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

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	Form 10-Q	
(Mark One) ☑ QUARTERLY REPORT PU EXCHANGE ACT OF 1934	RSUANT TO SECTION 13 OR 15	(d) OF THE SECURITIES
For	the quarterly period ended September 30	, 2016
☐ TRANSITION REPORT PU EXCHANGE ACT OF 1934	Or RSUANT TO SECTION 13 OR 15	(d) OF THE SECURITIES
	For the transition period from to	
	Commission File Number 001-34899	
Pu	Ilse Biosciences, I	<b>nc.</b>
Nevada (State or other jurisdiction of incorporation or organization	of n) I	46-5696597 (I.R.S. Employer dentification No.)
849 Mitten Road, Suite 1 Burlingame, CA (Address of principal executive o		94010 (Zip Code)
	(650) 697-3939 (Registrant's telephone number, including area code	e)
Securities Exchange Act of 1934 during th	registrant (1) has filed all reports required to e preceding 12 months (or for such shorter puch filing requirements for the past 90 days.	eriod that the registrant was required to file
Interactive Data File required to be submit	registrant has submitted electronically and poted and posted pursuant to Rule 405 of Reguler period that the registrant was required to s	lation S-T (§232.405 of this chapter) during
Indicate by check mark whether the smaller reporting company. See the definiting Rule 12b-2 of the Exchange Act. (Check of	registrant is a large accelerated filer, an accel ions of "large accelerated filer," "accelerated ne):	erated filer, a non-accelerated filer, or a filer" and "smaller reporting company" in
Large accelerated filer $\Box$ Non-accelerated filer $\Box$ (Do n	ot check if a smaller reporting company)	Accelerated filer $\square$ Smaller reporting company $\boxtimes$
Indicate by check mark whether the Yes $\square$ No $\boxtimes$	registrant is a shell company (as defined in R	ule 12b-2 of the Exchange Act).
Number of shares outstanding of the	issuer's common stock as of November 8, 2	2016: 13,315,297

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# PART I. FINANCIAL INFORMATION

# **Item 1. Financial Statements**

# PULSE BIOSCIENCES, INC.

# Condensed Consolidated Balance Sheets (Unaudited)

(in thousands except par value amounts)	September 30, 2016		]	December 31, 2015
ASSETS	· <u></u>	,		
Current assets:				
Cash and cash equivalents	\$	4,628	\$	3,606
Investments		14,085		_
Prepaid expenses and other current assets		294		44
Deferred offering costs				347
Total current assets		19,007		3,997
Equipment, net of accumulated depreciation		323		329
Intangible assets, net of accumulated amortization		6,709		7,208
Goodwill		2,791		2,791
Total assets	\$	28,830	\$	14,325
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	446	\$	262
Accrued expenses		521		398
Total current liabilities		967		660
Commitments and contingencies				
Stockholders' equity:				
Preferred stock, \$0.001 par value; authorized – 5,000 shares; issued and outstanding – none		_		
Common stock, \$0.001 par value: authorized – 45,000 shares; issued and outstanding – 13,315 shares and 7,565 shares		13		0
at September 30, 2016 and December 31, 2015, respectively				16.745
Additional paid-in capital		37,655		16,745
Accumulated comprehensive loss		(8)		(2.000)
Accumulated deficit		(9,797)	_	(3,088)
Total stockholders' equity	<del>.</del>	27,863	_	13,665
Total liabilities and stockholders' equity	\$	28,830	\$	14,325

See accompanying notes to the condensed consolidated financial statements.

# PULSE BIOSCIENCES, INC.

# Condensed Consolidated Statements of Operations (Unaudited)

	Three-Month Periods Ended September 30,				Nine-Month Periods Ended September 30,					
(in thousands, except per share amounts)		2016		2015	2016		2015			
Revenue	\$		\$		\$ 	\$	_			
Operating expenses:										
General and administrative		893		408	2,063		807			
Research and development		1,739		659	4,182		1,627			
Amortization of intangible assets		166		167	499		499			
Total operating expenses		2,798		1,234	6,744		2,933			
Other income:										
Interest income		31			35					
Total other income		31			35		_			
Loss from operations, before income taxes		(2,767)		(1,234)	(6,709)		(2,933)			
Income tax benefit		_		483	_		1,139			
Net loss	\$	(2,767)	\$	(751)	\$ (6,709)	\$	(1,794)			
Net loss per common share – basic and diluted	\$	(0.21)	\$	(0.10)	\$ (0.66)	\$	(0.24)			
Weighted average number of common shares outstanding – basic and diluted		13,315		7,565	10,235		7,565			

See accompanying notes to the condensed consolidated financial statements.

