

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 11, 2023

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)

Not Applicable
(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, \$0.001 par value 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 11, 2023, Pulse Biosciences, Inc. (the “Company”) announced its financial and operational results for the fiscal quarter ended March 31, 2023. A copy of the Company’s press release is attached hereto as Exhibit 99.1 and is incorporated herein by this 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 Number</u>	<u>Description</u>
99.1	Press Release issued by Pulse Biosciences, Inc. dated May 11, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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, thereunto duly authorized.

PULSE BIOSCIENCES, INC.

Date: May 11, 2023

By: /s/ Kevin P. Danahy
Kevin P. Danahy
Chief Executive Officer
(Principal Executive and Principal Financial Officer)

Pulse Biosciences Reports Business Updates and First Quarter 2023 Financial Results

HAYWARD, Calif. [Business Wire] – May 11, 2023 – Pulse Biosciences, Inc. (Nasdaq: PLSE), a company leveraging its novel and proprietary nanosecond pulsed field ablation (nsPFA™) technology for the treatment of atrial fibrillation, today announced financial results for the first quarter ended March 31, 2023.

Business Updates

- Announced the appointment of Gansevoort “Gan” Dunnington, MD, as Chief Medical Officer, Cardiac Surgery; Dr. Dunnington is a key opinion leading cardiothoracic surgeon pioneering novel less-invasive technologies to improve the lives of patients with atrial fibrillation.
- Completed a pre-submission meeting with the FDA to review the regulatory requirements for the Company’s nsPFA surgical ablation clamp as part of the standard Q-submission process; expect continued engagement with FDA to finalize the regulatory path for the device.
- Continued development across several preclinical studies for the Company’s nsPFA cardiac ablation catheter device to support a first-in-human feasibility study.
- Entered into a \$65 million private placement stock purchase agreement with Robert Duggan, the Company’s Executive Chairman, effectively canceling all indebtedness owed by the Company to Mr. Duggan.
- Announced decision to redeem all outstanding warrants from the Company’s June 2022 Rights Offering; the exercise of warrants in 2023 represents an opportunity to raise up to an additional \$15.0 million for the Company.

“In the first quarter we advanced our preclinical and regulatory objectives for our two novel nsPFA devices, the surgical ablation clamp and cardiac ablation catheter. Our preclinical evidence continues to demonstrate differentiated benefits of nsPFA that we believe can advance the treatment of atrial fibrillation,” said Kevin Danahy, Chief Executive Officer of Pulse Biosciences. “We are excited to expand our leadership team with the appointment of our Chief Medical Officer, Dr. Gan Dunnington. He has been actively involved with the preclinical studies of our nsPFA surgical ablation clamp and shares our enthusiasm about the potential of the technology. His continued contributions will be extremely valuable as we advance clinical, regulatory, and potential commercialization of the device.”

First Quarter 2023 Results

Total GAAP cost and expenses, representing cost of revenues, research and development, sales and marketing, and general and administrative expenses, for the three months ended March 31, 2023, were \$9.6 million, compared to \$17.7 million for the prior year period. Non-GAAP cost and expenses for the three months ended March 31, 2023, were \$8.3 million compared to \$14.7 million in the prior year period.

GAAP net loss for the three months ended March 31, 2023, was (\$9.8) million compared to (\$17.3) million for the three months ended March 31, 2022. Non-GAAP net loss for the three months ended March 31, 2023 was (\$8.6) million compared to (\$14.2) million for the three months ended March 31, 2023.

Cash and cash equivalents totaled \$54.1 million as of March 31, 2023, compared to \$12.7 million as of March 31, 2022 and \$61.1 million as of December 31, 2022. Cash used in the first quarter of 2023 was \$7.2 million compared to \$15.9 million in the same period in the prior year and \$8.0 million used in the fourth quarter of 2022. Cash used in the first quarter excludes \$200 thousand of net proceeds from the exercise of warrants.

Reconciliations of GAAP to non-GAAP cost and 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, May 11, 2023, beginning at 1:30pm PT. Investors interested in listening to the conference call may do so by dialing 1-877-704-4453 for domestic callers or 1-201-389-0920 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 Nanosecond Pulsed Field Ablation (nsPFA) technology delivers nano-second pulses of electrical energy to non-thermally clear cells while sparing adjacent non-cellular tissue. The Company is actively pursuing the development of its nsPFA technology for use in electrophysiology and the treatment of atrial fibrillation. Visit pulsebiosciences.com to learn more.

Pulse Biosciences, CellFX, Nano-Pulse Stimulation, NPS, nsPFA 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 and restructuring charges. 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 cost and 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 cost and expenses and net loss measures. Depreciation and amortization are non-cash charges to current operations.

Restructuring charges. The Company has excluded restructuring charges in calculating its non-GAAP cost and expenses and net loss measures. Restructuring programs involve discrete initiatives designed to improve operating efficiencies and include employee termination, contract termination, and other exit costs associated with the restructuring program. The Company believes that excluding discrete restructuring charges allows for better comparisons from period to period.

