UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2024

Or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 001-34899

Pulse Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**46-5696597**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
601 Brickell Key Drive Miami, FL	**33131**
(Address of principal executive offices)	**(Zip Code)**

(510) 906-4600
(Registrant's telephone number, including area code)

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of shares outstanding of the registrant's common stock as of October 25, 2024: 61,516,677

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"Pulse Biosciences," the Pulse logos and other trademarks or service marks that we use in connection with the operation of our business appearing in this quarterly report on Form 10-Q (this "Quarterly Report"), including CellFX, CellFX CloudConnect, CellFX Marketplace, Nano-pulse Stimulation, nsPFA, nano-PFA, CellFX nsPFA, and NPS, are the property of Pulse Biosciences, Inc. Solely for your convenience, some of our trademarks and trade names referred to in this Quarterly Report are listed without the ® and ™ symbols, but we will assert, to the fullest extent under applicable law, our rights to our trademarks and trade names. Also, this Quarterly Report may contain additional trade names, trademarks or service marks of others, which are the property of their respective owners. We do not intend our use or display of any other company's trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any of these other companies.

Unless expressly indicated or the context requires otherwise, the terms "Pulse," "Company," "we," "us," and "our," in this document refer to Pulse Biosciences, Inc., a Delaware corporation, and, where appropriate, its wholly owned subsidiaries.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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 portion	7,174	8,086
Total liabilities	13,915	14,794
Commitments and contingencies (Note 7)		
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

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues:				
Product revenues	$ —	$ —	$ —	$ —
Total revenues	—	—	—	—
Cost and expenses:				
Research and development	7,703	7,472	21,674	19,998
General and administrative	5,952	3,780	14,322	11,043
Total cost and expenses	13,655	11,252	35,996	31,041
Loss from operations	(13,655)	(11,252)	(35,996)	(31,041)
Other income:				
Interest income, net	975	686	1,796	764
Total other income	975	686	1,796	764
Loss from operations, before income taxes	(12,680)	(10,566)	(34,200)	(30,277)
Income tax benefit	—	—	—	—
Net loss	(12,680)	(10,566)	(34,200)	(30,277)
Comprehensive loss	$ (12,680)	$ (10,566)	$ (34,200)	$ (30,277)
Net loss per share:				
Basic and diluted net loss per share	$ (0.21)	$ (0.19)	$ (0.60)	$ (0.64)
Weighted average shares used to compute net loss per common share — basic and diluted	61,066	56,866	57,169	47,288

See accompanying notes to the condensed consolidated financial statements.

PULSE BIOSCIENCES, INC.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (34,200)	$ (30,277)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	391	404
Amortization of intangible assets	500	499
Stock-based compensation	6,793	3,837
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(394)	(343)
Other receivables	7	114
Right-of-use assets	668	596
Accounts payable	(194)	(174)
Accrued expenses	7	409
Lease liabilities	(777)	(656)
Accrued interest on related party note payable	—	(668)
Net cash used in operating activities	(27,199)	(26,259)
Cash flows from investing activities:		
Purchases of property and equipment	(72)	(78)
Net cash used in investing activities	(72)	(78)
Cash flows from financing activities:		
Proceeds from issuance of common stock under employee stock purchase plan	478	395
Proceeds from issuance of common stock and warrants in relation to rights offering, net of issuance costs	59,649	—
Proceeds from exercises of warrants	1,536	14,828
Proceeds from exercises of stock options	498	367
Issuance cost in relation to related party note extinguishment	—	(6)
Deferred issuance costs in relation to future at-the-market equity offering	(222)	—
Net cash provided by financing activities	61,939	15,584
Net increase (decrease) in cash and cash equivalents	34,668	(10,753)
Cash and cash equivalents at beginning of period	44,365	61,139
Cash and cash equivalents at end of period	$ 79,033	$ 50,386
Supplemental disclosure of noncash investing and financing activities:		
Equipment purchases included in accounts payable and accrued expenses	$ 13	$ 13
Rights offering deemed pro-rata distribution to shareholders	$ 47,700	$ —
Principal and accrued interest of related party note settled via issuance of common stock	$ —	$ 65,249
Other receivable from exercises of warrants	$ 30	$ —
Rights offering and at-the-market issuance costs in accounts payable	$ 72	$ —

See accompanying notes to the condensed consolidated financial statements.

PULSE BIOSCIENCES, INC.
Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(In thousands)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, June 30, 2024	55,228	$ 55	$ 385,349	$ —	$ (358,435)	$ 26,969
Issuance of common stock and warrants in connection with rights offering, net of issuance costs of $364	6,000	6	59,630	—	—	59,636
Issuance of common stock upon exercise of warrants	142	1	1,565	—	—	1,566
Issuance of common stock upon exercise of stock options	105	—	476	—	—	476
Issuance of shares under employee stock purchase plan	40	—	182	—	—	182
Issuance of shares in at-the-market offering, net of issuance costs of $24	1	—	—	—	—	—
Stock-based compensation expense	—	—	2,982	—	—	2,982
Net loss	—	—	—	—	(12,680)	(12,680)
Balance, September 30, 2024	61,516	$ 62	$ 450,184	$ —	$ (371,115)	$ 79,131

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2023	55,144	$ 55	$ 381,220	$ —	$ (336,915)	$ 44,360
Issuance of common stock and warrants in connection with rights offering, net of issuance costs of $364	6,000	6	59,630	—	—	59,636
Issuance of common stock upon exercise of warrants	142	1	1,565	—	—	1,566
Issuance of common stock upon exercise of stock options	111	—	498	—	—	498
Issuance of shares under employee stock purchase plan	118	—	478	—	—	478
Issuance of shares in at-the-market offering, net of issuance costs of $24	1	—	—	—	—	—
Issuance of equity-classified subscription rights as part of rights offering (Note 6)	—	—	47,700	—	—	47,700
Rights offering deemed pro-rata distribution to shareholders (Note 6)	—	—	(47,700)	—	—	(47,700)
Stock-based compensation expense	—	—	6,793	—	—	6,793
Net loss	—	—	—	—	(34,200)	(34,200)
Balance, September 30, 2024	61,516	$ 62	$ 450,184	$ —	$ (371,115)	$ 79,131

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, June 30, 2023	54,771	$ 55	$ 374,861	$ —	$ (314,416)	$ 60,500
Issuance of common stock upon exercise of stock options	135	—	309	—	—	309
Issuance of shares under employee stock purchase plan	85	—	103	—	—	103
Warrant exercise, issuance cost adjustment	—	—	1	—	—	1
Stock-based compensation expense	—	—	1,798	—	—	1,798
Net loss	—	—	—	—	(10,566)	(10,566)
Balance, September 30, 2023	54,991	$ 55	$ 377,072	$ —	$ (324,982)	$ 52,145

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount				
Balance, December 31, 2022	37,235	$ 37	$ 292,420	$ —	$ (294,705)	$ (2,248)
Issuance of common stock as part of debt extinguishment, net of issuance costs of $6	10,023	10	65,233	—	—	65,243
Issuance of shares upon exercise of warrants, net of issuance costs of $9	7,238	7	14,821	—	—	14,828

Issuance of shares under employee stock purchase plan	347	1	394	—	—	395
Issuance of common stock upon exercise of stock options	148	—	367	—	—	367
Stock-based compensation expense	—	—	3,837	—	—	3,837
Net loss	—	—	—	—	(30,277)	(30,277)
Balance, September 30, 2023	54,991	$ 55	$ 377,072	$ —	$ (324,982)	$ 52,145

See accompanying notes to the condensed consolidated financial statements.

PULSE BIOSCIENCES, INC.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Description of the Business

Pulse Biosciences, Inc. is a novel bioelectric medicine company committed to health innovation using its patented Nano-pulse Stimulation ("NPS") technology, a revolutionary energy modality that delivers nanosecond-duration pulses of electrical energy, each less than a millionth of a second long, to nonthermally clear targeted cells while sparing adjacent noncellular materials. NPS technology, also referred to as Nanosecond Pulsed-Field Ablation ("nsPFA" or "nano-PFA") technology when used to ablate cellular tissue, can be used to treat a variety of medical conditions for which an optimal solution remains unfulfilled. The Company developed its proprietary CellFX System, a novel nano-PFA delivery platform, and commercialized the initial application of its nano-PFA technology to treat benign lesions of the skin. In parallel, the Company has designed a variety of applicators, or disposables, to explore the potential use of the CellFX platform to treat disorders in other medical specialties, such as cardiology, gastroenterology, gynecology, and ear, nose and throat. These applicators include devices for open surgical procedures, endoscopic or minimally invasive procedures, and endoluminal catheters, and each has been used in preclinical studies. Based on our preclinical experience and the potential to significantly improve outcomes for patients in a large and growing market, the Company decided in 2022 to focus its primary efforts on the use of nsPFA energy and the CellFX platform in the treatment of atrial fibrillation ("AF") and in a select few other markets where it could have a profound positive impact on healthcare for both patients and providers, such as soft tissue ablation.

The Company was incorporated in Nevada on May 19, 2014. On June 18, 2018, the Company reincorporated from the State of Nevada to the State of Delaware. The Company is located in Miami, Florida, and continues to maintain its offices in Hayward, California. The Company maintains a website at www.pulsebiosciences.com where general information about the Company is available.

The Company's activities are subject to significant risks and uncertainties, including the need for additional capital. The Company does not currently have any material cash flows from operations. It currently generates no revenue and will need to raise additional capital to finance its operations. However, there can be no assurances that the Company will be able to obtain additional financing on acceptable terms and in the amounts necessary to fully fund its operating requirements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared on a basis consistent with the Company's December 31, 2023 audited Consolidated Financial Statements and include all adjustments, consisting of only normal recurring adjustments, necessary to fairly state the information set forth herein. The condensed consolidated financial statements have been prepared in accordance with the applicable rules and regulations of the Securities and Exchange Commission (the "SEC") and, as permitted by such rules and regulations, omit certain information and footnote disclosures necessary to present the financial statements in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). The condensed consolidated balance sheet as of December 31, 2023 was derived from the audited consolidated financial statements as of that date but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023. The results of operations for the three-month and nine-month periods ended September 30, 2024, are not necessarily indicative of the results to be expected for the entire year or any future periods.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the financial statements of Pulse Biosciences, Inc. and its wholly-owned subsidiaries. Intercompany balances and transactions, if any, have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make estimates that affect the amounts reported in the financial statements and accompanying notes to the financial statements. Estimates include, but are not limited to, the valuation and recognition of stock-based compensation, the valuation of equity-classified subscription rights, inventory valuation, warranty obligations, income taxes, and the useful lives assigned to long-lived assets. The Company evaluates its estimates and assumptions based on historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ materially from these estimates.

Significant Accounting Policies

The Company's significant accounting policies are described in the Company's Annual Report on Form 10-K for the year ended December 31, 2023. The Company continually evaluates the accounting policies and estimates used in preparing the consolidated financial statements. During both the year ended December 31, 2023, and the nine-month period ended September 30, 2024, the Company issued stock options to certain employees which contain market conditions related to overall market capitalization. Additionally, the Company has issued stock options to certain employees which contain performance conditions related to certain financial measures and achievements of strategic and operational milestones.

Stock-Based Compensation

The Company's stock-based compensation programs include stock options and an employee stock purchase program.

The Company periodically issues stock options to officers, directors, employees, and consultants for services rendered. Such issuances vest and expire according to terms established at the issuance date. Stock-based payments to officers, directors and employees, including grants of employee stock options, are recognized in the financial statements based on their grant date fair values, which are estimated using the Black-Scholes option-pricing model. Stock-based compensation expense is charged to operations on a straight-line basis over the vesting period. The Company has granted stock options with both time-based as well as performance-based vesting conditions. For stock awards with performance-based vesting conditions, the Company does not recognize compensation expense until it is probable that the performance-based vesting condition will be achieved. The analysis to determine such probability involves estimates and judgements from management and the estimate of expense may be revised periodically.

The Company has also issued certain stock options with market-based vesting conditions. These vesting conditions relate to the achievement of certain market capitalization targets of the Company. The grant date fair value for these stock options was determined using a Monte Carlo simulation. The expense is recognized over the requisite service period for each tranche of the awards. The requisite service period is the service period derived from the Monte Carlo simulation model. If the market capitalization targets are met sooner than the derived service period, the Company will accelerate the recognition of stock-based compensation expense to reflect the cumulative expense associated with the vested shares. The Monte Carlo simulation requires the Company to make assumptions and judgements about the variables used in the calculation including the expected term, volatility of the Company's common stock, an assumed risk-free interest rate, and cost of equity. The assumptions used in the option-pricing model represent management's best estimates. If factors change and different assumptions are used, the Company's stock-based compensation expense could be materially different in the future.

See Note 6 for a detailed discussion of the Company's stock plans and stock-based compensation expense.

Product Warranty

The Company provides a standard warranty on eligible products which provides the customer assurances that the products comply with the agreed-upon specifications. The standard warranty does not provide any services in addition to those assurances. The Company accrued a warranty reserve for products sold based upon the best estimate of the nature, frequency, and costs of future claims. These estimates are inherently uncertain given the short history of sales, and changes to the historical or projected warranty experience may cause material changes to the warranty reserve in the future. In June 2023, the Company reduced the accrued warranty liability to zero. Based upon the Company's shift in focus, there are a limited number of consoles currently covered under the standard warranty. All inventory has been fully written off, therefore the only incremental costs to fulfill a warranty claim in 2024 would be shipping costs or the costs to replace the CellFX nsPFA electrode, which would be immaterial in nature.

Warranty accrual activity consisted of the following for the three-month and nine-month periods ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Beginning balance	$ —	$ —	$ —	$ 50
Add: Accruals for warranties issued during the period	—	—	—	—
Less: Adjustment for inventory at cost and excessive and obsolete inventory	—	—	—	(50)
Ending balance	$ —	$ —	$ —	$ —

Net Loss per Share

The Company calculates basic net loss per share by dividing net loss by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by giving effect to all potential dilutive common stock equivalents outstanding during the period. For purposes of this calculation, options to purchase common stock and common stock warrants are considered common stock equivalents. Potential common shares that have an anti-dilutive effect (i.e., those that increase income per share or decrease loss per share) are excluded from the calculation of diluted net loss per share.

Based on the Accounting Standards Codification ("ASC") 260-10-55, *Earnings Per Share - Implementation Guidance and Illustrations*, the Company determined that the 2024 Rights Offering (Note 6), contained a bonus element. A rights offering is deemed to have a bonus element when the exercise price at issuance is less than fair value of the Company's stock. The Company has retroactively adjusted earnings per share and weighted average number of shares outstanding for the bonus element for prior periods presented.

Basic and diluted net loss per common share is the same for all periods presented because all warrants, stock options and restricted stock units outstanding are anti-dilutive.

The following outstanding stock options, and warrants were excluded from the computation of diluted net loss per share for the periods presented because including them would have had an anti-dilutive effect:

	Nine Months Ended September 30,	
	2024	2023
Common stock warrants	5,857,680	—
Common stock options	12,327,332	7,902,948
Total	18,185,012	7,902,948

Recent Accounting Pronouncements Not Yet Adopted

In March 2024, the FASB issued ASU No. 2024-02, *Codification Improvements - Amendments to Remove References to the Concepts Statements*, an amendment of the FASB Accounting Standards Codification. The amendments in this ASU are related to the removal of various references to FASB Concept Statements from the codification to make clear distinctions between authoritative and non-authoritative literature in the codification. This ASU is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company does not believe this standard will have an impact on its consolidated financial statements and related disclosures.

As of September 30, 2024, there were no additional material changes to the information provided regarding recent accounting pronouncements in Note 2, “Summary of Significant Accounting Policies” in the Company’s Form 10-K for the fiscal year ended December 31, 2023.

3. Fair Value of Financial Instruments

The authoritative guidance with respect to fair value established a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three levels, and requires that assets and liabilities carried at fair value be classified and disclosed in one of three categories, as presented below.

Level 1 - Observable inputs such as quoted prices in active markets for an identical asset or liability that the Company has the ability to access as of the measurement date. Financial assets and liabilities utilizing Level 1 inputs include money market funds.

Level 2 - Inputs, other than quoted prices included within Level 1, which are directly observable for the asset or liability or indirectly observable through corroboration with observable market data. The Company did not classify any of its investments within Level 2 of the fair value hierarchy.

Level 3 - Unobservable inputs for which there is little or no market data for the asset or liability which requires the reporting entity to develop its own assumptions. The Company did not classify any of its investments within Level 3 of the fair value hierarchy.

The following table sets forth the fair value of the Company's financial instruments measured on a recurring basis as of September 30, 2024 and December 31, 2023, respectively (in thousands):

		September 30, 2024			
Assets	**Classification**	**Level 1**	**Level 2**	**Level 3**	**Total**
Money market funds	Cash and cash equivalents	$ 76,386	$ —	$ —	$ 76,386
Total assets measured at fair value		$ 76,386	$ —	$ —	$ 76,386

		December 31, 2023			
Assets	**Classification**	**Level 1**	**Level 2**	**Level 3**	**Total**
Money market funds	Cash and cash equivalents	$ 41,184	$ —	$ —	$ 41,184
Total assets measured at fair value		$ 41,184	$ —	$ —	$ 41,184

The Company did not have any financial liabilities measured on a recurring basis as of September 30, 2024 or December 31, 2023.

4. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Leasehold improvements	$ 2,519	$ 2,519
Laboratory equipment	1,318	1,247
Furniture, fixtures and equipment	966	966
Software	272	272
Construction in progress	14	—
Total property and equipment	5,089	5,004
Less: Accumulated depreciation and amortization	(3,868)	(3,476)
Total property and equipment, net	$ 1,221	$ 1,528

Depreciation expense was $0.1 million for each of the three-month periods ended September 30, 2024 and 2023, and $0.4 million for each of the nine-month periods ended September 30, 2024 and 2023, respectively.

Intangible Assets, Net

Intangible assets primarily consist of acquired licenses to utilize certain patents, know-how and technology relating to the Company's NPS technology for biomedical applications acquired from Old Dominion University Research Foundation ("ODURF"), Eastern Virginia Medical School, and the University of Southern California. In addition, the Company entered into a Sponsored Research Agreement with Old Dominion University's Frank Reidy Research Center for Bioelectrics, which includes certain intellectual property rights arising from the research. The Company is amortizing the intangible assets over an estimated useful life of 12 years.

Intangible assets, net consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Acquired patents and licenses	$ 7,985	$ 7,985
Less: Accumulated amortization	(6,599)	(6,099)
Total intangible assets, net	$ 1,386	$ 1,886

A schedule of the amortization of intangible assets for the remainder of 2024 and the succeeding two fiscal years is as follows (in thousands):

Years ending December 31:	
2024 (remaining 3 months)	$ 165
2025	665
2026	556
Total	$ 1,386

Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Compensation expense	$ 3,111	$ 3,199
Clinical trial fees and costs	80	84
Professional fees	424	343
Other	206	188
Total accrued expenses	$ 3,821	$ 3,814

5. Goodwill

In 2014, the Company acquired three companies (the "Acquisitions") for aggregate consideration of $5.5 million. In accordance with ASC Topic 805, *Business Combinations*, the Company recorded goodwill of $2.8 million in connection with the Acquisitions as the consideration paid exceeded the fair value of the net tangible assets and the intangible assets acquired.

