

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): **October 30, 2024**

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.)

601 Brickell Key Drive, Suite 1000
Miami, Florida 33131
(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 October 30, 2024, Pulse Biosciences, Inc. (the “Company”) announced certain financial and operational results for the fiscal quarter ended September 30, 2024. 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 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 filing.

Item 8.01 Other Events.

On October 30, 2024, the Company announced the appointment of David Kenigsberg, M.D. as Chief Medical Officer of Electrophysiology. Andrea Natale, M.D. will become a medical advisor for the company, joining existing advisors Vivek Reddy, M.D. and Jacob Koruth, M.D., who altogether will continue to support the development and clinical efforts for the Pulse Biosciences nano-PFA 360 Cardiac Catheter. A copy of the Company’s press release is attached hereto as Exhibit 99.2 and is incorporated herein by this reference.

This information, as well as Exhibit 99.2, is intended to be furnished 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 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 October 30, 2024 - Business Update and Quarterly Results
99.2	Press Release issued by Pulse Biosciences, Inc. dated October 30, 2024 - Appointment of Chief Medical Officer of Electrophysiology
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: October 30, 2024

By: /s/ Burke T. Barrett

Burke T. Barrett

President and Chief Executive Officer

(Principal Executive and Principal Financial Officer)

Pulse Biosciences Reports Business Updates and Third Quarter 2024 Financial Results

MIAMI, Florida. [Business Wire] – October 30, 2024. Pulse Biosciences, Inc. (Nasdaq: PLSE) (the “Company” or “Pulse Biosciences”), a company leveraging its novel and proprietary Nanosecond Pulsed Field Ablation™ (nsPFA or nano-PFA) technology, today announced business updates and financial results for the third quarter ended September 30, 2024.

Recent Business Highlights

Soft Tissue Ablation

- Placed nsPFA Percutaneous Electrode Systems with seven sites in the U.S. as part of a pilot program for clinical assessment with commercial use expected to begin in the coming quarters.
- The Company expects to commence a pivotal clinical trial in mid-2025 to support a specific labeling indication to commercialize the Percutaneous Electrode System in the United States as a treatment for benign thyroid nodules.
- Clinical data from the European feasibility study on using nano-PFA to treat benign thyroid nodules will be presented at the American Thyroid Association Conference as an oral abstract on October 31, 2024.

Surgical AF Ablation

- Treated 9 patients and opened a second study site as part of the multi-center, first-in-human atrial fibrillation (AF) feasibility study underway in Europe.
- The Company expects to submit an IDE, enabling it to commence its pivotal clinical trial in mid-2025 to support a premarket approval (PMA) application for FDA approval to commercialize the nano-PFA Cardiac Surgical System in the United States as a treatment for AF.

Endocardial Catheter Ablation

- Treated over 50 patients with the nano-PFA 360° Cardiac Catheter and engaged two additional European clinical study sites in the first-in-human feasibility study for the treatment of AF.
- Announced the appointment of Dr. David Kenigsberg as Chief Medical Officer for Electrophysiology and the addition of Dr. Andrea Natale to its electrophysiology medical advisory board, joining existing advisors Dr. Vivek Reddy and Dr. Jacob Koruth.
- The Company expects to commence a U.S. IDE pivotal clinical study sometime in the middle of 2025.

“In the third quarter we made significant progress toward delivering the benefits of nano-PFA to patients and providers around the world. Our clinical work with each of our three devices continues to suggest that our differentiated nano-PFA technology has the potential to improve treatments for several disease states by eradicating cells in a better way than currently available modalities,” said Burke T. Barrett, President and Chief Executive Officer of Pulse Biosciences. “The work we have done to date positions us to begin pivotal clinical trials in the U.S. for each device next year and to also share select European trial data at medical conferences in the future. We are building our team and the infrastructure required to support our clinical and regulatory initiatives and anticipated growth, starting with commercial use of the nsPFA Percutaneous Electrode System in the coming quarters.”

Third Quarter 2024 Financial Results

Total GAAP costs and expenses, representing research and development and general and administrative expenses, for the three months ended September 30, 2024, were \$13.7 million, an increase of \$2.4 million, compared to \$11.3 million in the prior year period. The increase was primarily driven by stock-based compensation and other compensation and administrative expenses to support the expanding organization and the advancement of our nano-PFA devices. Non-GAAP costs and expenses for the three months ended September 30, 2024, were \$10.4 million, an increase of \$1.2 million compared to \$9.2 million in the prior year period.