# PULSE BIOSCIENCES, INC.

# Condensed Consolidated Statements of Cash Flows (Unaudited)

			Periods Ended iber 30,		
(in thousands)		2016		2015	
Cash flows from operating activities:					
Net loss	\$	(6,709)	\$	(1,794)	
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation of equipment		70		31	
Amortization of intangible assets		499		499	
Stock-based compensation		627		267	
Net premium amortization on investments		3		_	
Deferred income taxes		_		(1,139)	
Changes in operating assets and liabilities:					
Prepaid expenses and other current assets		(250)		(19)	
Deferred offering costs		(213)		(43)	
Accounts payable		184		157	
Accrued expenses		56		94	
Deferred grant revenue		_		(40)	
Net cash used in operating activities		(5,733)		(1,987)	
Cash flows from investing activities:					
Purchase of equipment		(64)		(73)	
Purchase of investments		(14,096)			
Net cash used in investing activities		(14,160)		(73)	
Cash flows from financing activities:					
Proceeds from issuance of common stock from initial public offering, net of issuance costs		20,915		_	
Net cash provided by financing activities		20,915			
Net increase (decrease) in cash		1,022		(2,060)	
Cash and cash equivalents at beginning of period		3,606		7,009	
Cash and cash equivalents at end of period	\$	4,628	\$	4,949	
		_		_	
Supplemental disclosure of noncash investing and financing activities:					
Reclassification of deferred offering costs to additional paid-in capital upon initial public offering	\$	627	\$	_	
See accompanying notes to the condensed consolidated financial	statem	ients.			

# PULSE BIOSCIENCES, INC. Notes to Condensed Consolidated Financial Statements Three and Nine-month Periods Ended September 30, 2016 and 2015 (Unaudited)

In this Quarterly Report on Form 10-Q (this "Quarterly Report"), references to "Pulse," "Pulse Biosciences," "we," "us," "our" and the "Company" refer to Pulse Biosciences, Inc. and its wholly owned subsidiaries, unless expressly indicated or the context otherwise requires.

#### 1. Description of the Business

Pulse Biosciences, Inc. is a medical technologies company developing commercial clinical applications for its proprietary Nano-Pulse Stimulation ("NPS") technology. NPS is a novel patented technology which leverages nano-second duration energy pulses that have demonstrated effective local tumor control and the initiation of an adaptive immune response in pre-clinical studies. The Company is pursuing a number of clinical applications for NPS, including human oncology, dermatology, aesthetics and other minimally invasive applications where NPS is believed to provide greater benefits compared to current therapies and treatments.

The Company is currently conducting research and development activities in pursuit of commercial applications for its NPS technology, but has not yet commercialized or recognized revenue from its technology.

The Company was incorporated in Nevada on May 19, 2014 under the name Electroblate, Inc. Electroblate, Inc. changed its name to Pulse Biosciences, Inc. effective December 8, 2015. The Company's corporate office and research facility are located in Burlingame, California.

#### **Initial Public Offering**

On May 13, 2016, the Company's registration statement on Form S-1 (File No. 333-208694), as amended (the "Registration Statement"), relating to its initial public offering ("IPO") was declared effective by the Securities and Exchange Commission ("SEC") and closed on May 23, 2016, whereby the Company sold 5,000,000 shares of common stock at \$4.00 per share. The shares began trading on the NASDAQ Capital Market under the trading symbol "PLSE" on May 18, 2016. On June 21, 2016, the underwriters exercised their overallotment option to purchase an additional 749,846 shares of the Company's common stock at \$4.00 per share, which transaction closed on June 21, 2016. The Company received net proceeds of approximately \$20.3 million from the IPO, including proceeds from the exercise of the overallotment option granted to the underwriters, net of underwriting discounts and commissions and other offering costs.

# 2. Summary of Significant Accounting Policies

#### **Basis of Presentation**

In the opinion of the Company's management, the accompanying unaudited condensed consolidated financial statements ("Financial Statements") have been prepared on a consistent basis with the Company's December 31, 2015 audited consolidated financial statements and include all adjustments, consisting of only normal recurring adjustments, necessary to fairly state the information set forth herein. The Financial Statements have been prepared in accordance with the rules and regulations of 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"). Certain items in prior period financial statements have been reclassified to conform to current period presentation.

These Financial Statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2015 included in the Registration Statement. The results of operations for the nine-month period ended September 30, 2016 are not necessarily indicative of the results to be expected for the entire year or any future periods.

# Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make estimates and assumptions 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 of cash equivalents and investments, the valuation and recognition of

share-based compensation, the useful lives assigned to long-lived assets and the computation provisions for income taxes. Actual results could differ materially from these estimates.