In accordance with ASC Topic 350, *Intangibles-Goodwill and Other* (as amended by Accounting Standards Update 2017-04), the Company reviews goodwill for impairment at least annually or whenever any events or circumstances indicate that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. As of September 30, 2024, there were no indicators of impairment and it was determined that no impairment of goodwill existed.

6. Stockholders' Equity and Stock-Based Compensation

2024 Rights Offering and Subscription Rights

On March 28, 2024, the Company announced that its Board of Directors ("Board") unanimously approved plans to initiate a rights offering, whereby the Company would distribute non-transferable subscription rights at no charge to all holders of the Company's common stock, par value $0.001 per share (the "Common Stock"), as of the close of business on a record date to be determined. On May 20, 2024, the Company announced that the Board had set May 31, 2024 as the record date (the "Record Date"). All holders of Common Stock as of the Record Date received non-transferable subscription rights to purchase up to an aggregate of six million units (the "2024 Units") with an aggregate offering value of up to $60 million (the "2024 Rights Offering") at a price per 2024 Unit equal to the lesser of: (i) $10 (the "Initial Price") and (ii) the volume weighted average price of the Common Stock for the ten trading day period through and including the expiration date, June 26, 2024 (the "Expiration Date"), of the Rights Offering (the "Alternate Price"). Each subscription right entitled the holder to purchase 0.10864186 2024 Units for each share of Common Stock owned as of the Record Date. Each 2024 Unit consisted of one share of Common Stock and two warrants, each being a warrant to purchase one-half of one share of Common Stock. The subscription rights were to expire and have no value if they were not exercised prior to the Expiration Date. The Company determined that the equity-classified subscription rights represent a pro-rata distribution issued to existing stockholders as of the Record Date, which is based on a purchase price of $10 per 2024 Unit as compared to (1) the price of $11.55 per one share of Common Stock on the Record Date, plus (2) the value of the warrants on the Record Date. The Company determined the fair value of the equity-classified subscription rights as of the Record Date, which involved the use of a Monte Carlo simulation to value the underlying warrants. The Monte Carlo simulation was based on certain significant unobservable inputs, such as a risk-free interest rate, stock price volatility, dividend yield, and expected term of the rights offering. The fair value of the equity-classified subscription rights was $47.7 million and was recorded in equity on the balance sheet as part of additional paid-in capital. The deemed pro-rata distribution to shareholders of $47.7 million was reflected as an offsetting reduction in additional paid-in capital. The Company is in an accumulated deficit position and has elected a policy of recognizing the deemed pro-rata distribution to shareholders as a reduction to additional paid-in capital rather than a further increase to its accumulated deficit.

On July 3, 2024, the Company announced the closing of its 2024 Rights Offering. The 2024 Rights Offering resulted in the sale of six million 2024 Units, at a price of $10.00 per 2024 Unit. Each 2024 Unit consisted of one share of the Company's common stock, par value $0.001 per share, and two warrants, each being a warrant to purchase one-half of one share of common stock. The common stock and warrants comprising the 2024 Units separated upon the closing of the 2024 Rights Offering and were issued individually. A total of 5,999,998 shares of common stock and warrants to acquire up to approximately an additional six million shares of common stock were issued in the offering. The Company received aggregate gross proceeds from the 2024 Rights Offering of $60 million. If exercised, additional gross proceeds of up to $66 million may be received through the exercise of warrants issued in the 2024 Rights Offering. See 2024 Rights Offering Warrants below for additional details of the warrants. Robert W. Duggan, the Company's majority stockholder and Co-Chairman, purchased approximately 88% of the units offered through the 2024 Rights Offering.

Private Placement Securities Purchase Agreement

On April 30, 2023, the Company entered into a Securities Purchase Agreement with Robert W. Duggan, the Company's majority stockholder and Co-Chairman, pursuant to which the Company agreed to issue and sell to Mr. Duggan 10,022,937 shares of the Company's common stock, par value $0.001 per share, in a Private Placement, at a price per share of $6.51. The parties completed the Private Placement on May 9, 2023, after satisfying all pre-closing conditions, and the Company issued the full number of shares to Mr. Duggan. The shares were paid for through the cancellation of the principal sum of $65.0 million borrowed by the Company pursuant to the 2022 Loan Agreement (See Note 7), together with all accrued and unpaid interest outstanding owed at the time of closing.

2022 Rights Offering

On June 9, 2022, the Company completed a rights offering (the "2022 Rights Offering") resulting in the sale of 7,317,072 units (the "2022 Units"), at a price of $2.05 per 2022 Unit, with each 2022 Unit consisting of one share of the Company's common stock, par value $0.001 per share, and one warrant (the "2022 Rights Offering Warrants") to purchase one share of common stock at a price of $2.05 per share. The common stock and warrants comprising the 2022 Units separated upon the closing of the 2022 Rights Offering and were issued individually. 7,317,072 shares of common stock and warrants to acquire up to an additional 7,317,072 shares of common stock were issued in the 2022 Rights Offering. The Company received aggregate gross proceeds from the 2022 Rights Offering of $15 million. In May 2023, the Company delivered an irrevocable notice of redemption to warrant holders and, on June 16, 2023, it redeemed the last of the outstanding 2022 Rights Offering Warrants at a price of $0.01 per warrant share. See the Common Stock Warrants section below for further details. Robert W. Duggan, the Company's majority stockholder and Co-Chairman, purchased approximately 56% of the shares offered through the 2022 Rights Offering.

Common Stock Warrants

2024 Rights Offering Warrants

In connection with the 2024 Rights Offering, the Company issued 2024 Rights Offering Warrants to purchase a total of 5,999,999 shares of its common stock at an exercise price of $11.00 per whole share, which equals 110% of the subscription price for the Units. The aggregate number of shares of our common stock issuable upon the exercise of each set of warrants included in a given subscription for Units was rounded up to the nearest whole share. Warrants are exercisable immediately and will expire on the fifth anniversary of the closing of the 2024 Rights Offering. Half of the warrants issued in the rights offering are redeemable for $0.01 per underlying share of common stock, on not less than thirty days' written notice, if the volume weighted average price of the Company's common stock equals or exceeds 150% of the exercise price for the warrants, or $16.50, for twenty consecutive trading days. The other half of the warrants issued in the rights offering are redeemable for $0.01 per underlying share of common stock, on not less than thirty days' written notice, if the volume weighted average price of the Company's common stock equals or exceeds 200% of the exercise price for the warrants, or $22.00, for twenty consecutive trading days. In both cases the Company can not redeem the warrants prior to the date that is three months after the issuance date. As of September 30, 2024, there were 2024 Rights Offering Warrants to purchase up to 5,857,680 shares of common stock, in aggregate, outstanding.

2022 Rights Offering Warrants

In connection with the 2022 Rights Offering, the Company issued 2022 Rights Offering Warrants to purchase a total of 7,317,072 shares of its common stock at an exercise price of $2.05. The 2022 Rights Offering Warrants were subject to redemption by the Company for $0.01 per underlying share of common stock, on not less than 30 days written notice, if the volume weighted average price of the Company's common stock equaled or exceeded 200% of the exercise price for the warrants, subject to adjustment, per share, for 20 consecutive trading days, provided that the Company could not redeem the warrants prior to the date that was three months after the issuance date. On May 10, 2023, the Company issued a press release announcing that on May 9, 2023 the terms for warrant redemption had been met. Pursuant to the redemption, the Company redeemed 66,175 warrants on the redemption date, June 16, 2023. Prior to the redemption date, warrants to purchase 7,250,897 shares were exercised, generating approximately $14.9 million of total gross proceeds to the Company. As of September 30, 2024, there were no 2022 Rights Offering Warrants outstanding.

Equity Plans

2017 Equity Incentive Plan and 2017 Inducement Equity Incentive Plan

The Board previously adopted, and the Company's stockholders approved, the Company's 2017 Equity Incentive Plan (the "2017 Plan").

The 2017 Plan has a 10-year term and provides for the grant of stock options, stock appreciation rights, restricted stock, RSUs, performance units, and performance shares to employees, directors and consultants of the Company and any parent or subsidiary of the Company, as the Compensation Committee of the Board may determine. Subject to an annual evergreen increase and adjustment in the case of certain capitalization events, the Company initially reserved 1,500,000 shares of the Company's common stock for issuance pursuant to awards under the 2017 Plan. In addition, shares remaining available under the Company's 2015 Equity Incentive Plan, as amended (the "2015 Plan"), and shares reserved but not issued pursuant to outstanding equity awards that expire or terminate without being exercised or that are forfeited or repurchased by the Company will be added to the shares of common stock available for issuance under the 2017 Plan. The 2017 Plan is administered by the Board's Compensation Committee. Effective at both January 1, 2024 and 2023, the number of shares of common stock available under the 2017 Plan increased by 1,200,000, respectively, pursuant to the evergreen provision of the 2017 Plan. Under the evergreen provision of the 2017 Plan, the share increase is determined based on the least of (i) 1,200,000 shares, (ii) 4% of the Company's common stock outstanding at December 31 of the immediately preceding year, or (iii) such number of shares as determined by the Board. Additionally, the number of shares of common stock available under the 2017 Plan increased by 1,375,000 shares as a result of a stockholder vote held at a special meeting of stockholders in December 2023. As of September 30, 2024, a total of 78,490 shares of common stock remained available for issuance under the 2017 Plan.

During November 2017, the Board adopted the 2017 Inducement Equity Incentive Plan (the "Inducement Plan") and reserved 1,000,000 shares of the Company's common stock for issuance pursuant to equity awards granted under the Inducement Plan. The Inducement Plan was adopted without stockholder approval.

The Inducement Plan has a 10-year term and provides for the grant of equity-based awards, including non-statutory stock options, RSUs, restricted stock, stock appreciation rights, performance shares, and performance units, and its terms are substantially similar to the 2017 Plan, including with respect to treatment of equity awards in the event of a "merger" or "change in control" as defined under the Inducement Plan. Options issued under the Inducement Plan may have a term up to ten years and have variable vesting provisions. New hire grants to non-executive employees generally vest 25% per year starting upon the first anniversary of the grant. New hire grants to executive employees generally consist of both time-vesting and performance-vesting options. Equity-based awards issued under the Inducement Plan are only issuable to individuals not previously engaged as employees or individuals returning to employment with the Company following a bona-fide period of non-employment. In May 2021, the Board approved an amendment to the Inducement Plan to reserve an additional 1,000,000 shares of the Company's common stock for issuance pursuant to the Inducement Plan. And, in March 2024, the Board approved a second amendment to the Inducement Plan to reserve an additional 2,000,000 shares of the Company's common stock for issuance pursuant to the Inducement Plan. As of September 30, 2024, 1,642,626 shares of common stock remained available for issuance under the Inducement Plan.

A summary of stock option activity under the 2015 Plan, 2017 Plan, and Inducement Plan for the nine-months ended September 30, 2024 is presented below:

	Stock Options Outstanding		
	Number of shares	Weighted average exercise price	Weighted average remaining life (in years)
Balances — December 31, 2023	9,466,036	$ 9.01	7.78
Options granted	3,017,643	10.38	
Options exercised	(110,847)	4.49	
Options canceled	(9,542)	15.19	
Options expired	(35,958)	19.82	
Balances — September 30, 2024	12,327,332	$ 9.35	7.67
Exercisable — September 30, 2024	4,178,088	$ 13.32	5.06

Time-based Options

The Company awards time-based options which vest and become exercisable, subject to the individual's continued employment or service through the applicable vesting date. Time-based options can have various vesting schedules, most commonly new hire grants which generally vest 25% per year starting upon the first anniversary of the grant.

A summary of the time-based stock option activity under the 2015 Plan, 2017 Plan and Inducement Plan for the nine-months ended September 30, 2024 is presented below:

	Stock Options Outstanding		
	Number of shares	Weighted average exercise price	Weighted average remaining life (in years)
Balances — December 31, 2023	6,141,906	$ 10.48	7.07
Options granted	2,123,643	11.3	
Options exercised	(100,897)	4.65	
Options canceled	(6,542)	20.82	
Options expired	(34,958)	20.3	
Balances — September 30, 2024	8,123,152	$ 10.71	7.18
Exercisable — September 30, 2024	3,745,410	$ 13.97	4.84

The fair value of the time-based options granted during the nine-month period ended September 30, 2024 was $18.7 million.

Performance-based Options

Certain stock options awarded by the Company contain performance conditions related to certain financial measures and achievements of strategic and operational milestones. Once a specific performance condition is fulfilled, the associated options will fully vest and become exercisable.

A summary of the performance-based option activity under the 2017 Plan and Inducement Plan for the nine-months ended September 30, 2024 is presented below:

	Stock Options Outstanding		
	Number of shares	Weighted average exercise price	Weighted average remaining life (in years)
Balances — December 31, 2023	1,224,130	$ 5.51	8.53
Options granted	39,000	8.44	
Options exercised	(9,950)	2.92	
Options canceled	(3,000)	2.92	
Options expired	(1,000)	2.92	
Balances — September 30, 2024	1,249,180	$ 5.63	7.84
Exercisable — September 30, 2024	432,678	$ 7.69	6.98

The fair value of the performance-based options granted during the nine-month period ended September 30, 2024 was $0.3 million.

Market-based Options

Certain stock options awarded by the Company contain market conditions related to achievement of certain market capitalization targets. The options will vest and become exercisable once the specific market capitalization targets are fulfilled.

A summary of the market-based option activity under the 2017 Plan for the nine-months ended September 30, 2024 is presented below:

	Stock Options Outstanding		
	Number of shares	Weighted average exercise price	Weighted average remaining life (in years)
Balances — December 31, 2023	2,100,000	$ 6.78	9.44
Options granted	855,000	8.16	
Options exercised	—	—	
Options canceled	—	—	
Options expired	—	—	
Balances — September 30, 2024	2,955,000	$ 7.18	8.95
Exercisable — September 30, 2024	—	—	—

The fair value of the market-based options granted during the nine-month period ended September 30, 2024 was $5.3 million.

The Company estimates the fair value of time-based and performance-based stock options on the grant date using the Black-Scholes option pricing model. The estimated fair value of these employee stock options is amortized on a straight-line basis over the requisite service period of the awards. The Company reviews, and when deemed appropriate, updates the assumptions used on a periodic basis. The fair value of time-based and performance-based stock options was estimated using the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Expected term in years	5.0 - 6.3	5.0	5.0 - 6.3	5.0 - 6.3
Expected volatility	93% - 97%	93%	91% - 97%	89% - 94%
Risk-free interest rate	4.5%	3.7%	4.0% - 4.5%	3.7% - 3.8%
Dividend yield	—	—	—	—

The Company estimates the fair value of market-based stock options on the grant date using a Monte Carlo simulation model. The estimated fair value of these employee stock options is amortized over the requisite service period for each tranche of the awards. The requisite service period is the service period derived from the Monte Carlo simulation model. If the market capitalization targets are met sooner than the derived service period, the Company will accelerate the recognition of stock-based compensation expense to reflect the cumulative expense associated with the vested shares. The fair value of market-based stock options was estimated using the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Expected term in years	2.2 - 4.2	4.0 - 6.3	2.2 - 5.8	4.0 - 6.3
Expected volatility	90%	90%	90%	90%
Risk-free interest rate	3.9%	3.7 - 3.8%	3.9% - 4.4%	3.4 - 3.8%
Dividend yield	—	—	—	—

2017 Employee Stock Purchase Plan

The Board previously adopted, and the Company's stockholders approved, the Company's 2017 Employee Stock Purchase Plan (the "2017 ESPP").

The 2017 ESPP is a broad-based plan that provides employees of the Company and its designated affiliates with the opportunity to become stockholders through periodic payroll deductions that are applied towards the purchase of Company common shares at a discount from the then-current market price. Subject to adjustment in the case of certain capitalization events, a total of 250,000 common shares of the Company were available for purchase at adoption of the 2017 ESPP. Pursuant to the 2017 ESPP, the annual share increase pursuant to the evergreen provision is determined based on the least of (i) 450,000 shares, (ii) 1.5% of the Company's common stock outstanding at December 31 of the immediately preceding year, or (iii) such number of shares as determined by the Board. In 2024, the Company reserved an additional 450,000 shares under the 2017 ESPP pursuant to the evergreen provision. In 2023, the Board waived the evergreen provision and no additional shares were reserved under the 2017 ESPP. During the nine months ended September 30, 2024, the Company issued 117,539 shares of common stock under the 2017 ESPP. As of September 30, 2024, 445,779 shares of common stock remained available for issuance under the 2017 ESPP.

The Company estimates the fair value of ESPP grants on their grant date using the Black-Scholes option pricing model. The estimated fair value of ESPP grants is amortized on a straight-line basis over the requisite service period of the grants. The Company reviews, and when deemed appropriate, updates the assumptions used on a periodic basis. The Company utilizes its estimated volatility in the Black-Scholes option pricing model to determine the fair value of ESPP grants. The fair value of ESPP grants was estimated using the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Expected term in years	0.5 - 1.0	0.5 - 1.0	0.5 - 1.0	0.5 - 1.0
Expected volatility	98%	83%	98%	83%
Risk-free interest rate	4.4% - 5.3%	5.4% - 5.5%	4.9% - 5.3%	5.1% - 5.5%
Dividend yield	—	—	—	—

Stock-based Compensation

Total stock-based compensation expense consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	1,108	982	3,058	1,758
General and administrative	1,874	816	3,735	2,079
Total stock-based compensation expense	$ 2,982	$ 1,798	$ 6,793	$ 3,837

As of September 30, 2024, not all of the performance conditions of the performance options are probable to be achieved. Compensation expense has only been recognized for those conditions that are assumed to be probable.

Total stock-based compensation expense by award type was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Time-based options	$ 2,131	$ 1,200	$ 4,609	$ 2,754
Performance-based options	5	87	27	292
Market-based options	788	464	1,978	622
ESPP	58	47	179	169
Total stock-based compensation expense	$ 2,982	$ 1,798	$ 6,793	$ 3,837

7. Commitments and Contingencies

2022 Loan Agreement

On September 20, 2022, the Company and Robert W. Duggan, the Company's majority stockholder and Co-Chairman, entered into a Loan Agreement ("2022 Loan Agreement") in connection with Mr. Duggan lending the principal sum of $65.0 million to the Company. The 2022 Loan Agreement bore interest at a rate per annum equal to 5.0%, payable quarterly commencing on January 1, 2023, with the principal sum payable on March 20, 2024. On March 17, 2023, the Company and Mr. Duggan amended certain terms of the 2022 Loan Agreement. There were no changes to the interest rate, but the principal sum repayment date was changed to September 30, 2024. During the year ended December 31, 2023, the Company made cash payments of $1.7 million for accrued interest on the loan, and recorded an additional $1.1 million of interest expense in relation to the 2022 Loan Agreement. On April 30, 2023, the Company entered into a Securities Purchase Agreement with Mr. Duggan, pursuant to which the Company agreed to issue and sell to Mr. Duggan 10,022,937 shares of the Company's common stock, par value $0.001 per share, in a Private Placement, at a price per share of $6.51. These shares were paid for through the cancellation of the amounts then owed by the Company under the 2022 Loan Agreement, the principal sum of $65.0 million and all accrued and unpaid interest outstanding, which totaled approximately $0.2 million as of April 30, 2023. The parties completed the Private Placement on May 9, 2023 and, upon closing and satisfaction of the outstanding debt, the 2022 Loan Agreement terminated, without early termination fees or penalties being owed by the Company. No additional amounts are owed to Mr. Duggan under the 2022 Loan Agreement.