GAAP net loss for the three months ended September 30, 2024 was (\$12.7) million compared to (\$10.6) million for the three months ended September 30, 2023. Non-GAAP net loss for the three months ended September 30, 2024 was (\$9.4) million compared to (\$8.5) million for the three months ended September 30, 2023.

Cash and cash equivalents totaled \$79.0 million as of September 30, 2024. The cash balance as of September 30, 2024 includes \$60 million in gross proceeds received from the rights offering that closed in July of 2024. The Company has the potential to raise an additional up to \$66 million through the exercise of warrants associated with this rights offering. Each warrant is exercisable for \$11 per share, which equals 110% of the subscription price for the Units. Warrants are exercisable immediately. Half of the warrants are redeemable by the Company if the Company’s stock trading price exceeds \$16.50 for twenty consecutive trading days and the other half of the warrants are redeemable by the Company if its stock trading price exceeds \$22.00 for twenty consecutive trading days. Holders of the warrants have the right to exercise them at any time until they are redeemed or expire.

Cash used in the third quarter of 2024 was \$8.5 million, excluding financing activity, compared to \$8.7 million used in the second quarter of 2024 and \$8.7 million in the third quarter of 2023.

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, October 30, 2024, beginning at 1:30pm PT. Investors interested in listening to the conference call may do so by dialing 1-877-407-0752 for domestic callers or 1-201-389-0912 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 CellFX® nsPFA™ technology delivers nanosecond pulses of electrical energy to non-thermally clear cells while sparing adjacent noncellular tissue. The Company is actively pursuing the development of its CellFX nsPFA technology for use in the treatment of atrial fibrillation and in a select few other markets where it could have a profound positive impact on healthcare for both patients and providers. Pulse Biosciences is now headquartered in Miami, Florida and maintains its office in Hayward, California.

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



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 time-based and performance-based options, such as options that vest as a result of the Company's market capitalization. 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 CellFX nsPFA technology and CellFX System to non-thermally clear cells while sparing adjacent non-cellular tissue, statements concerning the Company's future fundraising efforts and whether those efforts will be successful or allow the Company to continue current operations as planned, and statements concerning the Company's future clinical and regulatory initiatives anywhere in the world, 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)

	September 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 79,033	\$ 44,365
Prepaid expenses and other current assets	1,381	963
Total current assets	80,414	45,328
Property and equipment, net	1,221	1,528
Intangible assets, net	1,386	1,886
Goodwill	2,791	2,791
Right-of-use assets	6,588	7,256
Other assets	646	365
Total assets	\$ 93,046	\$ 59,154
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,727	\$ 1,836
Accrued expenses	3,821	3,814
Lease liability, current	1,193	1,058
Total current liabilities	6,741	6,708
Lease liability, less current	7,174	8,086
Total liabilities	13,915	14,794
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 – 61,516 shares and 55,144 shares at September 30, 2024 and December 31, 2023, respectively	62	55
Additional paid-in capital	450,184	381,220
Accumulated other comprehensive income (loss)	—	—
Accumulated deficit	(371,115)	(336,915)
Total stockholders' equity	79,131	44,360
Total liabilities and stockholders' equity	\$ 93,046	\$ 59,154

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

	Three-Month Periods Ended	
	September 30,	
	2024	2023
Revenues:		
Product revenues	\$ —	\$ —
Total revenues	—	—
Cost and expenses:		
Research and development	7,703	7,472
General and administrative	5,952	3,780
Total cost and expenses	13,655	11,252
Loss from operations	(13,655)	(11,252)
Other income:		
Interest income, net	975	686
Total other income	975	686
Net loss	(12,680)	(10,566)
Comprehensive loss	\$ (12,680)	\$ (10,566)
Net loss per share:		
Basic and diluted net loss per share	\$ (0.21)	\$ (0.19)
Weighted average shares used to compute net loss per common share — basic and diluted	61,066	56,866

	Three-Month Periods Ended	
	September 30,	
	2024	2023
Stock Based Compensation Expense:		
Research and development	1,108	982
General and administrative	1,874	816
Total stock-based compensation expense	\$ 2,982	\$ 1,798