#### Significant Accounting Policies

There have been no material changes to the Company's significant accounting policies during the nine-month period ended September 30, 2016, as compared to the significant accounting policies described in the Registration Statement. The policies described below are not changes but are accounting policies adopted as they became applicable to the Company.

#### Fair Value of Financial Instruments

The Company classifies its investments in money market funds within Level 1 of the fair value hierarchy because they are valued using bank balances or quoted market prices. The Company classifies its Level 2 instruments based on market pricing and other observable inputs. 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 assets measured on a recurring basis as of September 30, 2016 and December 31, 2015, respectively (in thousands):

			September 30, 2016								Dece	mber 31	, 2015		
Assets	Classification	Level 1		Level 2	Leve	13	7	Γotal	Le	vel 1	Le	vel 2	Level 3	T	otal
Money market funds	Cash and cash equivalents	\$ 2,694	\$	_	\$	_	\$	2,694	\$	_	\$	— \$	_	\$	
Corporate bond	Cash and cash equivalents	_	_	850		_		850		_		_	_		_
Asset-backed security	Cash and cash equivalents	_	_	850		_		850		_		_	_		_
Corporate bonds	Investments	_	_	13,585		_	1	13,585		_		_	_		_
Asset-backed security	Investments	_	_	500		_		500		_		_	_		_
Total assets measured at fair value		\$ 2,694	\$	15,785	\$	_ 5	\$ 1	18,479	\$		\$	<u> </u>		\$	

The Company did not have any financial liabilities measured on a recurring basis as of September 30, 2016 or December 31, 2015.

During the nine-month period ended September 30, 2016, there were no transfers between Level 1, Level 2 or Level 3 assets or liabilities reported at fair value on a recurring basis and the valuation techniques used did not change compared to the Company's established practice.

#### Cash, Cash Equivalents, Investments and Credit Risk

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents.

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents and investments. 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. Deposits held with banks may exceed the amount of insurance provided on such deposits. The Company has not experienced any losses on its deposits of cash and cash equivalents.

#### **Investments**

The Company has designated all investments as available-for-sale and therefore, such investments are reported at fair value, with unrealized gains and losses recognized in accumulated other comprehensive income (loss) ("OCI") in stockholders' equity. The cost of marketable securities is adjusted for the amortization of premiums and discounts to expected maturity. Premium and discount amortization is included in other income, net. Realized gains and losses, as well as interest income, on available-for-sale securities are also included in other income, net. Unrealized loss at September 30, 2016 was immaterial. The cost of securities sold is based on the specific identification method. The Company includes all of its available-for-sale securities in current assets.

All of the Company's investments are subject to a periodic impairment review. The Company recognizes an impairment charge when a decline in the fair value of its investments below the cost basis is judged to be other-than-temporary. Factors considered in determining whether a loss is temporary include the length of time and extent to which the

investments fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, extent of the loss related to credit of the issuer, the expected cash flows from the security, the Company's intent to sell the security and whether or not the Company will be required to sell the security before the recovery of its amortized cost. During the nine-month period ended September 30, 2016, the Company did not recognize any impairment charges on its investments as it is more likely than not that the Company will recover their amortized cost basis upon sale or maturity. The Company did not hold investment securities at any time during the prior year.

#### Other Comprehensive Income/Loss

The Company's other comprehensive loss is \$8,000 for the three and nine-month periods ending September 30, 2016. The Company did not have other comprehensive income or loss in the prior year.

#### **Recent Accounting Pronouncements**

During May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Updates ("ASU") No. 2014-09, Revenue from Contracts with Customers. This updated standard will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective and permits the use of either the retrospective or cumulative effect transition method. In August 2015, the FASB issued an update to defer the effective date of this update by one year. This updated standard becomes effective for the Company in the first quarter of fiscal year 2018, but allows the Company to adopt the standard one year earlier if it so chooses. In March 2016, the FASB issued updates to this guidance to clarify the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued guidance to clarify aspects related to identifying performance obligations and the licensing implementation guidance. The Company has not yet selected a transition method and is evaluating the effect that the updated standard will have on its consolidated financial statements and related disclosures.

During February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which amends the existing accounting standards for leases. The new standard requires lessees to record a right-of-use asset and a corresponding lease liability on the balance sheet (with the exception of short-term leases). For lessees, leases will continue to be classified as either operating or financing in the income statement. This ASU becomes effective for the Company in the first quarter of fiscal year 2019 and early adoption is permitted. This ASU is required to be applied with a modified retrospective approach and requires application of the new standard at the beginning of the earliest comparative period presented. The Company generally does not finance purchases of equipment or other capital, but does lease its facilities. The Company is evaluating the effect that this ASU will have on its consolidated financial statements and related disclosures.