Operating Leases

In January 2017, the Company entered into a five-year lease (the "Existing Lease") for approximately 15,700 square feet for its corporate headquarters located in Hayward, California. The lease commenced in July 2017.

In May 2019, the Company entered into Lease Amendment 1 (the "Lease Amendment") in relation to the Existing Lease and added the lease of new premises of approximately 13,300 square feet and 21,300 square feet, ("Expansion Premises 1" and "Expansion Premises 2", respectively). Additionally, the term of the Existing Lease was extended to October 2029 to be coterminous with Expansion Premises 1 and Expansion Premises 2.

The Company evaluated the lease amendment under the provisions of ASC 842. It concluded that the Lease Amendment would be accounted for as a single contract with the Existing Lease because the additional lease payments due to the Lease Amendment was not commensurate with the right-of-use asset granted to the Company. Though the Lease Amendment was accounted for as a single contract, the Existing Premises, Expansion Premises 1 (occupied in November 2019) and Expansion Premises 2 (occupied in May 2020) are accounted for as separate lease components. Accordingly, the Company measured and allocated consideration to each lease component as of the modification date.

Supplemental balance sheet information related to leases (in thousands):

Assets:	**September 30, 2024**	**December 31, 2023**
Right-of-use assets	$ 6,588	$ 7,256

Liabilities:	**September 30, 2024**	**December 31, 2023**
Current operating lease liabilities	$ 1,193	$ 1,058
Non-current operating lease liabilities	7,174	8,086
Total lease liabilities	$ 8,367	$ 9,144

Total cash paid for operating lease liabilities (in thousands):

	Nine Months Ended September 30,	
	2024	**2023**
Cash paid for operating lease liabilities	$ 1,425	$ 1,376

Maturities of operating lease liabilities were as follows (in thousands):

Year ending December 31:	
2024 (remaining 3 months)	$ 485
2025	1,977
2026	2,046
2027	2,117
Thereafter	4,074
Total lease payments	10,699
Less imputed interest	(2,332)
Total lease liabilities	$ 8,367

Weighted-average remaining lease term and discount rate, as of September 30, 2024, were as follows:

Weighted-average remaining lease term	5.08
Weighted-average discount rate	10%

Rent expense, including common area maintenance charges, was approximately $0.6 million for each of the three-month periods ended September 30, 2024 and 2023, respectively, and was approximately $1.8 million and $1.7 million for the nine-month periods ended September 30, 2024 and 2023, respectively.

Legal Proceedings

From time to time, we may be involved in a variety of claims, lawsuits, investigations, and proceedings relating to securities laws, product liability, patent infringement, contract disputes, and other matters relating to various claims that arise in the normal course of our business, including the matter described below. The outcome of any legal proceedings is unpredictable but, regardless of outcome, they can have an adverse impact on us because of defense and settlement costs, diversion of management resources, negative publicity, reputational harm, and other factors. We maintain insurance that may provide coverage for such matters, including customary employment practices liability insurance.

In November 2022, the employment of our former Chief Financial Officer, Sandra Gardiner, terminated. Ms. Gardiner's departure was not the result of any disagreement with the Company on any matter relating to its operations, accounting policies or practices, although the Company determined that she was not eligible to receive any severance benefits under the terms and conditions of her then existing employment agreement. In March 2023, Ms. Gardiner filed an arbitration demand with JAMS seeking severance benefits and other remedies, alleging breach of contract and unlawful termination in violation of public policy, among other things. We believe that Ms. Gardiner's claims are without merit and we intend to vigorously defend ourselves against them. Because of the difficulty in predicting the outcome of any legal proceeding, the Company is not able to conclude that a liability is probable and cannot predict what the final outcome of Ms. Gardiner's arbitration proceeding will likely be or provide a reasonable estimate for the range of ultimate possible loss, if any. However, at this time, we believe that the final resolution of this matter will not adversely affect our consolidated position, results of operations, or cash flows.

8. Segment Reporting

The Company operates and manages the business as one reportable and operating segment. The Company's Chief Executive Officer acts as the chief operating decision maker ("CODM") of the Company. The CODM reviews the results of the Company on a consolidated basis. All of the Company's long-lived assets are based in the United States.

9. Related Party Transactions

In May 2022, the Company determined not to renew its annual director and officer liability insurance policy due to disproportionately high premiums quoted by insurance companies. Instead, on May 31, 2022, the Company and Robert W. Duggan, majority stockholder and Co-Chairman, entered into a letter agreement (the "Letter Agreement") pursuant to which Mr. Duggan agreed with the Company to personally provide indemnity coverage for a one-year period, and he agreed to deposit cash and/or marketable securities into a third-party escrow, as security for these obligations, if requested by the Company. On May 31, 2023, the last day of the one-year period, the Company paid Mr. Duggan a fee of $1.0 million in consideration of the obligations set forth in the Letter Agreement. As of September 30, 2024, there were no additional amounts owed to Mr. Duggan under the Letter Agreement.

On September 20, 2022, the Company and Robert W. Duggan, the Company's majority stockholder and Co-Chairman, entered into the 2022 Loan Agreement in connection with Mr. Duggan lending the principal sum of $65.0 million to the Company. On April 30, 2023, the Company entered into a Securities Purchase Agreement with Mr. Duggan, pursuant to which the Company agreed to issue and sell to Mr. Duggan 10,022,937 shares of the Company's common stock, par value $0.001 per share, in a Private Placement, at a price per share of $6.51. These shares were paid for through the cancellation of the amounts then owed by the Company under the 2022 Loan Agreement, the principal sum of $65.0 million and all accrued and unpaid interest outstanding, which totaled approximately $0.2 million as of April 30, 2023. Upon closing of the Private Placement and satisfaction of the outstanding debt, the 2022 Loan Agreement terminated, without early termination fees or penalties being owed by the Company. No additional amounts are owed to Mr. Duggan under the 2022 Loan Agreement. See Note 7 for further details.

10. Restructuring Charges

In February 2023, the Company eliminated seven positions and incurred a discrete restructuring related charge of $0.1 million which was fully recorded in February 2023 and the related expenses are included within total cost and expenses on the condensed consolidated statement of operations for the nine months ended September 30, 2023. This charge represents the total amount incurred in connection with the activity.

11. Subsequent Events

In October 2024, the Board approved changes to the performance-based vesting conditions of certain unvested outstanding common stock option awards that were improbable of vesting. Specifically, certain performance-based stock option awards were changed to time-based vesting criteria and certain performance-based stock option awards were changed to market-based vesting criteria. Based on our preliminary analysis, the Company estimates it will recognize approximately $12 million of stock-based compensation expense over the next 1 to 4 years from these modified stock option awards.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and the related notes included in this Quarterly Report and those in our Annual Report on Form 10-K.

Special Note Regarding Forward-Looking Statements

This report contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements relate to expectations concerning matters that are not historical facts. Words such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "might," "plans," "projects," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, statements related to our expected business, new product introductions, results of clinical studies, expectations regarding regulatory clearance and the timing of FDA or non-US filings or approvals including meetings with FDA or non-US regulatory bodies, procedures and procedure adoption, future results of operations, future financial position, our ability to generate revenues, our financing plans and future capital requirements, anticipated costs of revenue, anticipated expenses, the effect of recent accounting pronouncements, our anticipated cash flows, our ability to finance operations from cash flows or otherwise, and statements based on current expectations, estimates, forecasts, and projections about the economies and markets in which we operate and intend to operate and our beliefs and assumptions regarding these economies and markets. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. You should read the "Risk Factors" section of this Quarterly Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained herein. We do not assume any obligation to update any forward-looking statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. This Quarterly Report and any documents incorporated by reference may contain market data that we obtain from industry sources. These sources do not guarantee the accuracy or completeness of the information. Although we believe that our industry sources are reliable, we do not independently verify the information. The market data may include projections that are based on other projections. While we believe these assumptions and projections are reasonable and sound, as of the date of this Quarterly Report, actual results may differ from the projections.

Overview

We are a novel ablation company committed to health innovation using our patented Nano-pulse Stimulation ("NPS") technology, a revolutionary energy modality that delivers nanosecond-duration pulses of electrical energy, each less than a millionth of a second long, to nonthermally clear or kill targeted cells. NPS technology, also referred to as Nanosecond Pulsed-Field Ablation ("nsPFA" or "nano-PFA") technology when used to ablate cellular tissue, can be used to treat a variety of medical conditions for which an optimal solution remains unfulfilled. We developed our proprietary CellFX System, a novel nsPFA delivery platform, and commercialized the initial application of its nsPFA technology to treat benign lesions of the skin. In parallel, we have designed a variety of applicators, or disposables, to explore the potential use of the CellFX platform to treat disorders in other medical specialties, such as cardiology, gastroenterology, gynecology, and ear, nose and throat. These applicators include devices for open surgical procedures, endoscopic or minimally invasive procedures, and endoluminal catheters, and each has been used in preclinical studies. Based on our preclinical experience and the potential to significantly improve outcomes for patients in a large and growing market, we decided in 2022 to focus our primary efforts on the use of nano-PFA energy and the CellFX platform 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, such as soft tissue ablation.

CellFX nsPFA Percutaneous Electrode System

Our first product for soft tissue ablation in a surgical setting, the CellFX nsPFA Percutaneous Electrode System, consists of a disposable, percutaneous, needle electrode for use with our proprietary CellFX nsPFA Console. This novel electrode is designed to harness and deliver the key advantages of nsPFA energy, enabling precise nonthermal removal of cellular tissue without inducing thermal necrosis.

After years of preclinical development and testing, in June 2023, we initiated a first-in-human study using our proprietary nsPFA-enabled percutaneous electrode. This study, which is still ongoing, is being conducted by Professor Stefano Spiezia at the Ospedale del Mare in Naples, Italy, to help us better understand and confirm the mechanism of action and tissue response of nano-PFA energy in internal organs such as the thyroid. To date, we have treated thirty study subjects, all of whom tolerated the procedure well with no reported serious side effects. Ultrasound images post procedure have shown that the treated portions of the benign thyroid nodules have mostly been resorbed with no sign of scarring or fibrosis, which can be a side effect of other ablation modalities. We expect to complete this study in 2025.

In parallel, in November 2023, we filed a premarket notification 510(k) with the FDA for clearance to commercialize our novel CellFX nsPFA Percutaneous Electrode System in the United States. In March 2024, we received FDA 510(k) clearance for our CellFX nsPFA Percutaneous Electrode System for use in the ablation of soft tissue in percutaneous and intraoperative surgical procedures. More recently, in July 2024, we received FDA 510(k) clearance for a second size of the percutaneous electrode needle, which we believe will provide our customers with an additional treatment option for their patients.

Having secured 510(k) clearance to market and sell the CellFX nsPFA Percutaneous Electrode System in the United States with different sizes of percutaneous electrode needles, we have engaged with experts in the field of soft tissue ablation to gather information that will help shape our future commercial endeavors. To date, we have placed our CellFX System with seven sites in the United States and these sites have been performing initial patient treatments and evaluating the CellFX System under short-term evaluation agreements. To date, the clinicians in our pilot program have completed more than twenty-five patient procedures. We expect to pursue more clinical evidenced-based milestones throughout 2024 and into 2025 in connection with evaluating the early pilot commercialization of our percutaneous electrodes, and we expect 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.

Our Cardiac Surgical Program

Atrial fibrillation ("AF") is a type of heart arrythmia, or irregular heartbeat, caused by faulty electrical signals in the heart. AF is a highly prevalent condition and is growing significantly with an ageing population. It is estimated that 43 million people worldwide are affected by AF. Treatment requires the precise and safe ablation of heart tissue to block or otherwise prevent these faulty electrical signals from causing the irregular heartbeat, and we believe nano-PFA technology is uniquely suited to perform an integral role for this application and that it will prove to be highly differentiated from standard thermal energy modalities in use

today.

The results of preclinical and clinical testing of both our nano-PFA cardiac products, namely our surgical ablation clamp and our endocardial ablation catheter, have exceeded our expectations and initial data have been presented at physician and industry conferences. While these devices serve different physicians, the application of the energy to safely and effectively ablate cardiac tissue and the treatment of AF are the same, and we believe there will be important synergies realized through their contemporaneous development. The Company's cardiac surgical ablation clamp and cardiac endocardial ablation catheter both generate our proprietary nano-PFA pulses of electrical energy. We discuss each of these products under development in more detail below.

CellFX nsPFA Cardiac Clamp

Our surgical cardiac ablation clamp is designed for use by cardiac surgeons during the surgical treatment of AF. The standard of care surgical procedure for the treatment of AF is performed by cardiac surgeons and called the Cox-Maze procedure. The Cox-Maze procedure typically uses thermal ablation technologies, such as heat with radiofrequency ablation or cold with cryoablation, to create specific ablation lines in the heart muscle. These ablation lines block the conduction of electrical impulses and can cure patients of their AF.

We believe our nsPFA technology can provide important advantages over today's thermal modalities in creating these ablation lines. For example, surgeons using the CellFX System should be able to deliver faster ablations through thicker tissue than thermal modalities because of the nonthermal mechanism of action that nano-PFA employs, which is not affected by heatsinks such as blood in the heart. In preclinical studies, our nsPFA Cardiac Clamp has consistently achieved transmural ablations in less than two seconds, independent of tissue type or thickness. Moreover, thermal modalities can cause char formation on electrode surfaces which can cause gaps in the ablation lines that might lead to treatment failure. This should not be an issue with nano-PFA ablation given its nonthermal nature. We believe these advantages will be important to cardiac surgeons, so we are working with leaders in the field to develop this technology quickly.

Over the last several years, we have been developing the cardiac ablation clamp from proof-of-concept to prototype, and we now have what we believe is our initial clinical design. We plan to pursue a PMA application for FDA approval to market the cardiac clamp, which will require pivotal clinical data to support the application. With PMA approval, we expect that we would commercialize the nsPFA Cardiac Surgical System in the United States specifically as a treatment for AF. If granted by the FDA, a specific treatment indication would permit direct marketing of the treatment benefits provided by the device. We expect to begin our pivotal clinical trial for AF in mid-2025. In parallel, we have initiated a multi-site clinical study to treat up to 30 patients in the Netherlands. The first five patients in this cardiac clamp study tolerated the procedure well and acute data have been encouraging. This study should provide information on first-in-human effectiveness and safety with our cardiac surgical ablation clamp.

In July 2024, we received Breakthrough Device Designation from the FDA for our CellFX nsPFA Cardiac Surgery System for the treatment of AF. The FDA's Breakthrough Devices Program is a voluntary program for certain medical devices that potentially provide for more effective treatment or diagnosis of a life-threatening or irreversibly debilitating disease or condition. More recently, our Cardiac Surgery System was enrolled in the FDA's Total Product Life Cycle (TPLC) Advisory Program (TAP). The FDA's Center for Devices and Radiological Health (CDRH) launched the TAP program to help generate more rapid development of high-quality, safe, effective, and innovative medical devices that are critical to public health. TAP's primary goal is to expedite patient access to innovative medical devices by providing early, frequent and strategic communications with the FDA and facilitating engagement with other key parties for developers of devices of public health importance. Both programs are designed to expedite the development, assessment, and review of medical devices for premarket approval, 510(k) clearance, or De Novo marketing authorization. Breakthrough Devices, even those enrolled in the FDA's TAP Program, must still meet the FDA's rigorous standards for device safety and effectiveness in order to be authorized for marketing, however.

CellFX nsPFA 360° Cardiac Catheter

We believe our cardiac, endocardial, catheter ablation device will have many of the same advantages that the surgical ablation clamp appears to have with respect to both performance and safety compared to standard thermal modalities. Our catheter is uniquely designed to provide a circumferential, or circular, ablation in a single treatment cycle. We believe this will enable faster treatment times compared to what is currently performed with thermal modalities, especially when ablating around the pulmonary veins, a common treatment approach for AF.

In recent years, Pulsed Field Ablation ("PFA") has gained attention in electrophysiology for the treatment of AF because of its safety profile and speed. Current clinical products employing PFA in AF treatment differ from CellFX nsPFA technology in that the pulse widths are longer, typically in the microsecond domain. We believe CellFX nsPFA technology, which delivers pulses of electrical energy that are each less than a millionth of a second long, can offer similar safety advantages as PFA and may provide improved efficacy advantages based on the circumferential design of our catheter and because it appears CellFX nsPFA technology can create deeper ablations.

Similar to the cardiac ablation clamp, our proprietary catheter has been in development for several years and we have been working with leaders in the electrophysiology field to test the catheter in preclinical studies. After seeing encouraging preclinical results, in December 2023, we initiated a clinical study in Prague, Czech Republic, to test our CellFX nsPFA 360° Cardiac Catheter in patients with AF and early acute data and remapping data from this study have been promising. We have therefore expanded the initial clinical protocol to enroll up to 60 patients, from 30, and to include participation by two additional sites. The study is now almost fully enrolled. Investigators have successfully remapped the first half of the study participants and we have been encouraged by the preliminary results seen in the study. We believe the catheter will need to go through the PMA process for FDA approval to market and sell our cardiac endocardial catheter in the United States. We expect to commence a U.S. IDE pivotal clinical study sometime in the middle of 2025.

The CellFX Console

The CellFX Console is a tunable, software-enabled, console-based platform, designed to accommodate the clinical workflow preferred by physicians. The CellFX System is configured to accept a variety of disposable end-effectors or electrodes across a range of clinical applications. In February 2021, we received 510(k) clearance from the FDA for the CellFX System for dermatologic procedures requiring ablation and resurfacing of the skin. In January 2021, we received Conformité Européene ("CE") marking approval for the CellFX System, which allows for marketing of the system in the European Union ("EU"). Shortly after these regulatory clearances, we began commercializing the CellFX System in dermatology for the treatment of benign skin lesions. However, in September 2022, we announced a shift in our focus from dermatology to cardiology and the treatment of AF. We have ceased all commercial sales and marketing operations in dermatology. At the present time, we continue to support our remaining commercial users and remain open to a potential commercial partnership. The CellFX System is being used for our current efforts in the treatment of AF and as part of the CellFX nsPFA Percutaneous Electrode System.

We continue to believe nano-PFA ablation, as well as NPS technology more broadly, has the potential to provide superior outcomes across a variety of medical disciplines and we may seek partnership opportunities to develop additional applications.