Forward-Looking Statements

All statements in this press release that are not historical are forward-looking statements, including, among other things, statements relating to the effectiveness of the Company's nsPFA technology and CellFX System to non-thermally clear cells while sparing adjacent non-cellular tissue, statements concerning the Company's expected product development efforts, such as advancement of its cardiac clamp through the appropriate FDA regulatory path and possible initiation of a first-in-human safety feasibility study of its nsPFA cardiac ablation catheter system, statements concerning the Company's future regulatory strategies and possible government clearances and approvals, statements concerning customer adoption and future use of the CellFX System to address a range of conditions such as atrial fibrillation, statements about the Company's redemption of warrants and other future financing opportunities and operating expenses, and Pulse Biosciences' expectations, whether stated or implied, regarding whether the Company's nsPFA technology will become a disruptive treatment option for treating cardiac arrhythmias and whether future clinical studies will show the CellFX System is safe and effective to treat atrial fibrillation or any other medical condition, 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 per share amounts)
(Unaudited)

	March 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 54,098	\$ 61,139
Prepaid expenses and other current assets	849	1,008
Total current assets	54,947	62,147
Property and equipment, net	1,865	1,961
Intangible assets, net	2,384	2,551
Goodwill	2,791	2,791
Right-of-use assets	7,869	8,062
Other assets	365	365
Total assets	<u>\$ 70,221</u>	<u>\$ 77,877</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,160	\$ 1,573
Accrued expenses	3,091	2,595
Deferred revenue	4	—
Lease liability, current	935	896
Related party note payable, current	801	917
Total current liabilities	6,991	5,981
Lease liability, less current	8,898	9,144
Related party note payable, current	65,000	65,000
Total liabilities	<u>80,889</u>	<u>80,125</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 – 37,593 shares and 37,235 shares at March 31, 2023 and December 31, 2022, respectively	37	37
Additional paid-in capital	293,801	292,420
Accumulated other comprehensive income (loss)	—	—
Accumulated deficit	(304,506)	(294,705)
Total stockholders' deficit	<u>(10,668)</u>	<u>(2,248)</u>
Total liabilities and stockholders' deficit	<u>\$ 70,221</u>	<u>\$ 77,877</u>

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

	Three-Month Periods Ended March 31,	
	2023*	2022
Revenues:		
Product revenues	\$ —	\$ 444
Total revenues	—	444
Cost and expenses:		
Cost of revenues	—	909
Research and development	5,829	6,769
Sales and marketing	—	5,541
General and administrative	3,733	4,498
Total cost and expenses	9,562	17,717
Loss from operations	(9,562)	(17,273)
Other expense:		
Interest expense, net	(239)	—
Total other expense	(239)	—
Net loss	(9,801)	(17,273)
Other comprehensive gain:		
Unrealized gain on available-for-sale securities	—	—
Comprehensive loss	\$ (9,801)	\$ (17,273)
Net loss per share:		
Basic and diluted net loss per share	\$ (0.26)	\$ (0.58)
Weighted average shares used to compute net loss per common share — basic and diluted	37,390	29,745

	Three-Month Periods Ended March 31,	
	2023*	2022
Stock Based Compensation Expense:		
Cost of revenues	\$ —	\$ 90
Research and development	258	457
Sales and marketing	—	454
General and administrative	638	1,006
Total stock-based compensation expense	\$ 896	\$ 2,007

*For the three month period ended March 31, 2023, the Company reclassified certain expenses as a result of the shift in focus from dermatology to cardiology. The Company is no longer selling the CellFX system into the dermatology market, and is therefore no longer incurring Cost of Revenues. Expenses previously included in Cost of Revenues are now recorded as a part of Research and Development, and expenses previously included in Sales and Marketing are now recorded as a part of General and Administrative. Going forward, the Company will evaluate the classification of expenses as research and development or general and administrative in accordance with ASC Topic 730, Research and Development.

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,	
	2023	2022
Reconciliation of GAAP to non-GAAP Cost of revenues:		
GAAP Cost of revenues	\$ —	\$ 909
Less: Stock-based compensation expense	—	(90)
Less: Depreciation and amortization	—	(5)
Less: Restructuring	—	(19)
Non-GAAP Cost of revenues	<u>\$ —</u>	<u>\$ 795</u>
Reconciliation of GAAP to non-GAAP Research and development:		
GAAP Research and development	\$ 5,829	\$ 6,769
Less: Stock-based compensation expense	(258)	(457)
Less: Depreciation and amortization	(57)	(59)
Less: Restructuring	(38)	(127)
Non-GAAP Research and development	<u>\$ 5,476</u>	<u>\$ 6,126</u>
Reconciliation of GAAP to non-GAAP Sales and marketing:		
GAAP Sales and marketing	\$ —	\$ 5,541
Less: Stock-based compensation expense	—	(454)
Less: Depreciation and amortization	—	(13)
Less: Restructuring	—	(546)
Non-GAAP Sales and marketing	<u>\$ —</u>	<u>\$ 4,528</u>
Reconciliation of GAAP to non-GAAP General and administrative:		
GAAP General and administrative	\$ 3,733	\$ 4,498
Less: Stock-based compensation expense	(638)	(1,006)
Less: Depreciation and amortization	(244)	(249)
Less: Restructuring	(12)	(41)
Non-GAAP General and administrative	<u>\$ 2,839</u>	<u>\$ 3,202</u>
Reconciliation of GAAP to non-GAAP Cost and expenses:		
GAAP Cost and expenses	\$ 9,562	\$ 17,717
Less: Stock-based compensation expense	(896)	(2,007)
Less: Depreciation and amortization	(301)	(326)
Less: Restructuring	(50)	(733)
Non-GAAP Cost and expenses	<u>\$ 8,315</u>	<u>\$ 14,651</u>
Reconciliation of GAAP to non-GAAP Net loss:		
GAAP Net loss	\$ (9,801)	\$ (17,273)
Add: Stock-based compensation expense	896	2,007
Add: Depreciation and amortization	301	326
Add: Restructuring	50	733
Non-GAAP Net loss	<u>\$ (8,554)</u>	<u>\$ (14,207)</u>