

**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 15, 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 November 15, 2021, Pulse Biosciences, Inc. announced its financial results for the fiscal quarter ended September 30, 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>
<u>99.1</u>	<u>Press Release issued by Pulse Biosciences, Inc. dated November 15, 2021.</u>
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, and Treasurer
(Principal Financial and Accounting Officer)

Date: November 15, 2021

Pulse Biosciences Reports Third Quarter 2021 Financial Results

HAYWARD, Calif. [Business Wire] – November 15, 2021 – Pulse Biosciences, Inc. (Nasdaq: PLSE), a novel bioelectric medicine company commercializing the CellFX® System powered by Nano-Pulse Stimulation™ (NPS™) technology, today announced financial results for the third quarter of 2021.

Recent Highlights

- Achieved third quarter 2021 revenue of \$574 thousand, representing 12 Controlled Launch Program participants opting to acquire their CellFX Systems and transition to commercial use
- Onboarded 68 CellFX System Controlled Launch Program participants to date and anticipate the remaining to be onboarded in Q4 to complete program enrollment across the U.S., Europe and Canada
- Completed enrollment of 150 patients in an FDA IDE approved pivotal comparison study to assess the treatment of cutaneous non-genital warts using the CellFX System, the corresponding 510(k) submission is on track to be completed in the first half of 2022
- Completed enrollment of 30 patients as part of a feasibility study to assess the treatment of basal cell carcinoma using the CellFX System, on track for tissue analysis to be completed in Q1 2022
- Strengthened the executive leadership team with the appointment of Mitchell E. Levinson as Chief Strategy Officer, to spearhead the Company's multi-specialty expansion efforts to leverage NPS technology, the CellFX platform and CellFX CloudConnect in applications outside of dermatology
- Appointed healthcare industry executive Lauren DeBuono to its Board of Directors

“We made important progress across the business in the third quarter resulting in our first quarter of revenue as the initial Controlled Launch Program participants elected to purchase their CellFX Systems and Cycle Units for commercial use,” said Darrin Uecker, President and CEO of Pulse Biosciences. “On the clinical front we continue to prioritize studies to support regulatory submissions to expand the CellFX System's indications for use in dermatology. At the same time, we are pleased about the investigational preclinical work being done with NPS across other medical specialties. We are laying a foundation to drive value creation and maximize the full potential of the CellFX platform.”

Third Quarter 2021 Results

Revenue for the three months ended September 30, 2021 was \$574 thousand. System revenue for the three months ended September 30, 2021 was \$490 thousand recognized on a non-cash basis resulting from the Controlled Launch Participants opting to acquire CellFX Systems. Cycle units revenue for the three months ended September 30, 2021 was \$84 thousand resulting from the purchase of initial cycle units to be used with commercial systems.

Total GAAP gross loss* for the three months ended September 30, 2021 was (\$0.2) million. Excluding non-cash expenses for stock-based compensation and depreciation and amortization, non-GAAP gross loss for the three months ended September 30, 2021 was (\$0.1) million. As the business transitioned to commercial operations in the third quarter of 2021, all uncapitalized manufacturing operations costs are now recorded in cost of revenue. Prior to commercialization, these costs were recorded in research and development expenses.

Total GAAP operating expenses representing research and development, sales and marketing and general and administrative expenses for the three months ended September 30, 2021 were \$14.1 million, compared to \$12.9 million for the prior year period. Non-GAAP operating expenses for the three months ended September 30, 2021 were \$12.3 million, compared to \$10.0 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 September 30, 2021 was (\$14.3) million compared to (\$12.9) million for the three months ended September 30, 2020. Non-GAAP net loss for the three months ended September 30, 2021, was (\$12.4) million compared to (\$10.0) million for the three months ended September 30, 2020.

Cash, cash equivalents and investments totaled \$42.0 million as of September 30, 2021 compared to \$47.4 million as of June 30, 2021. Cash used in the third quarter of 2021 totaled \$13.8 million excluding net proceeds received in the June 2021 private placement. This compares with \$8.3 million used in the same period in the prior year and \$15.0 million used in the second quarter of 2021.