Financing Our Business

Over the past few years, Robert Duggan, our majority stockholder and Co-Chairman, has made significant investments in our Company to fund its operations. In June 2022, we completed a common stock rights offering to our existing stockholders, which raised $15 million in aggregate. Mr. Duggan purchased approximately 56% of the shares offered through this offering. Then, in September 2022, we entered into a loan agreement with Mr. Duggan pursuant to which he lent us $65 million to fund our product development operations. In April 2023, this loan agreement was terminated when Mr. Duggan and the Company entered into a Securities Purchase Agreement whereby the shares were paid for through the cancellation of both the principal sum of $65.0 million and all accrued and unpaid interest owed at the time under the 2022 loan agreement, which totaled approximately $0.2 million. In June 2024, we completed a rights offering of units (each unit comprising a share of our common stock and two warrants, each to purchase a one-half share of our common stock) to our existing stockholders, which raised $60 million in aggregate. Mr. Duggan purchased approximately 88% of the shares offered through this offering. Mr. Duggan may or may not elect to participate in any number of future fundraisings by the Company, whether similar to those described above or otherwise, and he may choose to

invest more than his current pro rata share in any of these fundraisings, or alternatively he may offer to provide additional debt financing as may be needed in order to maintain the Company as a going concern.

The source, timing and availability of any future financing will depend largely upon market conditions and perceived progress in the Company's on-going product development initiatives, as well as future clinical and regulatory developments concerning the CellFX System and our other NPS-based technologies. Funding may not be available when needed, at all or on terms acceptable to us. Lack of necessary funds may require us to, among other things, delay, scale back or eliminate some or all of our commercial activities, reduce headcount, trim research and product development programs, discontinue clinical trials, stop all or some of our manufacturing operations, defer capital expenditures, deregister from being a publicly traded company and delist from Nasdaq, or license our potential products or technologies to third parties, possibly on terms that cannot sustain our current business. In addition, economic instability caused by the armed conflicts in the Middle East and Ukraine and high interest rates, together with other market factors, could have an adverse impact on potential sources of future financing.

We have incurred substantial operating losses and have used cash in our operating activities since inception. To fund our business, we may utilize some combination of public or private equity offerings, debt financings, or potential new collaborations in the future. There can be no assurance, however, that any additional financing or any revenue-generating collaboration will be available when needed or that we will be able to obtain financing or enter into a collaboration on terms acceptable to us.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with the rules and regulations of the U.S. Securities and Exchange Commission. The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our critical accounting policies and estimates. Our critical accounting policies and estimates are described in our Annual Report on Form 10-K for the year ended December 31, 2023.

Stock-Based Compensation

Our stock-based compensation programs include stock options and an employee stock purchase program. We periodically issue stock options to officers, directors, employees, and consultants for their services to the Company. Such issuances vest and expire according to terms established at the issuance date. Stock-based payments to officers, directors and employees, including grants of employee stock options, are recognized in the financial statements based on their grant date fair values, which are estimated using the Black-Scholes option-pricing model. Stock-based compensation expense is charged to operations on a straight-line basis over the requisite service period. We have granted stock options with time-based, performance-based, and market-based vesting conditions. In October 2024, our Board approved changes to the vesting conditions of certain outstanding common stock option awards so that the performance-based vesting criteria of those particular awards will be changed to either time-based or market-based vesting criteria.

For stock options with performance-based vesting conditions, we do not recognize compensation expense until it is probable that the performance-based vesting condition will be achieved. The analysis to determine such probability involves estimates and judgements from management. The estimate of expense may be revised periodically based on the probability of achieving the required performance targets.

The vesting conditions for stock options with market-based vesting conditions relate to the achievement of certain market capitalization targets of the Company. The grant date fair value for these stock options was determined using a Monte Carlo simulation. The expense is recognized over the requisite service period for each tranche of the awards. The requisite service period is the service period derived from the Monte Carlo simulation model. If the market capitalization targets are met sooner than the derived service period, we will accelerate the recognition of stock-based compensation expense to reflect the cumulative expense associated with the vested shares. The Monte Carlo simulation requires the Company to make assumptions and judgements about the variables used in the calculation including the expected term, volatility of the Company's common stock, an assumed risk-free interest rate, and cost of equity.

Recent Accounting Pronouncements

Refer to “Recent Accounting Pronouncements” in Note 2 of Notes to Condensed Consolidated Financial Statements of this Quarterly Report.

Segment and Geographical Information

We operate and manage our business as one reportable and operating segment. Our Chief Operating Decision Maker ("CODM") reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. All of our long-lived assets are based in the United States.

Results of Operations

Comparison of the three-month periods ended September 30, 2024 and 2023

Our condensed consolidated statements of operations as discussed herein are presented below:

(in thousands)	Three Months Ended September 30, 2024	2023	$ Change
Revenues:			
Product revenues	$ —	$ —	$ —
Total revenues	—	—	—
Cost and expenses:			
Research and development	7,703	7,472	231
General and administrative	5,952	3,780	2,172
Total cost and expenses	13,655	11,252	2,403
Loss from operations	(13,655)	(11,252)	(2,403)
Other income:			
Interest income, net	975	686	289
Total other income	975	686	289
Loss from operations, before income taxes	(12,680)	(10,566)	(2,114)
Income tax benefit	—	—	—
Net loss	$ (12,680)	$ (10,566)	$ (2,114)

Revenues

There were no revenues for the three-month periods ended September 30, 2024 and 2023.

Research and Development

Research and development expenses consist of compensation and other employee related expenses for research and development personnel, clinical trials and consulting costs related to the design, development and enhancement of our potential future products, prototype material and devices. Research and development expenses increased by $0.2 million to $7.7 million for the three-month period ended September 30, 2024, compared to $7.5 million during the same period in 2023 primarily due to increases of $0.4 million in supplies, $0.3 million in compensation and other employee-related expenses, and $0.1 million in stock-based compensation; partially offset by a decrease of $0.6 million in paid services.

General and Administrative

General and administrative expenses consist of compensation and other related employee expenses for executives, finance, legal, human resources, information technology, and administrative personnel, professional fees, patent fees and costs, insurance costs and other general corporate expenses. General and administrative expenses increased by $2.2 million to $6.0 million for the three-month period ended September 30, 2024, compared to $3.8 million during the same period in 2023 primarily due to increases of $1.1 million in stock-based compensation, $0.6 million in compensation and other employee-related expenses, and $0.5 million in paid services and general administrative costs.

Other Income, net

Interest income, net, increased by $0.3 million to $1.0 million for the three-month period ended September 30, 2024, compared to $0.7 million during the same period in 2023. Interest income increased by $0.3 million, driven by increased returns on higher cash balances.

Comparison of the nine-month periods ended September 30, 2024 and 2023

Our condensed consolidated statements of operations as discussed herein are presented below:

	Nine Months Ended September 30,		
(in thousands)	**2024**	**2023**	**$ Change**
Revenues:			
Product revenues	$ —	$ —	$ —
Total revenues	—	—	—
Cost and expenses:			
Research and development	21,674	19,998	1,676
General and administrative	14,322	11,043	3,279
Total cost and expenses	35,996	31,041	4,955
Loss from operations	(35,996)	(31,041)	(4,955)
Other income:			
Interest income, net	1,796	764	1,032
Total other income	1,796	764	1,032
Loss from operations, before income taxes	(34,200)	(30,277)	(3,923)
Income tax benefit	—	—	—
Net loss	$ (34,200)	$ (30,277)	$ (3,923)

Revenues

There were no revenues for the nine-month periods ended September 30, 2024 and 2023.

Research and Development

Research and development expenses consist of compensation and other employee related expenses for research and development personnel, clinical trials and consulting costs related to the design, development and enhancement of our potential future products, prototype material and devices. Research and development expenses increased by $1.7 million to $21.7 million for the nine-month period ended September 30, 2024, compared to $20.0 million during the same period in 2023 primarily due to increases of $1.3 million in stock-based compensation, $0.9 million in compensation and other employee-related expenses, and $0.3 million in supplies. These increases were partially offset by a decrease of $0.8 million in paid services.

General and Administrative

General and administrative expenses consist of compensation and other related employee expenses for executives, finance, legal, human resources, information technology, and administrative personnel, professional fees, patent fees and costs, insurance costs and other general corporate expenses. General and administrative expenses increased by $3.3 million to $14.3 million for the nine-month period ended September 30, 2024, compared to $11.0 million during the same period in 2023 primarily due to increases of $1.7 million in stock-based compensation, $0.8 million in compensation and other employee-related expenses, $0.6 million in paid services, and $0.2 million in facilities and IT cost allocations driven by our shift in focus.

Other Income, net

Interest income, net, increased by $1.0 million to $1.8 million for the nine-month period ended September 30, 2024, compared to $0.8 million during the same period in 2023. Interest income decreased by $0.1 million to $1.8 million for the nine-month period ended September 30, 2024, compared to $1.9 million during the same period in 2023. Interest expense decreased by $1.1 million to zero for the nine-month period ended September 30, 2024, compared to $1.1 million during the same period in 2023 driven by the extinguishment of the 2022 Loan Agreement.

Liquidity and Capital Resources

To date, we have not generated significant revenues from product sales. Since inception, we have funded our business primarily through the issuance of equity securities and debt. Over the next few years, we intend to invest in research and development to develop additional commercially viable products and to assess the feasibility of potential future products.

On June 9, 2022, we completed the 2022 Rights Offering resulting in the sale of 7,317,072 Units, at a price of $2.05 per Unit, with each Unit consisting of one share of the Company's common stock, par value $0.001 per share, and one warrant to purchase one share of common stock at $2.05 per share. 7,317,072 shares of common stock and warrants to acquire up to an additional 7,317,072 shares of common stock were issued in the 2022 Rights Offering. The Company received aggregate gross proceeds from the 2022 Rights Offering of $15 million. In May 2023, the Company delivered an irrevocable notice of redemption to warrant holders and, on June 16, 2023, it redeemed the last of the outstanding 2022 Rights Offering Warrants at a price of $0.01 per warrant share. Prior to the redemption date, warrants to purchase 7,250,897 shares were exercised, generating approximately $14.9 million of total gross proceeds to the Company. As of September 30, 2023, there were no 2022 Rights Offering Warrants outstanding. Robert W. Duggan, the Company's majority stockholder and Co-Chairman, purchased approximately 56% of the shares offered through the 2022 Rights Offering.

In September 2022, we entered into the 2022 Loan Agreement with Robert W. Duggan, our majority stockholder and Co-Chairman, in connection with Mr. Duggan lending the principal sum of $65.0 million to the Company. The 2022 Loan Agreement had a maturity date of March 20, 2024. Under the 2022 Loan Agreement, Mr. Duggan provided us, subject to certain conditions, an unsecured term loan facility in an original aggregate principal amount of $65.0 million. The 2022 Loan Agreement bore interest at a rate per annum equal to 5.0%, payable quarterly, commencing on January 1, 2023. On March 17, 2023, the Company and Mr. Duggan amended certain terms of the Loan Agreement. There were no changes to the interest rate, the principal sum repayment date was changed to September 30, 2024. However, on April 30, 2023, we entered into a Securities Purchase Agreement with Mr. Duggan, pursuant to which we agreed to issue and sell to Mr. Duggan 10,022,937 shares of our common stock, par value $0.001 per share, in a Private Placement, at a price per share of $6.51. These shares were paid for through the cancellation of the amounts then owed by the Company under the 2022 Loan Agreement, the principal sum of $65.0 million and all accrued and unpaid interest outstanding, which totaled approximately $0.2 million as of April 30, 2023. The parties completed the Private Placement on May 9, 2023 and, upon closing and satisfaction of the outstanding debt, the 2022 Loan Agreement terminated, without early termination fees or penalties being owed by the Company. No additional amounts are owed to Mr. Duggan under the 2022 Loan Agreement.

On July 3, 2024, we announced the closing of our 2024 Rights Offering. The 2024 Rights Offering resulted in the sale of six million 2024 Units, at a price of $10.00 per 2024 Unit. Each 2024 Unit consisted of one share of our common stock, par value $0.001 per share, and two warrants, each being a warrant to purchase one-half of one share of common stock. The common stock and warrants comprising the 2024 Units separated upon the closing of the 2024 Rights Offering and were issued individually. A total of 5,999,998 shares of common stock and warrants to acquire up to approximately an additional six million shares of common stock were issued in the offering. We received aggregate gross proceeds from the 2024 Rights Offering of $60 million. If exercised, additional gross proceeds of up to $66 million may be received through the exercise of warrants issued in the 2024 Rights Offering. Each warrant will be exercisable for $11.00 per whole share, which equals 110% of the subscription price for the Units. Warrants are exercisable immediately and will expire on the fifth anniversary of the closing of the 2024 Rights Offering. Half of the warrants issued in the rights offering are redeemable by us if our stock trading price exceeds $16.50 for twenty consecutive trading days and the other half of the warrants issued in the rights offering are redeemable by us if our stock trading price exceeds $22.00 for twenty consecutive trading days. As of September 30, 2024, we have received $1.5 million in gross proceeds from exercises of the 2024 Rights Offering warrants.

Our condensed consolidated statements of cash flows as discussed herein are presented below:

	Nine Months Ended September 30,	
(in thousands)	**2024**	**2023**
Net cash used in operating activities	$ (27,199)	$ (26,259)
Net cash used in investing activities	(72)	(78)
Net cash provided by financing activities	61,939	15,584
Net increase (decrease) in cash and cash equivalents	$ 34,668	$ (10,753)

To date, we have generated limited revenue and used cash in our operating activities. As a result, we have incurred significant operating losses in each year since our inception and we may continue to incur additional losses for the next several years. As of September 30, 2024, we had cash and cash equivalents of $79.0 million. We believe that our existing cash and cash equivalents will be sufficient to fund our projected operating requirements for at least the next twelve months from the filing date of this Quarterly Report on Form 10-Q. However, we plan to raise additional capital in the future. We can give no assurance, at this time, that additional financing or a collaboration will be available when needed on terms acceptable to us, however.

These expectations are based on our current operating and financing plans which are subject to change. Until we are able to generate sustainable product revenues at profitable levels, we expect to finance our future cash needs through public or private equity offerings, debt financings, and/or potential new collaborations. Such additional funds may not be available on terms acceptable to us or at all. If we raise funds by issuing equity or equity-linked securities, the ownership of some or all of our stockholders may be diluted, and the holders of new equity securities may have priority rights over our existing stockholders. If adequate funds are not available, we may be required to curtail operations significantly or obtain funds by entering into agreements on unattractive terms. Our inability to raise capital could have a material adverse effect on our business, financial condition, results of operations and cash flows. For example, lack of necessary funds may require us to, among other things, reduce headcount, trim research and product development programs, discontinue clinical trials, defer capital expenditures, deregister from being a publicly traded company and delist from Nasdaq, or license our potential products or technologies to third parties, possibly on terms that cannot sustain our current business. In addition, instability in economic activity caused by the armed conflicts in the Middle East and Ukraine and high interest rates, together with other market factors, could have an adverse impact on potential sources of future financing.

Operating Activities

During the nine months ended September 30, 2024, we used cash in the amount of $27.2 million in operating activities. The difference between cash used in operating activities and net loss consisted primarily of stock-based compensation, depreciation and amortization, as well as a decreases in accounts payable and an increase in prepaids and other current assets.

During the nine months ended September 30, 2023, we used cash in the amount of $26.3 million in operating activities. The difference between cash used in operating activities and net loss consisted primarily of stock-based compensation, depreciation and amortization, as well as increases in accrued expenses and right-of-use assets, offset by accrued interest on related party note payable and lease liabilities.

Investing Activities

Our investing activities consist primarily of investment purchases, sales and maturities and capital expenditures.

During the nine months ended September 30, 2024, $0.1 million of cash used in investing activities was driven by the purchase of property and equipment.

During the nine months ended September 30, 2023, $0.1 million of cash used in investing activities was driven by the purchase of property and equipment.

Financing Activities

During the nine months ended September 30, 2024, cash provided by financing activities was $61.9 million, primarily due to $59.6 million of net proceeds from the 2024 Rights Offering, $1.5 million of proceeds from the exercise of warrants, $0.5 million of proceeds from issuance of common stock under employee stock purchase plan and $0.5 million of proceeds from the exercise of stock options, offset by $0.2 million of deferred issuance costs in relation to a future at-the-market equity offering.

During the nine months ended September 30, 2023, cash provided by financing activities was $15.6 million, primarily due to $14.8 million of proceeds from the exercise of warrants, $0.4 million of proceeds from issuance of common stock under employee stock purchase plan and $0.4 million of proceeds from the exercise of stock options.

Contractual Obligations

There have been no material changes outside the ordinary course of our business to the contractual obligations disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023.

Off-Balance-Sheet Arrangements

At September 30, 2024, we did not have any transactions, obligations or relationships that constitute off-balance sheet arrangements.

In the ordinary course of business, we enter into standard indemnification arrangements. Pursuant to these arrangements, we indemnify, hold harmless, and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified party in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology, or from claims relating to our performance or non-performance under a contract. The maximum potential amount of future payments we could be required to make under these agreements is not determinable because it involves claims that may be made against us in future periods, but have not yet been made. To date, we have not incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

We also enter and have entered into indemnification agreements with our directors and officers that may require us to indemnify them against liabilities that arise by reason of their status or service as directors or officers, except as prohibited by applicable law. In addition, we may have obligations to hold harmless and indemnify third parties involved with our fundraising efforts and their respective affiliates, directors, officers, employees, agents or other representatives against any and all losses, claims, damages and liabilities related to claims arising against such parties pursuant to the terms of agreements entered into between us and such third parties in connection with such fundraising efforts. No liability associated with such indemnification agreements has been recorded as of September 30, 2024.

Trends, Events and Uncertainties

Research and development of new technologies are, by their nature, unpredictable. Although we undertake development efforts with commercially reasonable diligence, there can be no assurance that the net proceeds from our financings will be sufficient to enable us to develop our technology to the extent needed to generate future sales to sustain our operations. If we do not continue to have enough funds to sustain our operations, we will consider other options to continue the research and development of our technology, including, but not limited to, additional financing through follow-on stock offerings, debt financings, or co-development agreements and /or other alternatives.

We cannot assure investors that our technology will be adopted or that we will ever achieve sustainable revenues sufficient to support our operations. Even if we are able to generate revenues, there can be no assurances that we will be able to achieve profitability or positive operating cash flows. There can be no assurances that we will be able to secure additional financing in the future on acceptable terms or at all. If our technology cannot be used to successfully treat AF or tumors and nodules or if our cash resources are insufficient to satisfy our ongoing cash needs, we would be required to, among other things, delay, scale back or eliminate some or all of our activities, reduce headcount, trim research and product development programs, discontinue clinical trials, stop all or some of our manufacturing operations, defer capital expenditures, deregister from being a publicly traded company and delist from Nasdaq, license our potential products or technologies to third parties, possibly on terms that cannot sustain our current business, or curtail, suspend or discontinue our operations entirely.