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 September 30,	
	2024	2023
Reconciliation of GAAP to non-GAAP Research and development:		
GAAP Research and development	\$ 7,703	\$ 7,472
Less: Stock-based compensation expense	(1,108)	(982)
Less: Depreciation and amortization	(47)	(55)
Less: Restructuring	—	—
Non-GAAP Research and development	\$ 6,548	\$ 6,435
Reconciliation of GAAP to non-GAAP General and administrative:		
GAAP General and administrative	\$ 5,952	\$ 3,780
Less: Stock-based compensation expense	(1,874)	(816)
Less: Depreciation and amortization	(246)	(242)
Less: Restructuring	—	—
Non-GAAP General and administrative	\$ 3,832	\$ 2,722
Reconciliation of GAAP to non-GAAP Cost and expenses:		
GAAP Cost and expenses	\$ 13,655	\$ 11,252
Less: Stock-based compensation expense	(2,982)	(1,798)
Less: Depreciation and amortization	(293)	(297)
Less: Restructuring	—	—
Non-GAAP Cost and expenses	\$ 10,380	\$ 9,157
Reconciliation of GAAP to non-GAAP Net loss:		
GAAP Net loss	\$ (12,680)	\$ (10,566)
Add: Stock-based compensation expense	2,982	1,798
Add: Depreciation and amortization	293	297
Add: Restructuring	—	—
Non-GAAP Net loss	\$ (9,405)	\$ (8,471)

Pulse Biosciences Announces Appointment of David Kenigsberg, M.D. as Chief Medical Officer of Electrophysiology

Adds Andrea Natale, M.D. as a medical advisor, joining existing advisors Vivek Reddy, M.D. and Jacob Koruth, M.D.

MIAMI, Florida. [Business Wire] – October 30, 2024. Pulse Biosciences, Inc. (Nasdaq: PLSE), a company leveraging its novel and proprietary Nanosecond Pulsed Field Ablation™ (nsPFA™) technology, today announced the appointment of David Kenigsberg, M.D. as Chief Medical Officer of Electrophysiology. Andrea Natale, M.D. will become a medical advisor for the company, joining existing advisors Vivek Reddy, M.D. and Jacob Koruth, M.D., who altogether will continue to support the development and clinical efforts for the Pulse Biosciences nano-PFA 360 Cardiac Catheter.

“I am inspired by the potential of nano-PFA and the unique catheter design of the 360 catheter that is already demonstrating the ability to isolate pulmonary veins with ease and speed,” said Dr. David Kenigsberg, Chief Medical Officer of Electrophysiology of Pulse Biosciences. “I was impressed when I saw the 360 catheter in use and am excited to work with Pulse to deliver robust clinical data with the 360, which I believe will substantially advance the treatment of atrial fibrillation. I look forward to supporting this team through its next phase of clinical development.”

Dr. Kenigsberg is a practicing cardiac electrophysiologist with a passion for treating atrial fibrillation over his career. He is the founder of Florida Heart Rhythm Specialists and Ft. Lauderdale Heart & Rhythm Surgical Center. He has been the Medical Director of the Electrophysiology Lab at HCA Westside Medical Center in Plantation, Florida, since 2007. He has published numerous scholarly articles in peer-reviewed medical journals. He has advised in the development and has been the primary investigator/co-investigator in a myriad of clinical trials involving ablation tools. Dr. Kenigsberg is a fellow of the American College of Cardiology and the Heart Rhythm Society. He is the President of the Florida Chapter of the American College of Cardiology and sits on the American College of Cardiology Board of Governors.

“This is an exciting time in electrophysiology as pulsed field ablation technologies are becoming widely adopted and advancing the standard of care. I am excited to support the Pulse team in the clinical efforts for the 360 catheter,” added Dr. Andrea Natale.

Dr. Andrea Natale is the Executive Medical Director of the Texas Cardiac Arrhythmia Institute at St. David’s Medical Center in Austin, Texas, and the National Medical Director of Cardiac Electrophysiology for HCA Healthcare. A dedicated researcher and pioneer, Dr. Andrea Natale focuses on innovative advances in the treatment of atrial fibrillation. He has been, and continues to be, involved in many first-in-human trials to test investigational devices, recently performing the first pre-clinical and clinical studies to develop and perfect ablation catheters utilizing a novel, groundbreaking ablation energy source known as irreversible electroporation.

Burke T. Barrett, President and Chief Executive Officer of Pulse Biosciences concluded, “We are significantly strengthening our team with the addition of these renowned physicians who will contribute to generating high quality clinical data that demonstrates the clinical performance profile of the 360 catheter. I want to thank Drs. Reddy and Koruth for their significant contributions in the pre-clinical and clinical evaluations of the 360 catheter to date.”

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 CellFX® nsPFA™ technology delivers nanosecond pulses of electrical energy to non-thermally clear cells while sparing adjacent noncellular tissue. The Company is actively pursuing the development of its CellFX nsPFA technology for use in the treatment of atrial fibrillation and in a select few other markets where it could have a profound positive impact on healthcare for both patients and providers. Pulse Biosciences is now headquartered in Miami, Florida and maintains its office in Hayward, California.

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

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