* Gross loss is calculated as total revenues less cost of revenues.

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.”

Webcast and Conference Call Information

Pulse Biosciences’ management will host a conference call today, November 15, 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 <https://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 Company’s proprietary Nano-Pulse Stimulation 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. Visit pulsebiosciences.com to learn more.

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. 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 management and investors. 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 to drive growth, including the timing for onboarding KOLs, broader commercial launch and future regulatory clearances, statements relating to the effectiveness of the Company's NPS technology and the CellFX System to improve patient outcomes, statements relating to the Company's current and planned future clinical studies, the timing for completion of such studies, and the ability of the Company to execute such studies, as well as the anticipated results of any such studies, statements relating to the Company's pipeline of product candidates, market opportunities and commercial launch plans, including the market for aesthetic dermatologic procedures, and statements relating to 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, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 41,991	\$ 12,463
Investments	—	8,012
Accounts Receivable	72	—
Inventory	4,281	—
Prepaid expenses and other current assets	2,866	1,864
Total current assets	49,210	22,339
Property and equipment, net	2,446	2,478
Intangible assets, net	3,382	3,882
Goodwill	2,791	2,791
Right-of-use assets	8,954	9,438
Other assets	365	365
Total assets	<u>\$ 67,148</u>	<u>\$ 41,293</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,706	\$ 1,717
Accrued expenses	4,971	5,326
Deferred revenue	7	—
Lease liability, current	749	542
Note payable, current	1,086	—
Total current liabilities	9,519	7,585
Lease liability, less current	10,242	10,814
Total liabilities	<u>19,761</u>	<u>18,399</u>
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 – 29,631 shares and 25,550 shares at September 30, 2021 and December 31, 2020, respectively	29	25
Additional paid-in capital	268,142	195,410
Accumulated other comprehensive income (loss)	—	(1)
Accumulated deficit	(220,784)	(172,540)
Total stockholders' equity	<u>47,387</u>	<u>22,894</u>
Total liabilities and stockholders' equity	<u>\$ 67,148</u>	<u>\$ 41,293</u>

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

	Three-Month Periods Ended		Nine-Month Periods Ended	
	September 30,		September 30,	
	2021	2020*	2021	2020*
Revenues:				
Product revenues	\$ 574	\$ —	\$ 574	\$ —
Total revenues	574	—	574	—
Cost and expenses:				
Cost of revenues	727	—	727	—
Research and development	6,460	6,968	22,982	19,019
Sales and marketing	3,404	1,746	10,697	4,926
General and administrative	4,256	4,191	13,772	12,264
Total cost and expenses	14,847	12,905	48,178	36,209
Loss from operations	(14,273)	(12,905)	(47,604)	(36,209)
Other income (expense):				
Interest income (expense), net	(9)	9	(640)	108
Total other income (expense)	(9)	9	(640)	108
Net loss	(14,282)	(12,896)	(48,244)	(36,101)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	—	1	1	(3)
Comprehensive loss	\$ (14,282)	\$ (12,895)	\$ (48,243)	\$ (36,104)
Net loss per share:				
Basic and diluted net loss per share	\$ (0.48)	\$ (0.51)	\$ (1.76)	\$ (1.60)
Weighted average shares used to compute net loss per common share — basic and diluted	29,612	25,223	27,400	22,540

Stock Based Compensation Expense:	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2021	2020*	2021	2020*
Cost of revenues	\$ 37	\$ —	\$ 37	\$ —
Research and development	418	1,183	4,586	2,957
Sales and marketing	65	312	2,326	903
General and administrative	1,057	1,154	4,041	3,826
Total stock-based compensation expense	\$ 1,577	\$ 2,649	\$ 10,990	\$ 7,686

*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.