Other than as discussed above and elsewhere in this Quarterly Report, we are not currently aware of any trends, events or uncertainties that are likely to have a material effect on our financial condition in the near term, although it is possible that new trends or events may develop in the future that could have a material effect on our financial condition.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

There have been no material changes in market risk from the information provided in our Annual Report on Form 10-K for the year ended December 31, 2023. We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in interest rates. We do not hold financial instruments for trading purposes.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer, who is our principal executive officer and principal financial officer, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934, as amended, as of the end of the period covered by this Quarterly Report. Based on this evaluation, our Chief Executive Officer has concluded that, as of September 30, 2024, our disclosure controls and procedures were effective (a) to ensure that information that we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and (b) to include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act, as amended, that occurred during the quarter ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Internal control over financial reporting means a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP.

Inherent Limitations on Effectiveness of Controls

Our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in a variety of claims, lawsuits, investigations, and proceedings relating to securities laws, product liability, patent infringement, contract disputes, and other matters relating to various claims that arise in the normal course of our business, including the matter described below. The outcome of any legal proceedings is unpredictable but, regardless of outcome, they can have an adverse impact on us because of defense and settlement costs, diversion of management resources, negative publicity, reputational harm, and other factors. We maintain insurance that may provide coverage for such matters, including customary employment practices liability insurance.

In November 2022, the employment of our former Chief Financial Officer, Sandra Gardiner, terminated. Ms. Gardiner's departure was not the result of any disagreement with the Company on any matter relating to its operations, accounting policies or practices, although the Company determined that she was not eligible to receive any severance benefits under the terms and conditions of her then existing employment agreement. In March 2023, Ms. Gardiner filed an arbitration demand with JAMS seeking severance benefits and other remedies, alleging breach of contract and unlawful termination in violation of public policy, among other things. We believe that Ms. Gardiner's claims are without merit and we intend to vigorously defend ourselves against them. Because of the difficulty in predicting the outcome of any legal proceeding, the Company is not able to conclude that a liability is probable and cannot predict what the final outcome of Ms. Gardiner's arbitration proceeding will likely be or provide a reasonable estimate for the range of ultimate possible loss, if any. However, at this time, we believe that the final resolution of this matter will not adversely affect our consolidated position, results of operation, or cash flows.

Item 1A. Risk Factors

Summary

Below is a summary of the principal factors that make an investment in Pulse Biosciences, Inc. speculative or risky. The following summary does not contain all of the information that may be important to you, and you should read the below summary in conjunction with the more detailed discussion of risks set forth following the summary.

Risks Related to Our Financial Position and Need for Additional Capital

- We will need to obtain additional funding to finance our operations and complete the development and any commercialization of our products. If we do not receive substantial capital when needed, we may be forced to restrict our operations or delay, reduce or eliminate our product development programs.
- We depend heavily on the success of NPS to nonthermally clear targeted cells while sparing adjacent noncellular tissue. If we are unable to successfully develop and commercialize this patented technology, or experience significant delays in doing so, we may extend the period in which we will incur significant financial losses as an organization.
- We are a development-stage company with very limited experience commercializing products. We have incurred significant losses since our inception. We anticipate that we will continue to incur losses for at least the next several years and may never generate profits from operations or maintain profitability.
- We will need to raise additional capital, which may result in further dilution to our investors, or incur additional indebtedness. The servicing of future debt may impair our liquidity position.

Risks Related to the Development and Commercialization of our Medical Products

- We can provide no assurance that our clinical product candidates, including our product candidates for the treatment of atrial fibrillation ("AF"), our CellFX nsPFA Cardiac Clamp and our CellFX nsPFA 360° Cardiac Catheter and our soft tissue ablation product specifically indicated for treatment of benign thyroid nodules, will obtain regulatory approval or that the results of clinical studies will be favorable.
- Medical device development and commercialization is a complex, time-consuming and expensive process. Our industry is fraught with risk and a high rate of failure.
- We have very limited sales and marketing experience and no experience commercializing our CellFX nsPFA Percutaneous Electrode System or either of our cardiac products currently under development. We can give no assurances that our devices will be adopted by surgeons or other physicians to treat any medical condition.
- Regulatory requirements and timelines may affect the scope and timeline of our trials and the potential market for our product candidates, including the possibility of significant delays to any product launch.
- The medical device industry is characterized by intense competition, rapid technological changes, new product introductions and enhancements, and evolving industry standards. If we do not develop and obtain regulatory clearances or approvals for new products or product enhancements in time to meet market demand, or if there is insufficient demand for our products or enhancements, our results of operations will suffer.
- If we experience any number of possible unforeseen events in connection with our clinical trials, potential marketing approval or commercialization of our product candidates could be delayed or prevented.
- If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory bodies, such as the U.S. Food and Drug Administration or the European Medicines Agency, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our medical devices.
- Regulatory requirements and timelines may affect the scope and timeline of our trials and the potential market for our product candidates.

Risks Related to Our Industry and Market

- We face substantial competition, which may result in others developing or commercializing products before or more successfully than we do.
- We compete against well-established incumbent technologies offering products in cardiology, oncology, and dermatology, as well as in minimally invasive procedures. All of these companies currently have greater financial, technical, research, and/or other resources than we do and have larger and more established manufacturing capabilities and marketing, sales, and support functions.
- We may pursue business development opportunities to expand or enhance our pipeline of potential products, including through potential acquisitions of and/or collaborations with other entities or the acquisition of products unrelated to NPS technology, which may not achieve intended results or could increase the number of our outstanding shares or amount of outstanding debt or result in a change of control.

Legal, Tax, Regulatory, and Compliance Risks

- Our ability to commercialize any of our product candidates is subject to substantial regulatory and legislative uncertainty, including as to pricing, reimbursement practices or other healthcare initiatives which could harm our business.
- We may face costly legal claims, in particular related to product liability and intellectual property infringement.
- We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

Risks Related to Our Intellectual Property, Cybersecurity and Data Privacy

- We rely upon patents to protect our technology. We may be unable to protect our intellectual property rights and we may be liable for infringing the intellectual property rights of others.
- Our actual or perceived failure to comply with stringent and changing obligations related to data privacy and security could lead to regulatory investigations and actions, litigation, fines and penalties, disruptions to our business operations, reputational harm, loss of revenue and profits, and other adverse business impacts.
- We are exposed to risks related to cybersecurity and data privacy threats and incidents and we are subject to restrictions and changes in laws and regulations governing our data privacy and data protection, any of which could have a material adverse effect on our business.

Risks Related to Corporate Governance and Employee Relations

- Our future success depends on our ability to retain our Chief Executive Officer, our Chief Technology Officer, our Chief Commercial Officer, our Chief Strategy Officer, and other key executives and to attract, retain and motivate qualified personnel.
- Our Co-Chairman owns more than a majority of the voting power of the outstanding shares of our common stock and, as a result, investors may have limited ability to affect either the corporate governance of the Company or the taking of certain major decisions.

Risks Related to Owning Our Common Stock

- Substantial future sales of our shares of common stock in the public market, or the perception that these sales could occur, could cause the price of the shares to decline significantly, even if our business is doing well.
- The prices of our shares of common stock may be volatile and fluctuate substantially, which could result in substantial losses for our stockholders.
- 73% of our outstanding shares are owned by our Co-Chairman, Robert Duggan, and his affiliates, which can reduce liquidity of our stock. Historically, our trading volume on Nasdaq has been low.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Quarterly Report, including our financial statements and related notes, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. The risks described below are not the only risks facing us. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially affect our business, financial condition, results of operations, and prospects. In addition, any worsening of the economic environment may exacerbate the risks described below, any of which could have a material impact on us.

Risks Relating to Our Business, Industry and Financial Condition

Because we have a limited operating history and no significant revenue stream, it is difficult to evaluate the future of our business.

We are a bioelectric medicine technology company with no significant revenue producing operations. To date, our operations on a consolidated basis have consisted almost entirely of the continued development and clinical studies of our technologies and implementation of the early parts of our business plan. We have incurred significant operating losses in each year since our inception and we may continue to incur additional losses for the next several years. In addition, a high percentage of our expenses will continue to be fixed; accordingly, our losses may be greater than expected and our operating results may suffer. We have limited historical financial data upon which we may base our projected revenue and base our planned operating expenses. Our limited operating history makes it difficult to evaluate our technology, operations, and business prospects.

We have not generated significant revenue, and we may never become profitable.

To date, we have not generated significant revenue, and we have historically relied on financing from the sale of equity securities and loans to fund our operations. We expect that our future financial results will depend primarily on our success in launching, selling, and supporting our therapies and procedures using our NPS technology. We expect to expend significant resources on hiring of personnel, continued scientific and product research and development, potential product testing and preclinical and clinical investigation, intellectual property development and prosecution, capital expenditures, working capital, general and administrative expenses, and fees and expenses associated with our capital raising efforts. We expect to incur costs and expenses related to consulting costs, laboratory development costs, hiring of scientists, engineers, sales representatives, and other operational personnel, and the continued development of relationships with potential partners. We are incurring significant operating losses, we expect to continue to incur additional losses for at least the next several years, and we cannot assure you that we will generate substantial revenue or be profitable in the future. There are no assurances that our future products will be cleared or approved or become commercially viable or accepted for use. Even with commercially viable applications of our technology, which may include licensing, we may never recover our research and development expenses.

Investment in medical technology is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product will fail to demonstrate adequate efficacy or clinical utility. Our past successes in dermatology may not translate into similar results in cardiology or elsewhere. Investors should evaluate an investment in us in light of the uncertainties typically encountered by developing medical technology companies in a competitive environment. There can be no assurance that our efforts will be successful, either in cardiology or otherwise, or that we will ultimately be able to achieve profitability. Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could adversely affect the market price of our common stock and could significantly impair our ability to raise capital, expand our business, or continue to implement our business plan.

We can give no assurance that our internal and external sources of liquidity will be sufficient for our cash requirements.

We must have sufficient sources of liquidity to fund our working capital requirements and execute on our strategic initiatives. Future new product launches or investments in other growth initiatives may demand increased working capital before any long-term return is realized from increased revenue. Our ability to achieve our business and cash flow plans is based on a number of assumptions which involve significant judgments and estimates of future performance, borrowing capacity and credit availability, and financing opportunities which cannot at all times be assured. There is no assurance that cash flows from operations and other internal and external sources of liquidity will at all times be sufficient for our cash requirements. If necessary, we may need to consider actions and steps to improve our cash position and mitigate any potential liquidity shortfall, such as modifying our business plans, pursuing additional financing to the extent available, reducing capital expenditures, suspending certain activities or programs, pursuing and evaluating other alternatives and opportunities to obtain additional sources of liquidity, and other potential actions to reduce costs. There can be no assurance that any of these actions would be successful, sufficient or available on favorable terms. Any inability to generate or obtain sufficient levels of liquidity to meet our cash requirements at the level and times needed could have a material adverse impact on our business and financial position.

If we are unable to obtain sufficient funding, we may be unable to execute our business plan and fund operations. We may not be able to obtain additional financing on commercially reasonable terms, or at all.

We have experienced operating losses, and we expect to continue to incur operating losses for the next several years as we implement our business plan. Currently, we have no significant revenue from operations, and we do not have arrangements in place for all the anticipated financing that would be required to fully implement our business plan. Our prior losses, combined with expected future losses, have had, and will continue to have, for the foreseeable future, an adverse effect on our stockholders' equity and working capital.

We will need to raise additional capital in order to continue to execute our business plan. If we are unable to raise sufficient additional funds, we may need to scale back our future operations. Also, the ongoing armed conflicts in the Middle East, Ukraine, and elsewhere, which have negatively impacted the global macroeconomic environment and capital markets, may make it more difficult for us to raise additional funds.

We cannot give any assurance that we will be able to obtain all the necessary funding that we may need. In addition, we believe that we will require additional capital in the future to fully develop and bring to market our technologies and planned products. We have pursued and may pursue additional funding through various financing sources, including the private sale of our equity securities, debt financings, licensing fees for our technology, joint ventures with capital partners, and project type financing. If we raise funds by issuing equity or equity-linked securities, dilution to some or all our stockholders would result. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings could impose significant restrictions on our operations. We also may seek government-based financing, such as development and research grants. There can be no assurance that funds will be available on commercially reasonable terms, if at all.

Any future indebtedness could impose on us restrictive covenants, including further limitations on our ability to incur additional debt, limitations on our ability to issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. Also, in the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish, or license to a third party on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves or reserve certain opportunities for future potential arrangements when we might otherwise be able to achieve more favorable terms. In addition, we may be forced to work with a partner on one or more of our products or market development

programs, which could lower the economic value of those programs to us.

If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may be required to, among other things, delay, scale back or eliminate some or all of our activities, reduce headcount, trim research and product development programs, discontinue clinical trials, stop all or some of our manufacturing operations, defer capital expenditures, deregister from being a publicly traded company and delist from Nasdaq, or license our potential products or technologies to third parties, possibly on terms that cannot sustain our current business, or curtail, suspend or discontinue our operations entirely. If any of these things were to occur, our ability to grow and support our business and to respond to market challenges could be significantly limited or we may be unable to continue operations, in which case you could lose your entire investment.

Because our business is not profitable, from time to time, we may undergo a reduction in force to reduce our operating expenses. However, any corporate restructuring or headcount reduction may not result in anticipated savings, could result in total costs and expenses and attrition that are greater than expected and could disrupt our business.

As a consequence of our corporate realignment, we experienced employee turnover in 2022 higher than industry norms, and in February 2023 we continued to reduce headcount by eliminating another seven positions at the Company. If we decide to further reduce headcount to lower our operating expenses, we may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from such a restructuring because of unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from such a restructuring, our operating results and financial condition would be adversely affected. Any restructuring activities would be disruptive to our operations and could result in material delays in our new product development programs. Also, any headcount reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, or increase difficulties in our day-to-day operations. Headcount reductions could also harm our ability to attract and retain qualified management, scientific, clinical, regulatory, manufacturing, engineering, and other personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing and commercializing our new product candidates in the future.

Our revenues and future profitability are entirely dependent upon one family of products, the CellFX System, and one platform technology, Nano-pulse Stimulation.

Our revenue to date has been generated entirely from the CellFX System, which consists of a console, connectors and end-effectors, and these products and all our potential products under development are based upon the same patented platform technology, Nano-pulse Stimulation ("NPS"). Our future revenue is therefore dependent on the success of these products under development and platform technology. Reliance on a single family of products and single platform technology could negatively affect our results of operations and financial condition. Our ability to become profitable will depend upon the commercial success of these future products and platform technology.

We intend to market the CellFX nsPFA Percutaneous Electrode System primarily to Otolaryngologists, Endocrine Surgeons, and Interventional Radiologists ("surgeons") who may be slow or fail to adopt our products or who may use our products in only a small percentage of their eligible patients for a variety of reasons, including but not limited to:

- lack of experience with our products;
- lack of adequate reimbursement or cost to the patient;
- lack of conviction regarding evidence supporting cost benefits or cost effectiveness of our products over existing alternatives;
- lack of clinical data showing longer-term patient benefits;
- the possible introduction of new technologies competitive to our products; and
- liability risks generally associated with the use of new products and procedures.

Moreover, our products, including our platform NPS technology, could be rendered obsolete or economically impractical by numerous factors, many of which are beyond our control, including but not limited to:

- entrance of new competitors into our markets;
- technological advancements of alternative technologies;
- loss of key relationships with suppliers, group purchasing organizations, or end-user customers;
- manufacturing or supply interruptions;
- product liability claims;
- our reputation and product market acceptance;
- loss of existing regulatory approvals or the imposition of new requirements to maintain such approvals or to receive new approvals; and
- product recalls or safety alerts.

We may fail to meet our publicly announced guidance or other expectations about our business and future operating results, which could cause our stock price to decline.

The Company may, from time to time, provide financial guidance about its business and future operating results. In developing this guidance, the Company's management must make certain assumptions and judgments about its future operating performance, including but not limited to projected hiring of sales professionals, growth of revenue in the relevant device markets, increase or decrease of its market share, costs of production of its recently introduced products, and stability of the macro-economic environment in the Company's key markets. Furthermore, analysts and investors may develop and publish their own projections of the Company's business, which may form a consensus about the Company's future performance. The Company's business results may vary significantly from such guidance or that consensus due to a number of factors, many of which are outside of the Company's control, and which could adversely affect its operations and operating results. Furthermore, if the Company makes downward revisions of its own previously announced guidance, or if the Company's publicly announced guidance of future operating results fails to meet expectations of securities analysts, investors or other interested parties, the price of the Company's common stock could decline.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control and may be difficult to predict, including:

- the timing and cost of, and level of investment in, research, development, and commercialization activities relating to our product and product candidates, which may change from time to time;
- the timing of receipt of approvals or clearances for our product candidates from regulatory authorities internationally or in the United States, such as the U.S. FDA;
- the timing and status of enrollment for our clinical trials;
- coverage and reimbursement policies with respect to our product and product candidates, including the degree to which procedures using our products are covered and receive adequate reimbursement from third-party payors, and potential future drugs or devices that compete with our products;
- the costs of manufacturing our products, as well as building out our supply chain, which may vary depending on the quantity of production and which will vary significantly depending upon the terms of our agreements with manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- the level of demand for our product and any product candidates, if approved or cleared, which may vary significantly over time;
- litigation, including patent, employment, securities class action, stockholder derivative, general commercial, and other lawsuits;
- future accounting pronouncements or changes in our accounting policies; and
- the timing and success or failure of nonclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met our previously publicly stated revenue or earnings guidance.

Because we operate in highly competitive markets, we can expect to face competition from large well-established manufacturers of medical technologies, devices and similar products; we may not be able to compete effectively against companies with significantly more resources.

The medical technology, medical device, biotechnology, and pharmaceutical industries are characterized by intense and dynamic competition to develop new technologies and proprietary therapies. We face competition from a number of sources, such as pharmaceutical companies, medical device companies, generic drug companies, biotechnology companies, and academic and research institutions. For example, Abbott Laboratories, AtriCure, Inc., Boston Scientific Corporation, Johnson & Johnson (Biosense Webster), Medtronic plc, and several other companies all sell ablation-based surgical and catheter-based medical devices for the treatment of heart arrhythmias, including AF, and additionally, many of these companies are also actively developing PFA products for the treatment of AF. We will find ourselves in competition with one or more of these companies, all of which may have competitive advantages over us, such as:

- significantly greater name recognition;
- established relationships with healthcare professionals, customers, and third-party payers;
- competitive products with greater efficacy or better safety profiles;
- established distribution networks;
- additional lines of products and the ability to offer rebates, higher discounts, or incentives to gain a competitive advantage;
- greater experience in obtaining patents and regulatory approvals for product candidates;
- greater experience conducting new product research and development, manufacturing therapies, conducting clinical trials, obtaining regulatory approval for products, and marketing approved products; and
- greater financial and human resources for product development, sales and marketing.

We may also face increased competition in the future as new companies enter our markets and as scientific developments surrounding electro-signaling therapeutics continue to accelerate. For example, the current standard of care in cardiac tissue ablation for the treatment of AF is the use of thermal ablation modalities, primarily the use of radiofrequency ablation but has recently seen increased use of a different type of PFA called micro-PFA. While we will seek to expand our technological capabilities to remain competitive, research and development by others may render our technology or product candidates obsolete or noncompetitive or result in treatments or cures superior to any therapy developed by us.

