for a general dermatologic indication. Potential clearance remains on track to be received as early as the first quarter of 2021.
- Received FDA Investigational Device Exemption (IDE) approval and completed enrollment ahead of schedule in a pivotal comparison study to evaluate the treatment of sebaceous hyperplasia (SH) lesions using the CellFX System, accelerating the planned 510(k) submission into the first quarter of 2021 versus the previous estimate of the second quarter of 2021.
- Submitted a Medical Device License application to Health Canada for the CellFX System after receiving the Medical Device Single Audit Program certification, now on track for a potential Health Canada license as early as the first quarter of 2021.
- Advanced the interactive review process with the notified body and on track for potential controlled launch in the European Union as early as the first quarter of 2021.
- Clinical results from four studies of the CellFX System were presented at the American Society for Dermatologic Surgery virtual annual meeting on October 9-11, 2020.

“We made excellent progress over the last several months on our clinical and regulatory objectives. We remain on track to potentially receive marketing clearances for our CellFX System in our three top geographies, the United States, Canada, and the European Union by the end of the first quarter of 2021. Additionally, completing enrollment in our sebaceous hyperplasia pivotal study in just over five weeks, two months ahead of schedule, is a testament to the interest physicians and patients have regarding the CellFX procedure for this application,” said Darrin Uecker, President and CEO of Pulse Biosciences. “Importantly, I would like to thank our team for their hard work and recognize their accomplishments during this last quarter.”

Financial Update

Cash, cash equivalents and investments totaled $29.6 million as of September 30, 2020, compared to $37.8 million as of June 30, 2020. Cash used in the third quarter of 2020 totaled $8.2 million. This compares with $7.9 million used in the second quarter of 2020 net of the rights offering proceeds.

Operating expenses for the three months ended September 30, 2020 were $12.9 million, compared to $12.0 million for the prior year period. Third quarter 2020 operating expenses included stock-based compensation expense of $2.6 million, compared to $2.7 million in the third quarter of 2019. The increase in operating expenses was primarily driven by general and administrative increases for facilities expansion, and research and development increases for headcount growth.

Operating expenses for the nine months ended September 30, 2020 were $36.2 million, compared to $34.0 million for the prior year period. Stock-based compensation expense for the nine months ended September 30, 2020 was $7.7 million, consistent with the prior year period. The increase in operating expenses was primarily driven by the expansion of operational infrastructure and increased headcount to support commercial preparations.

Net loss for the three months ended September 30, 2020 was ($12.9) million compared to ($11.7) million for the three months ended September 30, 2019. Net loss for the nine months ended September 30, 2020 was ($36.1) million compared to ($33.2) million for the nine months ended September 30, 2019.

Impact of COVID-19
Operations in the third quarter of 2020 experienced minimal impacts as a result of the COVID-19 pandemic. Product development and regulatory timelines have not been materially affected at this time but due to the uncertain scope and duration of the pandemic, future impact to our operations and financial results cannot be reasonably estimated.

Webcast and Conference Call Information
Pulse Biosciences' management will host a conference call today, November 9, 2020 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. If cleared, the CellFX® System will be 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. Subject to regulatory approval, the initial commercial use of the CellFX System is expected 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 is intended to offer customer value with a utilization-based revenue model across a spectrum of clinical applications. To learn more please visit www.pulsebiosciences.com.

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

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 regulatory clearance and the timing of FDA and other regulatory filings or approvals, including meetings with FDA and the ability of the Company to successfully complete a 510(k) submission for the CellFX System, the ability of the Company to prepare and provide data to FDA and the notified body responsible for conducting CE mark review, the ability of the Company to obtain a CE mark or Health Canada approval for the CellFX System, NPS technology including the effectiveness of such technology and the effectiveness of related clinical studies in predicting outcomes resulting from the use of NPS technology, the CellFX System including the benefits of the CellFX System and commercialization of the CellFX System, current and planned future clinical studies and the ability of the Company to execute such studies and results of any such studies, other matters related to its pipeline of product candidates, the Company's market opportunity and commercialization plans, including the market for the treatment of SH, the Company's ability to effectively use capital raised through the rights offering, 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)

	September 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,070	$ 6,899
Investments	22,516	18,499
Prepaid expenses and other current assets	748	1,005
Total current assets	30,334	26,403
Property and equipment, net	2,562	2,566
Intangible assets, net	4,048	4,547
Goodwill	2,791	2,791
Right-of-use assets	9,595	5,114
Other assets	365	494
Total assets	$ 49,695	$ 41,915
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,432	$ 1,963
Accrued expenses	4,111	2,496
Lease liability, current	457	—
Total current liabilities	6,000	4,459
Lease liability, less current portion	10,991	6,719
Total liabilities	16,991	11,178
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 – 25,290 shares and 20,825 shares at September 30, 2020 and December 31, 2019, respectively	25	21
Additional paid-in capital	191,468	153,401
Accumulated other comprehensive income	1	4
Accumulated deficit	(158,790)	(122,689)
Total stockholders' equity	32,704	30,737
Total liabilities and stockholders' equity	$ 49,695	$ 41,915

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

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2020	2019	2020	2019
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
General and administrative	5,771	5,606	16,691	15,153
Research and development	6,968	6,192	19,019	18,371
Amortization of intangible assets	166	166	499	500
Total operating expenses	12,905	11,964	36,209	34,024
Other income:				
Interest income	9	218	108	841
Total other income	9	218	108	841
Net loss	(12,896)	(11,746)	(36,101)	(33,183)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	1	(14)	(3)	9
Comprehensive loss	$ (12,895)	$ (11,760)	$ (36,104)	$ (33,174)
Net loss per share:				
Basic and diluted net loss per share	$ (0.51)	$ (0.57)	$ (1.60)	$ (1.60)
Weighted average shares used to compute net loss per common share — basic and diluted	25,223	20,774	22,540	20,728

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
Stock Based Compensation Expense:	2020	2019	2020	2019
General and administrative	$ 1,465	$ 1,735	$ 4,729	$ 4,881
Research and development	1,183	944	2,957	2,858
Total stock-based compensation expense	$ 2,648	$ 2,679	$ 7,686	$ 7,739