PULSE BIOSCIENCES, INC.
Consolidated Revenue Financial Highlights
(In thousands)
(Unaudited)

	Three-Month Periods Ended				Nine-Month Periods Ended				
	September 30,				September 30,				
	2021		2020		2021		2020		
Revenue by category:									
Systems	\$ 490	85%	\$ —	-	\$ 490	85%	\$ —	-	-
Cycle units	84	15%	—	-	84	15%	—	-	-
Total revenue	<u>\$ 574</u>	<u>100%</u>	<u>\$ —</u>	<u>-</u>	<u>\$ 574</u>	<u>100%</u>	<u>\$ —</u>	<u>-</u>	<u>-</u>
Revenue by geography:									
North America	\$ 405	71%	\$ —	-	\$ 405	71%	\$ —	-	-
Rest of World	169	29%	—	-	169	29%	—	-	-
Total revenue	<u>\$ 574</u>	<u>100%</u>	<u>\$ —</u>	<u>-</u>	<u>\$ 574</u>	<u>100%</u>	<u>\$ —</u>	<u>-</u>	<u>-</u>

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 Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2021	2020	2021	2020
Reconciliation of GAAP to non-GAAP Cost of revenues:				
GAAP Cost of revenues	\$ 727	\$ —	\$ 727	\$ —
Less: Stock-based compensation expense	(37)	—	(37)	—
Less: Depreciation and amortization	(3)	—	(3)	—
Non-GAAP Cost of revenues	<u>\$ 687</u>	<u>\$ —</u>	<u>\$ 687</u>	<u>\$ —</u>
Reconciliation of GAAP to non-GAAP Research and development:				
GAAP Research and development	\$ 6,460	\$ 6,968	\$ 22,982	\$ 19,019
Less: Stock-based compensation expense	(418)	(1,183)	(4,586)	(2,957)
Less: Depreciation and amortization	(43)	(41)	(123)	(123)
Non-GAAP Research and development	<u>\$ 5,999</u>	<u>\$ 5,744</u>	<u>\$ 18,273</u>	<u>\$ 15,939</u>
Reconciliation of GAAP to non-GAAP Sales and marketing:				
GAAP Sales and Marketing	\$ 3,404	\$ 1,746	\$ 10,697	\$ 4,926
Less: Stock-based compensation expense	(65)	(312)	(2,326)	(903)
Non-GAAP Sales and marketing	<u>\$ 3,339</u>	<u>\$ 1,434</u>	<u>\$ 8,371</u>	<u>\$ 4,023</u>
Reconciliation of GAAP to non-GAAP General and administrative:				
GAAP General and administrative	\$ 4,256	\$ 4,191	\$ 13,772	\$ 12,264
Less: Stock-based compensation expense	(1,057)	(1,154)	(4,041)	(3,826)
Less: Depreciation and amortization	(241)	(223)	(722)	(686)
Non-GAAP General and administrative	<u>\$ 2,958</u>	<u>\$ 2,814</u>	<u>\$ 9,009</u>	<u>\$ 7,752</u>
Reconciliation of GAAP to non-GAAP Cost and expenses:				
GAAP Cost and expenses	\$ 14,847	\$ 12,905	\$ 48,178	\$ 36,209
Less: Stock-based compensation expense	(1,577)	(2,649)	(10,990)	(7,686)
Less: Depreciation and amortization	(287)	(264)	(848)	(809)
Non-GAAP Cost and expenses	<u>\$ 12,983</u>	<u>\$ 9,992</u>	<u>\$ 36,340</u>	<u>\$ 27,714</u>

**Reconciliation of GAAP to non-
GAAP Net loss:**

GAAP Net loss	\$ (14,282)	\$ (12,896)	\$ (48,244)	\$ (36,101)
Add: Stock-based compensation expense	1,577	2,649	10,990	7,686
Add: Depreciation and amortization	287	264	848	809
Non-GAAP Net loss	<u>\$ (12,418)</u>	<u>\$ (9,983)</u>	<u>\$ (36,406)</u>	<u>\$ (27,606)</u>