We may rely on third parties for our sales, marketing, manufacturing, and/or distribution activities, and these third parties may not perform satisfactorily.

To be able to commercialize our products and planned products, we may elect to internally develop aspects of sales, marketing, large-scale manufacturing, or distribution, or we may elect to use third parties with respect to one or more of these functions. Our reliance on these third parties may reduce our control over these functions; however, reliance on third parties does not relieve us of our responsibility to ensure compliance with all required legal, regulatory, and scientific standards. Any failure of these third parties to perform satisfactorily and in compliance with relevant laws and regulations could lead to delays in the development of our products or planned products, including delays in our clinical trials, or failure to obtain necessary regulatory approvals, or failure to successfully commercialize our products or other future products. Some of these events could be the basis for FDA or other regulatory action, including injunction, recall, seizure, or total or partial suspension of production.

We believe that developing the commercialization aspects of a company will take a substantial amount of capital and commitment of time and effort. We may seek development and marketing partners and license our technology to others in order to avoid our having to provide the marketing, manufacturing, and distribution capabilities within our organization. There can be no assurance that we will find any development and marketing partners or companies that are interested in licensing our technology. If we are unable to establish and maintain adequate sales, marketing, manufacturing, and distribution capabilities, independently or with others, we will not be able to generate product revenue and may not become profitable.

If we lose key management personnel, our ability to identify, develop and commercialize new or next generation product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.

We are highly dependent upon the principal members of our management team, including our Chief Executive Officer, Burke Barrett, our Chief Commercial Officer, Kevin Danahy, and our Chief Technology Officer, Darrin Uecker, and members of our scientific and engineering teams. These persons have significant experience and knowledge with sub-microsecond pulsed electric fields and more broadly in life sciences and medical technologies. The loss of any team member could impair our ability to design, identify, and develop new intellectual property and new scientific or product ideas. The loss of a key employee, the failure of a key employee to perform in his or her current position, or our inability to attract and retain skilled employees could result in our inability to continue to grow our business or to implement our business strategy. We compete for qualified management and scientific personnel with other life science companies, academic institutions, and research institutions. Our employees could leave our Company with little or no prior notice. They are free to work for a competitor. If one or more of our senior executives or other key personnel were unable or unwilling to continue in their present positions, we may not be able to replace them easily or at all, and other senior management may be required to divert attention from other aspects of the business. In addition, we do not have "key person" life insurance policies covering any member of our management team or other key personnel. The loss of any of these individuals or any inability to attract or retain qualified personnel, including scientists, engineers, and others, could prevent us from pursuing collaborations and materially and adversely affect our product development and introductions, business growth prospects, results of operations, and financial condition.

There is a limited talent pool of experienced professionals in our industry. If we are not able to retain and recruit personnel with the requisite technical skills, we may be unable to successfully execute our business strategy.

The specialized nature of our industry results in an inherent scarcity of experienced personnel in the field. Our future success depends upon our ability to attract and retain highly skilled personnel, including scientific, technical, commercial, business, regulatory, and administrative personnel, necessary to support our anticipated growth, develop our business and perform certain contractual obligations. Given the scarcity of professionals with the scientific knowledge we require and the intense competition that exists for qualified personnel among life science businesses, we may not succeed in attracting or retaining the personnel we require to continue and grow our operations.

We have very limited experience selling the CellFX System.

Successfully commercializing medical devices such as ours is a complex and uncertain process. We began marketing and selling the CellFX System in the United States, Canada, and certain limited European markets in late 2021 to dermatologists through a limited direct sales force. In January 2022, we established an operating company in the Netherlands to further enhance our operations in Europe. However, in 2022 and 2023 we eliminated all of our full-time sales and marketing positions and, as of December 31, 2023, we had no U.S. or international sales force. We have only just recently begun to hire employees to help market and sell our CellFX nsPFA Percutaneous Electrode System. We therefore have limited experience marketing and selling the CellFX System and our revenues and cash flows have been volatile and difficult to predict.

We intend to hire and train a very limited number of sales representatives and clinical specialists with backgrounds and experience in the relevant markets, especially those familiar with energy-based therapies and who have existing relationships with otolaryngologists, endocrine surgeons, interventional radiologists, and cardiothoracic surgeons. However, we expect that our sales force will require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. Furthermore, the use of our product will often require or benefit from direct support from us.

Our commercialization efforts depend on the efforts of our management and sales team, our third-party manufacturers and suppliers, physicians and medical clinics, and general economic conditions, among other factors, including the following:

- the effectiveness of our marketing and sales efforts in the United States and internationally;
- our success in educating surgeons and other physicians and patients about the benefits, administration and use of our products;
- the acceptance by physicians and patients of the safety and effectiveness of our products;
- the availability, perceived advantages, relative cost, relative safety, and relative efficacy of alternative and competing therapies; and
- our ability to achieve and maintain compliance with all regulatory requirements applicable to our products.

While few in number, we expect our direct sales representatives to develop long-lasting relationships with the surgeons they serve. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled direct sales representatives with significant technical knowledge in various areas, such as cardiology, minimally invasive surgery, and ablation technologies. New hires require training and take time to achieve full productivity. If we fail to train new hires adequately, or if we experience high turnover in our sales force in the future, we cannot be certain that new hires will become as productive as may be necessary to maintain or increase our sales. Also, if our direct sales representatives or third-party distributors fail to adequately promote, market and sell our products or decide to leave or cease to do business with us, our sales could significantly decrease or grow at a rate too slow to become profitable. In addition, our future sales will largely depend on our ability to increase our marketing efforts and adequately address our customers' needs. If we are unable to adequately address our customers' needs, it could negatively impact sales and market acceptance of our products, and we may not generate sufficient revenue to become profitable. If we are unable to expand our sales and marketing capabilities domestically and internationally, we may not be able to effectively commercialize our products, which would adversely affect our business, results of operations, and financial condition.

Rapidly changing technology in life sciences could make the products we are developing obsolete.

The life sciences industries are characterized by rapid and significant technological changes, frequent new product introductions and enhancements, and evolving industry standards. Our future success will depend on our ability to continually develop and then improve the products that we design and to develop and introduce new products that address the evolving needs of our customers on a timely and cost-effective basis. Also, we will need to pursue new market opportunities that develop as a result of technological and scientific advances. These new market opportunities may be outside the scope of our proven expertise or in areas which have unproven market demand. Any new products developed by us may not be accepted in the intended markets. Our inability to gain market acceptance of new products could harm our future operating results.

If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be harmed.

From time to time, we have experienced rapid growth in our business. Recent and future growth imposes significant added responsibilities on management, including the need to identify, recruit, train, and integrate additional employees. Rapid expansion in personnel could mean that fewer experienced people carry out our research and development activities, manufacture, market, and sell CellFX Systems and NPS therapies and procedures, which could result in inefficiencies and unanticipated costs, reduced quality, and disruptions to our operations. In addition, rapid and significant growth may strain our administrative and operational infrastructure, and the failure to continue to upgrade our technical, administrative, operating, and financial control systems, or the occurrence of other unexpected expansion difficulties, could have a material adverse effect on our business, financial condition and results of operations, and our ability to timely execute our business plan. We may be unable to maintain the quality of, or delivery timelines of, our products or satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. We may implement new enterprise software systems in a number of areas affecting a broad range of business processes and functional areas. The time and resources required to implement these new systems is uncertain and failure to complete this in a timely and efficient manner could harm our business. We cannot guarantee that any of the personnel, systems, procedures, and controls we put in place will be adequate to support the manufacture and distribution of our products. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

We must successfully educate and train surgeons and their staff on the proper use of the CellFX System; if our customers do not adopt our technology into their medical practices, or adopt our technology slower than expected, our business could suffer.

Although most surgeons may have adequate knowledge on how to use our novel CellFX System based on their clinical training and experience, we believe that the most effective way to introduce and build market demand for our products is by directly training surgeons and other physicians in the use of our products. Convincing them to dedicate the time and energy necessary for adequate training is challenging, and we cannot assure you that we will succeed in these efforts. If surgeons and other physicians are not properly trained, they may not use our products and, as a result, we may not maintain or grow our sales or achieve or sustain profitability. If surgeons and other physicians are not properly trained, they may also misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes, patient injury, negative publicity, or lawsuits against us, any of which could have a significant adverse effect on our business, financial condition and results of operations.

Additionally, our strategy includes educating key opinion leaders in the industry. If these key opinion leaders determine that alternative technologies are more effective or that the benefits offered by our products are not sufficient to justify their higher cost, or if we encounter difficulty promoting adoption or establishing these systems as a standard of care, our ability to achieve market acceptance of the products we introduce could be significantly limited and our business could suffer.

We may encounter manufacturing problems or delays that could result in lost revenue or slower than anticipated product development. Additionally, we currently rely on third-party suppliers for critical components needed to manufacture the CellFX System and related applicators. Any problems experienced by these suppliers could result in a delay or interruption of their supply to us and, as a result, we may face delays in the development and commercialization of products.

We currently rely upon third-party suppliers to manufacture and supply components for the CellFX System and for our products under development. We perform final assembly of our CellFX devices at our facility in California. The manufacture of the CellFX components in compliance with the FDA's regulations requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medical device products often encounter difficulties in production, including difficulties with production costs and yields, quality control, quality assurance testing, shortages of qualified personnel, as well as compliance with applicable regulations, both foreign and domestic.

We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with applicable regulatory requirements, and if our contract manufacturers cannot successfully manufacture the components needed for our products and products under development in a manner that conforms to our specifications and these strict regulatory requirements, we may not be able to rely on their manufacturing facilities in the future. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds these facilities inadequate for the manufacture of our components or if such facilities are subject to enforcement action in the future or are otherwise inadequate with respect to complying with applicable regulatory requirements, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop and market our product or to obtain regulatory approval or clearance for our product candidates.

We currently purchase components for our products under purchase orders and do not have long-term contracts with most of the suppliers of these materials. If suppliers were to delay or stop producing our components, or if the prices they charge us were to increase significantly, or if they elected not to sell to us, we would need to identify other suppliers and we may not be able to secure alternative suppliers on favorable terms, or at all. Any failure of these suppliers to perform satisfactorily could adversely impact our business and results of operations and we may experience delays in manufacturing of our devices while finding another acceptable supplier.

We may not become commercially viable if our ultimate commercialized products or related treatments fail to obtain an adequate level of reimbursement by Medicare and other third-party payers.

We believe that the commercial viability of the CellFX System and any potential devices and products and related treatments, and therefore our commercial success as a company, may be affected by the availability of government reimbursement and medical insurance coverage and reimbursement for newly approved medical therapies, technologies, and devices. Insurance coverage and reimbursement are not assured. It typically takes a period of use in the marketplace before coverage and reimbursement are granted, if it is granted at all. In the United States and in many other jurisdictions, surgeons and other physicians and other healthcare providers generally rely on insurance coverage and reimbursement for their revenues, therefore this is an important factor in the overall commercialization plans of a proposed product and whether it will be accepted for use in the marketplace. Without insurance coverage and reimbursement for our planned products, we would expect to earn only diminished revenues, if any revenues are earned.

Medicare, Medicaid, health maintenance organizations, and other third-party payers are increasingly attempting to contain healthcare costs by limiting both the scope of coverage and the level of reimbursement of new medical technologies and products. As a result, they may not cover or provide adequate payment for the use of the CellFX System or planned products in development. In order to obtain satisfactory reimbursement arrangements, we may have to agree to reduce our fee or sales price below what we currently expect to charge customers, which could adversely affect our profit margins. Moreover, each plan may separately require us to provide scientific and clinical support for the use of our products and, as a result, the coverage determination process is often a time-consuming and costly process with no assurance that coverage and adequate reimbursement will be applied consistently or obtained at all. Even if Medicare and other third-party payers decide to cover procedures involving the CellFX System and our proposed devices and products, we cannot be certain that the reimbursement levels will be adequate. Accordingly, even if these products are approved for commercial sale, unless government and other third-party payers provide adequate coverage and reimbursement for our devices and products, some surgeons and other physicians may be discouraged from using them, and our sales would suffer.

Medicare reimburses for medical technologies and products in a variety of ways, depending on where and how the item is used. However, Medicare only provides reimbursement if CMS determines that the item should be covered and that the use of the device or product is consistent with the coverage criteria. A coverage determination can be made at the local level by the Medicare administrative contractor, a private contractor that processes and pays claims on behalf of CMS for the geographic area where the services were rendered, or at the national level by CMS through a national coverage determination. There are statutory provisions intended to facilitate coverage determinations for new technologies, but it is unclear how these provisions might apply to the CellFX System or to any of our proposed devices and products, as they are still largely in the development stages. Coverage presupposes that the technology, device, or product has been cleared or approved by the FDA and further, that the coverage will be consistent with the approved intended uses of the device or product as approved or cleared by the FDA, but coverage can be narrower. A coverage determination may be so limited that relatively few patients will qualify for a covered use of a device or product.

Obtaining a coverage determination, whether local or national, is a time-consuming, expensive and highly uncertain proposition, especially for a new technology, and inconsistent local determinations are possible. On average, Medicare coverage determinations for medical devices and products lag behind FDA approval or clearance. The Medicare statutory framework is also subject to administrative rulings, interpretations and discretion that affect the amount and timing of reimbursement made under Medicare. Medicaid coverage determinations and reimbursement levels are determined on a state-by-state basis, because Medicaid, unlike Medicare, is administered by the states under a state plan filed with the Secretary of the U.S. Department of Health and Human Services ("HHS"). Medicaid generally reimburses at lower levels than Medicare. Moreover, Medicaid programs and private insurers are frequently influenced by Medicare coverage determinations.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred net losses since our inception and anticipate that we may continue to incur significant losses for the foreseeable future. If not utilized, some of our federal and state net operating losses ("NOLs") carryforwards will begin to expire in various years beginning after 2034. Under the Internal Revenue Code of 1986, as amended, or the Code, and certain similar state tax provisions, we are generally allowed to carry forward our NOLs from a prior taxable year to offset our future taxable income, if any, until such NOLs are used or expire, subject to certain limitations. The same is true of other unused tax attributes, such as tax credits.

In addition, under Section 382 of the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. We believe that we have had one or more ownership changes, and, as a result, a portion of our existing NOLs may be subject to limitation. Future changes in our stock ownership could result in additional limitations. We may not be able to utilize a material portion of our NOLs even if we attain profitability.

We have a substantial amount of goodwill and intangible assets which over time may have to be written down as we make the required periodic assessments as to their value as reflected in our financial statements.

A significant portion of our total assets are comprised of goodwill and intangibles that arose from our 2014 business acquisitions. We review goodwill for impairment at least annually or whenever changes in circumstances indicate that the carrying value of the goodwill may not be recoverable. We also review our intangible assets for impairment at each fiscal year end or when events or changes in circumstances indicate the carrying value of these assets may exceed their current fair values. If we take an impairment charge for either goodwill or intangible assets, the overall assets will be reduced. Such an impairment charge may result in a change in the perceived value of the Company and ultimately may be reflected as a reduction in the market price of our securities. Additionally, an impairment charge may also adversely influence our ability to raise capital in the future.

Risks Related to Product Development and Product-Related Risks

Our CellFX System and any future product candidates may cause serious adverse side effects or have other properties that could delay or prevent their regulatory approval, limit their commercial desirability or result in significant negative consequences.

The risk of failure of clinical development is high. For example, the vast majority of our *in vivo* data has been a result of animal testing outside of cardiac animal models, and we have only completed a limited number of feasibility studies in humans. Undesirable side effects caused by the CellFX System, NPS pulses, or any of our planned future products could cause us, any partners of ours, or regulatory authorities to interrupt, delay or halt clinical trials or to revoke previously granted regulatory approvals. Undesirable side effects could also result in more restrictive labeling requirements or the delay or denial of regulatory approval of planned future products by the FDA or other comparable foreign regulatory authority.

Additionally, if we or others identify undesirable side effects caused by the CellFX System, a number of potentially significant negative consequences could result, including:

- we may be forced to recall such product and suspend the marketing of such product;
- regulatory authorities may withdraw their approvals of such product;
- regulatory authorities may require additional warnings on the label and/or narrow the indication of use for the product which could diminish the usage or otherwise limit the commercial success of such product;
- the FDA or other regulatory authorities may issue safety alerts, "Dear Healthcare Provider" letters, press releases, or other communications containing warnings about such product;
- the FDA may restrict distribution of our product and impose burdensome implementation requirements on us;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation could suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the CellFX System or of any future particular planned product, if approved.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure or delay can occur at any time during the clinical trial process. For example, success in nonclinical studies and early feasibility clinical studies does not ensure that the expanded clinical trials needed to support regulatory submissions will be successful. Setbacks can be caused by, among other things, nonclinical findings made while clinical trials are underway, safety or efficacy observations made in clinical trials, including previously unreported adverse events, or post-approval observations. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval or clearance for our product candidates or to expand the existing approvals or clearances for our existing products. To date, we have had only preclinical experience using NPS technology in animal models of cardiac disease and very limited clinical experience treating AF with our CellFX nsPFA 360° Cardiac Catheter; our past successes in dermatology may not translate into similar results in cardiology. In particular, the safety and efficacy data we have generated using NPS technology and the CellFX System to treat benign lesions in the skin and the preliminary feasibility results we have seen in benign thyroid nodules might not be replicated in other areas of medicine, including the use of CellFX nsPFA technology and the CellFX System to treat AF or other cardiac disease.

Our long-term growth depends on our ability to develop marketable products to treat AF, tumors and nodules through our research and development efforts, and if we fail to do so we may be unable to compete effectively or we may decide to scale back or eliminate some or all of our activities or otherwise curtail, suspend or discontinue our operations entirely.

The medical device industry is characterized by intense competition, rapid technological changes, new product introductions and enhancements, and evolving industry standards. Our business prospects depend in part on our ability to develop new products and applications for our NPS technology, including in new markets that develop as a result of technological and scientific advances. New technologies, techniques or products could emerge that might offer better combinations of price and performance than our products. It is important that we anticipate changes in technology and market demand, as well as physician, hospital, and healthcare provider practices to successfully develop, obtain clearance or approval, if required, and successfully introduce new, enhanced and competitive technologies to meet our prospective customers' needs on a timely and cost-effective basis.

If we do not develop and obtain regulatory clearances or approvals for new products or product enhancements in time to meet market demand, or if there is insufficient demand for these products or enhancements, our results of operations will suffer. Our research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology, material, or other innovation. In addition, even if we are able to develop enhancements or new generations of our products successfully, these enhancements or new generations of products may not produce sales in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features.

Moreover, if our technology cannot be used to successfully treat AF, we may decide to, among other things, delay, scale back or eliminate some or all of our activities, reduce headcount, trim research and product development programs, discontinue clinical trials, stop all or some of our manufacturing operations, defer capital expenditures, deregister from being a publicly traded company and delist from Nasdaq, or license our potential products or technologies to third parties, possibly on terms that cannot sustain our current business, or curtail, suspend or discontinue our operations entirely.

Interim "top-line" and preliminary results from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim top-line or preliminary results from our clinical trials. Interim results from clinical trials that we may announce are subject to the risk that one or more of the clinical outcomes may materially change as more follow-up data are gathered, patient enrollment continues and more patient data become available. Preliminary or top-line results, including our preliminary data from our feasibility thyroid nodule study and our first-in-human cardiac catheter study, also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published or announced. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

If we fail to maintain necessary regulatory clearance for our products, or if clearances or approvals for future devices and indications are delayed or not issued, the commercial prospects for our CellFX System and other NPS technologies would be harmed.

Our product candidates under development are medical devices that are subject to extensive regulation by the FDA in the United States and by regulatory agencies in other countries where we do business. Government regulations specific to medical devices are wide-ranging and govern, among other things:

- device design, development and manufacture;
- laboratory, preclinical and clinical testing, labeling, packaging, and storage;
- premarketing clearance or approval;
- record keeping;
- device marketing, promotion and advertising, sales and distribution; and
- post-marketing surveillance, including reporting of deaths and serious injuries and recalls and correction and removals.

Before a new medical device, or a new intended use for an existing device, can be marketed in the United States, the device's manufacturer must first submit and receive either 510(k) clearance or Premarket Approval ("PMA") from the FDA, unless an exemption applies. In the 510(k)-clearance process, the FDA will determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate reasonable safety and effectiveness of the device based on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing, and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). Either process can be expensive, lengthy and unpredictable.

The FDA may not approve or clear our 510(k), de novo, or PMA applications on a timely basis or at all. Such delays or refusals could have a material adverse effect on our business operations and financial condition. The FDA may also change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other action which may prevent or delay approval or clearance of our products under development. Any of these actions could have a material adverse effect on our business operations and financial condition.

The FDA and the U.S. Federal Trade Commission ("FTC") also regulate the advertising and promotion of our devices to ensure that the claims we make are consistent with our regulatory clearances or approvals, that there are adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or the FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including FDA warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions, among others:

- adverse publicity, warning letters, fines, injunctions, consent decrees, and civil penalties;
- obligations to repair, replace, refund, or recall our marketed devices, or government seizure of them;
- operating restrictions, partial suspension, or total shutdown of production;
- refusing our requests for 510(k) clearance or premarket approval of new devices, new intended uses or modifications to existing devices;
- withdrawing 510(k) clearance or premarket approvals that have already been granted; and
- criminal prosecution.

If any of these events were to occur, our business and financial condition would be harmed.

The mechanism of action of NPS technology platform has not been fully determined or validated.

The exact mechanism(s) of action(s) of our NPS technology platform, including nano-PFA, is not fully understood, and data are still being gathered regarding its use. Furthermore, there are only a relatively small number of scientists and researchers who can be considered experts in the use of this emerging technology. Insofar as potential regulators, partners or investors value a clear understanding of a technology's mechanism of action, this limitation could make it more challenging for us to obtain requisite regulatory approvals, investments or a partnership on favorable terms as a result.

We may find it difficult to enroll patients in our clinical trials. If we cannot enroll a sufficient number of eligible patients to participate in our clinical trials, we may not be able to initiate or continue them, which could delay or prevent development of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates as well as completion of required follow-up periods. In general, if patients are unwilling to participate in our trials because of negative publicity from adverse events in the health care industry or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting trials and obtaining regulatory approval or clearance of planned products may be delayed. If there are delays in accumulating the required patients and patient data, there may be delays in completing the trial. Further, if any of our clinical trial sites fail to comply with required good clinical practices, we may be unable to use the data gathered at those sites. Also, if our clinical investigators fail to carry out their contractual duties or regulatory obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be delayed, suspended, or terminated. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether, and delays in obtaining regulatory authorization for our products.

Laboratory conditions differ from commercial conditions and field conditions, and the safety and effectiveness of our product candidates may depend on the technique of the user.

Observations and developments that may be achievable under laboratory circumstances may not be able to be replicated in broader research and development phases, in commercial settings, or in the use of any of any product or product candidates in the field. Furthermore, our NPS technologies will be administered by healthcare professionals and will require a degree of training and practice to administer correctly. Treatment results achieved in the laboratory or in clinical trials conducted by us or by other investigators may not be representative of the results actually encountered during commercial use of our products due to variability in administration technique. The training and skills of investigators in our clinical trials may not be representative of the training and skills of future product users, which could negatively affect treatment results and the reputation of the Company or its products. In addition, there may be a selection bias in the patients and/or sites of administration chosen for any clinical trials that would positively affect treatment results that may not be representative or predictive of real-world experience with our products, including the CellFX System.

Issues with our firmware and software may negatively affect the function of our devices.

The safety and effectiveness of CellFX procedures and therapies may depend, in part, on the function of firmware run by the microprocessors embedded in the device and associated software. This firmware and software is proprietary to us. While we have made efforts to test the firmware and software extensively, both are potentially subject to malfunction which in turn may harm patients. Further, our proprietary firmware and software may be vulnerable to physical break-ins, hackers, improper employee or contractor access, computer viruses, programming errors, data breaches, or similar problems. Any of these might result in harm to patients or the unauthorized release of confidential medical, business or other information belonging to us or to other persons.

Risks Related to Intellectual Property, Cybersecurity, Data Privacy, & Litigation

If we are unable to protect our intellectual property, then our financial condition, results of operations and the value of our technology and products could be adversely affected.

Patents and other proprietary rights are essential to our business and our ability to compete effectively with other companies is dependent upon the proprietary nature of our technologies. Similarly, our future success partnering our NPS technologies, including our CellFX System, will depend greatly on the perceived strength and reach of the patents protecting those technologies against unlicensed competitors. We also rely upon trade secrets, know-how, continuing technological innovations, and licensing opportunities to develop, maintain and strengthen our competitive position. We seek to protect these, in part, through confidentiality agreements with certain employees, consultants and other parties. Our success will depend in part on the ability of our licensors and us to obtain, to maintain (including making periodic filings and payments) and to enforce patent protection for the licensed intellectual property, in particular, those patents to which we have secured rights. We may not successfully prosecute or continue to prosecute the patent applications which we have licensed. Even if patents are issued in respect of these patent applications, we may fail to maintain these patents or may determine not to pursue litigation against entities that are infringing upon these patents. Without adequate protection for the intellectual property that we own or license, other companies might be able to offer substantially identical products for sale, which could unfavorably affect our competitive business position and harm our business prospects. Even if issued, patents may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection that we may have for our products.

Litigation or third-party claims of intellectual property infringement or challenges to the validity of our patents would require us to use resources to protect our technology and may prevent or delay our development, regulatory approval or commercialization of our product candidates.

If we are the target of claims by any third party asserting that our products or intellectual property infringe upon the rights of others, we may be forced to incur substantial expenses or divert substantial employee resources from our business. If successful, such claims could result in our having to pay substantial damages or could prevent us from developing one or more products or product candidates. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing, or sales of the product or product candidate that is the subject of the suit.

If we, or our collaborators, experience patent infringement claims, or if we elect to avoid potential claims others may be able to assert, we or our collaborators may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly. The cost to us of any litigation or other proceeding, regardless of its merit, even if resolved in our favor, could be substantial. Some of our competitors may be able to bear the costs of such litigation or proceedings more effectively than we can because of their having greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may, regardless of their merit, also absorb significant management time and employee resources.

Our intellectual property rights will not necessarily provide us with competitive advantages.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us or our future commercial partners to maintain a competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- others may independently develop similar or alternative technologies without infringing on our intellectual property rights;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we may obtain patents for certain products many years before we obtain marketing approval for products utilizing such patents, and because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of our patents may be limited;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may fail to develop additional proprietary technologies that are patentable;
- the laws of certain foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, or we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and
- the patents of others may have an adverse effect on our business, for example by preventing us from marketing one or more of our product candidates for one or more indications.

Any of the aforementioned threats to our competitive advantage could harm our business.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely upon, among other things, unpatented proprietary technology, processes, trade secrets, and know-how. Any involuntary disclosure to, or misappropriation by, third parties of our confidential or proprietary information could enable competitors to duplicate or surpass our technological achievements, potentially eroding our competitive position in our market. We seek to protect confidential and proprietary information in part by confidentiality agreements with our employees, consultants and third parties. While we require, as a matter of company policy, that all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be improperly disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. These confidentiality agreements may be terminated or breached, and we may not have adequate remedies for any such termination or breach. Furthermore, these agreements may not provide meaningful protection for our trade secrets and know-how in the event of unauthorized use or disclosure.

If we are unable to protect the intellectual property used in our products, others may be able to copy our innovations which may impair our ability to compete effectively in our markets.

Evaluating the strength and enforceability of our patents involves complex legal and scientific questions and can be uncertain. Both our patents and patent applications can be challenged by third parties and our patent applications may fail to result in issued patents. Moreover, both our existing and future patents may be too narrow to prevent third parties from developing or designing around our intellectual property and, in that event, we may lose competitive advantage and our business may suffer.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our current or future product candidates, if any, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

If our information technology systems or data, or those of third parties upon whom we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, regulatory investigations and actions; litigation (including class claims); fines and penalties; a disruption of our business operations such as our clinical trials; reputational harm; loss of revenue and profits; and other adverse consequences.

We depend on our information technology systems for the efficient functioning of our business, including the manufacture, distribution and maintenance of our products, as well as for accounting, data storage, compliance, purchasing, inventory management, and other related functions. We do not have redundant information technology in all aspects of our systems at this time. Despite the implementation of security and back-up measures, our information technology systems as well as those of our third-party partners, consultants, contractors, suppliers, and service providers, may be vulnerable to attack, damage and interruption from physical or electronic break-ins, accidental or intentional exposure of our data by employees or others with authorized access to our networks, computer viruses, malware, ransomware, malicious code, phishing attacks and other social engineering schemes, denial or degradation of service attacks, attacks by sophisticated nation-state and nation-state-supported actors, supply chain attacks, natural disasters, terrorism, war, telecommunication and electrical failure, denial of service, and other cyberattacks or disruptive incidents that could result in unauthorized access to, use or disclosure of, corruption of, or loss of sensitive, and/or proprietary data, including health-related and other personal information.

In the ordinary course of our business, we (and third parties upon whom we rely) may collect, receive, store, use, transfer, make accessible, protect, secure, dispose of, transmit, disclose or otherwise process proprietary, confidential and sensitive information, including personal data, such as health-related data and participant study related data, intellectual property, and trade secrets (collectively, "sensitive data"). We may share or receive sensitive data with or from third parties whose information security measures may not be adequate. In particular, the COVID-19 pandemic has caused us to modify our information technology practices including that our employees may work remotely which increases the risk of data breaches. Additionally, the prevalent use of mobile devices that access our sensitive data increases the risk of data breaches.

While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our business operations, whether due to a loss, corruption or unauthorized disclosure of our trade secrets, personal information or other proprietary or sensitive information or other similar disruptions. The costs to us to attempt to protect against such breaches can be significant and could potentially require us to modify our business, including non-clinical and clinical trial activities. While we have implemented security measures designed to protect our information technology systems and to identify and remediate potential vulnerabilities, such measures may not be successful. We may not be able to detect vulnerabilities in our information technology systems because such threats and techniques used by threat actors change frequently are sophisticated in nature and may not be detected until after a security incident has occurred.

If we, or others upon whom we rely, experience or are perceived to have experienced a breach, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits and inspections), interruptions in our operations (including disruptions to our clinical trials), interruptions or restrictions on processing sensitive data (which could result in delays in obtaining, or our inability to obtain, regulatory approvals and significantly increase our costs to recover or reproduce the sensitive data), unauthorized, unlawful or accidental loss, corruption, access, modification, destruction, alteration, acquisition or disclosure of sensitive data, such as clinical trial data, reputational harm, litigation (including class-action claims), indemnification obligations, monetary fund diversions, financial loss and other harms. In particular, ransomware attacks are becoming increasingly prevalent and severe and can lead to significant disruptions to operations, loss of data and income, reputational harm and diversion of funds. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. Such theft could also lead to loss of intellectual property rights through disclosure of our proprietary business information, and such loss may not be capable of remedying. In addition, such a breach may require notification of the breach to relevant stakeholders. Such disclosures are costly and the disclosure or the failure to comply with such requirements could lead to adverse consequences. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

Product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of our product or any future products that we may develop.

We face an inherent risk of product liability exposure related to the sale of our product and the future sale of planned products and the use of these in human clinical studies. For example, we may be sued if our product or any of our product candidates, including any that are developed in combination therapies, allegedly causes injury, or is found to be otherwise unsuitable during product testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, or a breach of warranties. We may also be subject to liability for a misunderstanding of, or inappropriate reliance upon, the information we provide. If we cannot successfully defend ourselves against claims that our product or planned products caused injuries, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in, among other things:

- decreased demand for our product or any planned products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of patients from our clinical studies or cancellation of studies;
- significant costs to defend the related litigation and distraction to our management team;
- substantial monetary awards to patients;
- loss of revenue;
- government investigations or enforcement actions; and
- the inability to commercialize any future products that we may develop.

For example, during the course of treatment, patients may suffer adverse events for reasons that may or may not be related to the CellFX System or our NPS technology. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact, or end our opportunity to receive or maintain regulatory approval to market those products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our product, the investigation into the circumstance may be time consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval processes, or impact and limit the type of regulatory approvals our products could receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could harm our business.

We currently maintain product liability insurance coverage, which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Government Regulation

We are subject to stringent domestic and foreign regulation. Any unfavorable regulatory action or adverse change in law may materially and adversely affect our future financial condition and business operations and prospects.

The CellFX System and any other potential devices and products we develop are, and will continue to be, subject to extensive, rigorous, and ongoing regulation by numerous government agencies, including the FDA and similar foreign regulatory authorities. To varying degrees, each of these agencies monitors and enforces our compliance with laws and regulations governing the development, testing, manufacturing, labeling, marketing, distribution, and the safety and effectiveness of our medical technology. The process of obtaining and maintaining marketing approval or clearance from the FDA and similar foreign regulatory authorities for new devices and products, or for enhancements, expansion of the indications or modifications to existing products, could:

- take a significant indeterminate amount of time;
- require the expenditure of substantial resources;
- involve rigorous preclinical and clinical testing, and possibly post-market surveillance;
- involve modifications, repairs or replacements of our products;
- require design changes of our products;
- result in limitations on the indicated uses of our products; and
- result in our never being granted the regulatory approval or clearance we seek.

If we experience any of these occurrences, our operations may suffer and we might experience harm to our competitive standing, which could adversely affect our financial condition.

We are subject to, and will have ongoing responsibilities under, FDA and international regulations, both before and after a product is approved or cleared and commercially released. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections. If an inspection were to conclude that we are not in compliance with applicable laws or regulations, or that any of our devices are ineffective or pose an unreasonable health risk, the FDA or similar foreign regulatory authorities could ban such devices or products, detain or seize such devices or products, order a recall, repair, replacement, or refund of such devices or products, or require us to notify health professionals and others that the therapies, devices or products present unreasonable risks of substantial harm to the public health. Additionally, the FDA or similar foreign regulatory authorities may impose other operating restrictions, enjoin and restrain certain violations of applicable law pertaining to our devices and products or assess civil or criminal penalties against our officers, employees, or us. The FDA and similar foreign regulatory authorities have been increasing their scrutiny of the industry and governments are expected to continue to scrutinize the industry closely with inspections and possibly enforcement actions. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively manufacturing, marketing and selling our devices and products, including the CellFX System. In addition, negative publicity and product liability claims resulting from any adverse regulatory action could have a material adverse effect on our financial condition and results of operations.

U.S. Healthcare Reform

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future solutions. Changes in healthcare policy could increase our costs, decrease our revenues, and impact sales of and reimbursement for our current and future solutions. The Affordable Care Act substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts our industry. The Affordance Care Act contains a number of provisions that impact our business and operations, some of which in ways we cannot currently predict, including those governing enrollments in federal healthcare programs and reimbursement changes.

There will continue to be proposals by legislators at both the federal and state levels, regulators, and third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our current and future solutions or the amounts of reimbursement available for our current and future solutions from governmental agencies or third-party payors. While in general it is too early to predict specifically what effect the Affordable Care Act and its implementation or any future healthcare reform legislation or policies will have on our business, current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

All our product development depends upon maintaining strong working relationships with physicians.

The development, marketing, and sale of any future products in development depends upon our ability to maintain strong working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing, and sale of our products. Physicians assist us in clinical trials and as researchers, marketing and product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could harm our business, financial condition and results of operations. The medical device industry's relationship with physicians is under increasing scrutiny by the Office of Inspector General ("OIG"), the Department of Justice ("DOJ"), state attorneys general, and other foreign and domestic government agencies. Our failure to comply with laws, rules and regulations governing our relationships with physicians, or an investigation into our compliance by the OIG, DOJ, state attorneys general, and other government agencies, could significantly harm our business, including compromising the use or integrity of our clinical data in regulatory submissions to the FDA or similar regulatory authorities.

We are subject to healthcare and other laws and regulations relating to our business and could face substantial penalties if we are determined not to have fully complied with such laws, which could have an adverse impact on our business.

We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, any commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate applicable laws or regulations. There are many federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our products for which we obtain marketing approval or clearance.

We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, any commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate applicable laws or regulations. There are many federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our products for which we obtain marketing approval or clearance. Such laws include:

- U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program, such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value, and the government can find a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the law or a specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government;

- HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by HITECH, and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;

- the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by these physicians and their immediate family members;

- the CCPA requires covered companies to, among other things provide new disclosures to California consumers and afford such consumers new abilities to opt-out of certain sales of personal information. We cannot yet predict the impact of the CCPA or the recently approved CPRA on our business or operations, but it may require us to modify our data processing practices and policies and could cause us to incur substantial costs and expenses in an effort to comply;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous state and non-U.S. laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and state and non-U.S. laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

We have implemented compliance related programs and procedures consistent with our stage of development to help identify and deter healthcare and other violations by employees and other third parties that perform services for us. Notwithstanding our efforts, however, it is possible that governmental authorities may conclude that our business practices do not comply with current or future statutes, regulations, agency guidance, or case law involving applicable healthcare or other applicable laws.

Also, any material changes to any of the laws or regulations applicable to our business could harm our business, financial condition and results of operations.

To obtain the necessary device approvals or clearances from regulatory authorities for our future product candidates, we will have to conduct various preclinical and clinical tests, which may be costly and time consuming, and may not provide results that will allow us to seek regulatory approval or clearance.

The number of preclinical and clinical tests that will be required for regulatory clearance or approval varies depending on the disease or condition to be treated, the method of treatment, the nature of the device, the jurisdiction in which we are seeking approval or clearance and the applicable regulations. Regulatory agencies, including those in the United States, Canada, Europe, and other jurisdictions where medical devices and products are regulated can delay, limit or deny approval of a product for many reasons. For example, regulatory agencies:

- may not deem a technology or device to be reasonably safe or effective for any intended use or indication;
- may interpret data from preclinical and clinical testing differently than we do;
- may determine our manufacturing facility or processes do not comply with quality system regulations;
- may conclude that our products do not meet quality standards for durability, long-term reliability, biocompatibility, electromagnetic compatibility, or electrical safety; or
- may change their approval or clearance policies or adopt new regulations in a manner that is adverse to us.

These regulators may make requests or disagree with us regarding the design or conduct of our clinical trials, resulting in an increased risk of difficulties or delays in obtaining regulatory approval or clearance on future product candidates, or expanded indications of use for our existing products, and increased costs.

Even if a potential device or product ultimately is cleared or approved by regulatory authorities, it may be cleared or approved only for narrow indications which may render it commercially less viable.

Even if we complete clinical testing and a potential device or product of ours is cleared or approved, it may not be cleared or approved for the indications that are necessary or desirable for a successful commercialization. Regulators may grant marketing authorization contingent on the performance of costly additional clinical trials which may be required after approval or clearance. Regulators also may approve or clear our lead product candidates, including the CellFX System, for a more limited indication or a narrower patient population than we originally requested. Our preference will be to obtain as broad an indication as possible for use in connection with the particular disease or treatment for which it is designed. However, the final indication or labeling may be more limited than we originally seek. Any limitation on use may make the device or product commercially less viable and more difficult, if not impractical, to market. Therefore, we may not obtain the revenues that we seek in respect of the proposed product, and we will not be able to become profitable and provide an investment return to our investors.

We will be subject to ongoing requirements and inspections that could lead to the restriction, suspension or revocation of our clearance.

We, as well as any potential third-party manufacturer, will be required to adhere to FDA quality systems requirements, which include testing, control, and documentation requirements. We will be subject to similar regulations in foreign countries. Even when regulatory approval or clearance of a product is granted, the approval or clearance may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or clearance, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Ongoing compliance with quality system regulations and other applicable regulatory requirements is strictly enforced in the United States through periodic inspections by state and federal agencies, including the FDA, and in international jurisdictions by comparable agencies. Failure to comply with regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure to obtain premarket clearance or premarket approval for devices, withdrawal of approvals or clearances previously obtained, and criminal prosecution. The restriction, suspension or revocation of regulatory approvals or clearances, or any other failure to comply with regulatory requirements would limit our ability to operate and could materially increase our costs.

Our employees, collaborators and other personnel may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, collaborators and other personnel, which could include intentional, reckless and/or negligent conduct or disclosure that violates: (i) the laws of the FDA and other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; or (iii) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws. These laws may impact, among other things, future sales, marketing and education programs. The promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud and abuse, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs, and other business arrangements generally. Activities subject to these laws also involve the use of information obtained in the course of patient recruitment for clinical trials.

We adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent unlawful activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business and financial condition.

We are subject to environmental regulations and any failure to comply with applicable laws could subject us to significant liabilities and harm our business.

We are subject to a variety of local, state, federal, and foreign government regulations relating to the storage, discharge, handling, emission, generation, manufacture, and disposal of toxic or other hazardous substances used in the manufacture of our products. The failure to comply with past, present or future laws could result in the imposition of fines, third-party property damage and personal injury claims, investigation and remediation costs, the suspension of production, or a cessation of operations. We also expect that our operations will be affected by other new environmental and health and safety laws on an ongoing basis. Although we cannot predict the ultimate impact of any such new laws, they will likely result in additional costs, and may require us to change how we manufacture our products, which could have a material adverse effect on our business.

We could be negatively impacted by actual or perceived violations of applicable anti-corruption law or our own internal policies designed to ensure ethical business practices.

We are subject to anti-bribery, anti-corruption, and anti-money laundering laws, including the U.S. Foreign Corrupt Practices Act of 1977, or FCPA, and similar anti-bribery laws in non-U.S. jurisdictions, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. As we grow our international presence and global operations, we will be increasingly exposed to trade and economic sanctions and other restrictions imposed by the United States, the European Union, and other governments and organizations.

Anti-corruption laws, such as the FCPA and the U.K. Anti-Bribery Act, generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. The FCPA also imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments. Numerous other laws restrict, and in some cases prohibit, U.S. companies from directly or indirectly selling goods, technology or services to people or entities in certain countries. In addition, these laws require that we exercise care in structuring our sales and marketing practices and effecting product registrations in foreign countries. Compliance with these regulations is costly.

We participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under these anti-corruption laws. In addition, we cannot predict the nature, scope, or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. Although we have implemented company policies requiring our employees and consultants to comply with the FCPA and similar laws, such policies may not be effective at preventing all potential FCPA or other violations. There can be No assurance that none of our employees and agents, or those companies to which we outsource certain portions of our business operations, will not take actions that violate our policies or applicable laws, for which we may be ultimately held responsible. Our development of infrastructure designed to identify anti-corruption matters and monitor compliance is at an early stage. If we are not in compliance with these laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations, and liquidity. Likewise, any investigation of any potential violations of these laws by respective government bodies could also have an adverse impact on our reputation, our business, results of operations, and financial condition.

Risks Related to Owning Our Common Stock

The price of our common stock has been, and we expect it to continue to be, highly volatile, and you may be unable to sell your shares at or above the price you paid to acquire them.

The market price of our common stock has been highly volatile, and we expect it to continue to be highly volatile for the foreseeable future in response to many risk factors listed in this section, and others beyond our control, including:

- results of clinical trials of our planned products or those of our competitors;
- actions by regulatory bodies, such as the FDA, that affect our business or have the effect of delaying or rejecting approval or clearance of our planned products;
- actual or anticipated fluctuations in our financial condition and operating results;
- announcements by our customers, partners or suppliers relating directly or indirectly to our products, services or technologies;
- announcements of technological innovations by us or our competitors;
- changes in laws or regulations applicable to the CellFX System or to our planned end-effectors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, capital commitments, or achievement of significant milestones;
- additions or departures of key personnel;
- competition from existing products or new products that may emerge;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- disputes or other developments related to proprietary rights, including patents, litigation matters or our ability to obtain intellectual property protection for our technologies;
- actual or alleged security breaches;
- announcements or expectations of additional financing efforts;
- sales of our common stock by us or our stockholders;
- stock price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- reports, guidance and ratings issued by securities or industry analysts;
- overall conditions in our industry and market, including the negative impact of armed conflicts, health epidemics and climate change on the global economy and markets; and
- general economic and market conditions.

Any of the above may cause our stock price or trading volume to decline. Stock markets in general, and the market for companies in our industry in particular, have experienced price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies, including ours. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively impact the market price of our common stock. Investors may not realize any return on their investment in us and may lose some or all of their investment. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. The high volatility of our stock price, the composition of our Board and governance practices, including our Co-Chairman's repeated interest in acquiring additional shares in our Company through related party transactions, as well as countless other factors not identified above, increase the risk of securities litigation or shareholder derivative litigation against the Company and its Directors. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns and adversely impact our ability to raise capital to fund our operations, which could seriously harm our business.

Sales or purchases of shares of our common stock may adversely affect the market for our common stock.

If we or our stockholders, particularly our directors, executive officers and significant stockholders, sell or purchase, register for sale, or indicate an intent to sell or purchase, shares of our common stock in the public market, it may have a material adverse effect on the market price of our common stock. In particular, Robert W. Duggan, our majority stockholder and Co-Chairman, is not subject to any contractual restrictions with us on his ability to sell or transfer the shares of our common stock that he holds, and these sales or transfers could create substantial declines in the price of our securities or, if these sales or transfers were made to a single buyer or group of buyers, could contribute to a transfer of control of our Company to a third party. Many of Mr. Duggan's shares in the Company have been registered for resale pursuant to an effective registration statement on Form S-3. Sales by Mr. Duggan of a substantial number of shares, or the expectation of such sales, could cause a significant reduction in the market price of our common stock.

We do not know whether an active, liquid and orderly trading market will exist for our common stock and as a result it may be difficult for you to sell your common stock.

Prior to our initial public offering in May 2016, there was no public market for our common stock. Although our common stock is listed on The Nasdaq Capital Market ("Nasdaq"), the market for our shares has demonstrated varying levels of trading activity. As a result of these and other factors, you may not be able to sell your common stock quickly, at or above the price paid to acquire the stock or at all. Further, an inactive market may also harm our ability to raise capital by selling additional common stock and may harm our ability to enter into strategic collaborations or acquire companies or products by using our common stock as consideration.

Concentration of ownership by our principal stockholder limits the ability of others to influence the outcome of director elections and other transactions requiring stockholder approval, or create the potential for conflicts of interest.

A majority percentage of our outstanding stock is held by Robert W. Duggan, Co-Chairman of our Board, who beneficially owns approximately 73% of our common stock outstanding as of the date of this Quarterly Report. As a result, Mr. Duggan has control over corporate actions requiring stockholder approval, including the following actions:

- to elect or defeat the election of our directors;
- to amend or prevent amendment of our certificate of incorporation or bylaws;
- to effect or prevent a merger, sale of assets or other corporate transaction; and
- to control the outcome of any other matter submitted to our stockholders for vote.

Mr. Duggan's controlling interest in the Company also creates the potential for conflicts of interest which be viewed unfavorably by minority stockholders, thereby hurting our stock price. For example, in November 2021, we engaged outside legal counsel to represent the Company even though the same legal counsel currently represents Mr. Duggan personally in other matters. This legal counsel represented Mr. Duggan in certain related party transactions described herein and could represent both the Company and Mr. Duggan in future related party transactions. Three of our directors, including Mr. Duggan and Manmeet Soni, our Lead Independent Director and Audit Committee Chairman, are executives at Summit Therapeutics Inc., another company in which Mr. Duggan holds a controlling equity interest. There are no family relationships among any of our directors or executive officers, however, Mr. Duggan and Dr. Zanganeh have a personal relationship with each other.

Additionally, because Mr. Duggan owns a majority of our outstanding shares, we are considered to be a "controlled" company under applicable Nasdaq rules. As such, we may voluntarily elect not to comply with certain of Nasdaq's corporate governance requirements, such as certain rules concerning the setting of executive compensation and the appointment of directors. Accordingly, during the period we remain a controlled company and during any transition period following a time when we are no longer a controlled company, other stockholders may not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of the Nasdaq Stock Market. As a member of our Board, Mr. Duggan will adhere to the corporate governance standards adopted by the Company.

Even though we have not yet elected to take advantage of any of these corporate governance exemptions permitted by Nasdaq, Mr. Duggan's stock ownership and our status as a "controlled" company may discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of our Company, which in turn could reduce our stock price or prevent our stockholders from realizing a premium over our stock price. In addition, Mr. Duggan is not subject to any contractual restrictions on his ability to acquire additional shares of common stock and any such purchases, including purchases of equity securities in connection with any rights offerings or any alternative equity or equity-linked offering that we may conduct, could result in his acquisition of a larger percentage of our common stock.

Management currently beneficially holds a small percentage of our common stock. Other than their positions as directors or officers, and the restriction on the stockholders being able to call a special meeting limited to holders of 15% or more of the outstanding shares of common stock, our management will not be able to greatly influence corporate actions requiring stockholder approval.

Robert W. Duggan's controlling ownership position may impact our stock price and may deter or prevent efforts by others to acquire us, which could prevent our stockholders from realizing a control premium.

Robert W. Duggan is our Co-Chairman, and he beneficially owns approximately 73% of our common stock outstanding as of the date of this Quarterly Report. In addition, Mr. Duggan is not subject to any contractual restrictions on his ability to acquire additional shares of common stock, and any such purchases, including purchases of equity securities in connection with any rights offerings or any alternative equity or equity-linked offering that we may conduct, could result in his acquisition of a majority of our common stock. As a result of Mr. Duggan's controlling ownership and position as Co-Chairman,

others may be less inclined to pursue an acquisition of us and therefore we may not have the opportunity to be acquired in a transaction that stockholders might otherwise deem favorable, including transactions in which our stockholders might realize a substantial premium for their shares. In addition, public speculation regarding Mr. Duggan, as well as our relationship with Mr. Duggan, could cause our stock price to fluctuate.

We have incurred and will continue to incur costs as a result of operating as a public company and our management has been and will be required to devote substantial time to public company compliance initiatives.

As a public company, listed in the United States, we have incurred and will continue to incur significant legal, accounting and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC and Nasdaq. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance.

Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact, in ways we cannot currently anticipate, the manner in which we operate our business. Our management and other personnel have and will continue to devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations and, as a result of the new corporate governance and executive compensation related rules, regulations, and guidelines prompted by the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, and further regulations and disclosure obligations expected in the future, we will likely need to devote additional time and costs to comply with such compliance programs and rules. New laws and regulations as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act, the Dodd-Frank Act, and rules adopted by the SEC and Nasdaq, will likely result in increased costs to us as we respond to their requirements. We are currently evaluating and monitoring developments with respect to these rules and regulations, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

Furthermore, these and future rules and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our executive officers.

We are a "smaller reporting company"; we cannot be certain if the applicable reduced disclosure requirements will make our common stock less attractive to investors.

We qualify as a "smaller reporting company," as defined in the Exchange Act, and so long as we remain a smaller reporting company, we benefit from and may take advantage of scaled disclosure requirements. We cannot know if investors find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our reporting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our market price and trading volume could decline.

The trading market for our common stock will depend on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We currently have only limited analyst coverage of us and there can be no assurance that analysts will continue to cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock, our market price would likely decline. If analysts cease coverage of our Company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

We have not paid dividends in the past and have no plans to pay dividends.

For the foreseeable future, we plan to reinvest all of our earnings, to the extent we have earnings, into our product research and development efforts, so we have no plans to pay any cash dividends with respect to our securities. We cannot assure you that we would, at any time, generate sufficient surplus cash that would be available for distribution to the holders of our common stock as a dividend. Therefore, you should not expect to receive cash dividends on our outstanding common stock.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Certain anti-takeover provisions of Delaware law and provisions in our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control or changes in our management. These provisions could also make it difficult for stockholders to elect directors that are not nominated by the current members of our board of directors or take other corporate actions, including effecting changes in our management. Our certificate of incorporation and bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, up to 50,000,000 shares of preferred stock and up to approximately 500,000,000 shares of authorized but unissued shares of common stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairman of our board of directors, any of our officers, or any stockholder holding at least fifteen percent (15%) of the voting power of the capital stock issued and outstanding and entitled to vote;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- require the affirmative vote of holders of at least 66 2/3% of the voting power of all the then outstanding shares of our voting stock, voting together as a single class, to amend provisions of our certificate of incorporation or our bylaws;
- give our board of directors the ability to amend our bylaws by majority vote; and
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board, which is responsible for appointing the members of our management. Furthermore, our bylaws provide that unless

we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for (a) any derivative action or proceeding brought on behalf of us, (b) any action asserting a claim of breach of fiduciary duty owed by any director, officer or other employee of us to us or our stockholders, (c) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (d) any action asserting a claim governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein; provided that, if and only if the Court of Chancery dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in Delaware. Our bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. These exclusive-forum provisions may discourage lawsuits against us or our directors, officers, and employees. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to engage in certain types of transactions with us.

General Risk Factors

Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including the negative impact of armed conflicts, health epidemics and global warming on the global economy and markets. A global financial crisis or a banking crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets. The Company places its cash equivalents and investments with high credit quality financial institutions and, by policy, limits the amounts invested with any one financial institution or issuer and restricts the Company's investments to U.S. treasuries and money market instruments. However, in general the Company's deposits held with banks exceed the amount of insurance provided on such deposits. Despite our low-risk investment policies, a severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy, banking crisis or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our products. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

If we experience material weaknesses in the future or otherwise fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. GAAP. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. The identification of one or more material weaknesses would preclude a conclusion that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

We are required to disclose changes made in our internal control and procedures on a quarterly basis. However, our independent registered public accounting firm will not be required to report on the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act until we are no longer a "small reporting company." At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. Our remediation efforts may not enable us to avoid a material weakness in the future. If we are unable to assert that our internal control over financial reporting is effective, or when required in the future, if our independent registered public accounting firm is unable to express an unqualified opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected, and we could become subject to litigation risk and to investigations by Nasdaq, the stock exchange on which our securities are listed, by the SEC, and by other regulatory authorities, which could require additional financial and management resources.

If the interpretations, estimates or judgments we use to prepare our financial statements prove to be incorrect, investors and others may lose confidence in our financial data, which could cause our stock price to decline.

We, like all publicly traded companies, are subject to complex securities laws and regulations and accounting principles and interpretations. The preparation of our financial statements requires us to interpret accounting principles and guidance and to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. We base our interpretations, estimates and judgments on our historical experience, appropriate accounting guidance and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for the preparation of our financial statements. However, accounting guidance can sometimes be conflicting, especially with respect to accounting for complex corporate transactions, such as accounting for the issuance of warrants as equity. Warrants classified as liabilities result in non-cash fair value measurement adjustments that are recorded in other income (expense). Moreover, generally accepted accounting principles presentation is subject to interpretation by the SEC, the Financial Accounting Standards Board ("FASB") and various other bodies formed to interpret and create appropriate accounting principles and guidance. If one of these bodies disagrees with our accounting recognition, measurement or disclosure or any of our accounting interpretations, estimates or assumptions, we may have to retroactively revise our previously reported results and our investors could lose confidence in the accuracy and completeness of our financial reports, which could cause our stock price to decline.

We may become involved in litigation that may materially adversely affect us.

From time to time, we may be involved in a variety of claims, lawsuits, investigations, or proceedings relating to securities laws, product liability, patent infringement, contract disputes, and other matters relating to various claims that arise in the normal course of our business in addition to governmental and other regulatory investigations and proceedings. In addition, third parties may, from time to time, assert claims against us. Such matters can be time-consuming, divert management's attention and resources, cause us to incur significant expenses or liability and/or require us to change our business practices. Because of the potential risks, expenses and uncertainties of litigation, we may, from time to time, settle disputes, even where we have meritorious claims or defenses, by agreeing to settlement agreements. Because litigation is inherently unpredictable, we cannot assure you that the results of any of these actions will not have a material adverse effect on our business, financial condition, results of operations and prospects. See the section entitled "Legal Proceedings" for more detail on our current legal proceedings.

Our facilities in California are located near known earthquake faults, and the occurrence of an earthquake or other catastrophic disaster could cause damage to our facilities and equipment, which could require us to cease or curtail operations.

Our facilities in Hayward, California are located near known earthquake fault zones and are vulnerable to damage from earthquakes. We are also vulnerable to damage from other types of disasters, including fire, floods, power loss, communications failures, and similar events. If any disaster were to occur, our ability to operate our business at our facilities would be seriously, or potentially completely, impaired. In addition, the nature of our activities could make it difficult for us to recover from a natural disaster. The insurance we maintain may not be adequate to cover our losses resulting from disasters or other business interruptions. Accordingly, an earthquake or other disaster could materially and adversely harm our ability to conduct business.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

During the three-month period ended September 30, 2024, we completed no unregistered sale of our securities.

Item 3. Default Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Trading Arrangements

During the three-month period ended September 30, 2024, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement" as such terms are defined under Item 408 of Regulation S-K.

Item 6. Exhibits

Exhibit Number	Exhibit Description
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* The certification attached as Exhibit 32.1 that accompanies this Quarterly Report is deemed furnished and not filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Pulse Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report, irrespective of any general incorporation language contained in such filing.

Signatures

Pursuant to the requirements of the Securities 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)