During March 2016, the FASB issued ASU No. 2016-09, Improvements to Employee Share-based Payment Accounting. This ASU simplifies the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. This ASU requires that excess tax benefits and deficiencies be recognized as income tax benefit or expense in the income statement. The Company currently plans to implement this ASU as required in the first quarter of fiscal year 2017. The Company is evaluating the effect that this ASU will have on its consolidated financial statements and related disclosures.

During June 2016, the FASB issued ASU 2016-13, Financial Instruments — Measurement of Credit Losses on Financial Instruments, which requires measurement and recognition of expected credit losses for financial assets held. ASU 2016-13 is effective for the Company beginning January 1, 2020 and the Company is currently evaluating the impact that ASU 2016-13 will have on its consolidated financial statements.

#### Net Loss per Share

The following outstanding common stock options and warrants to purchase common stock 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-Month Periods Ended			
	September 30,			
	2016	2015		
Common stock warrants	874,610	299,625		
Common stock options	1,254,790	659,809		
Total	2,129,400	959,434		

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# 3. Equipment

Equipment consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
Laboratory equipment	\$ 406	\$ 356
Software	20	10
Furniture, fixtures, and equipment	24	20
	450	386
Less: Accumulated depreciation	(127)	(57)
•	\$ 323	\$ 329

Depreciation expense was \$25,000 and \$11,000 for the three-month periods ended September 30, 2016 and 2015, respectively. Depreciation expense was \$70,000 and \$31,000 for the nine-month periods ended September 30, 2016 and 2015, respectively.

# 4. Intangible Assets

Intangible assets consisted of the following (in thousands):

	September 30,	$\mathbf{D}^{c}$	ecember 31,
	2016		2015
Acquired technology	\$ 4,200	\$	4,200
License	3,785		3,785
	7,985	_	7,985
Less: Accumulated amortization	(1,276)		(777)
	\$ 6,709	\$	7,208

# 5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30,	December 31,		
	2016	2015		
Compensation expense	\$ 204	\$ 34		
Offering costs	10	240		
Professional fees	307	84		
Other	_	40		
	\$ 521	\$ 398		

#### 6. Stockholders' Equity and Stock-Based Compensation

#### **Equity Plans**

As of September 30, 2016, the Company had one active equity compensation plan, the 2015 Stock Incentive Plan (the "2015 Plan").

The following table summarizes stock option activity for the 2015 Plan for the nine-month period ended September 30, 2016 (in thousands, except per share amounts):

	Stock Options Outstanding								
	Number of shares		Weighted average exercise price	Weighted average remaining life (in years)					
Balances — December 31, 2015	875	\$	3.51	7.77					
Options granted	405		4.44						
Options exercised	_		_						
Options canceled	(6)		4.00						
Options expired	(19)		2.68						
Balances — September 30, 2016	1,255	\$	3.82	7.94					
Exercisable	246								

# Stock-based Compensation

During the nine-month period ended September 30, 2016, in connection with the closing of the IPO, the Company issued warrants as compensation to the underwriters of the IPO to purchase a total 574,985 shares of the Company's common stock at \$5.00 per share. The warrants become exercisable 180 days after issuance and are exercisable for a period of five years. The value of the warrants totaled \$1,443,000, valued at the date of grant using the Black-Scholes Option Pricing Model and was recorded as part of the costs of the IPO as additional paid-in capital.

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

	Three-Month Periods Ended September 30,				Nine-Month Periods Ended September 30,					
		2016		2015		2016		2015		
General and administrative	\$	183	\$	105	\$	478	\$	267		
Research and development		55		_		149		_		
Total stock-based compensation expense	\$	238	\$	105	\$	627	\$	267		

The Company estimated the fair value of employee stock options on the grant date using the Black-Scholes option pricing model. The estimated fair value of employee stock options is amortized on a straight-line basis over the requisite service period of the awards. The fair value of employee stock options was estimated using the following weighted average assumptions:

		Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,		
	2016	2015	2016	2015		
Expected term in years	6.1	6.1	6.1	4.5		
Expected volatility	80%	89%	80%	89%		
Risk-free interest rate	1.20%	1.60%	1.28%	1.17%		
Dividend vield	_	_				

#### 7. Research Grants and Agreements

#### Research Grants

The Company's subsidiary, BioElectromed ("BEM") was acquired by Pulse Biosciences, Inc. on November 6, 2014. BEM had been funded by grants from the National Cancer Institute of the National Institutes of Health (the "NIH"), including grants from the NIH Small Business Innovation Research ("SBIR") Program, to conduct research and develop devices that will provide health benefits utilizing bioelectric technology. At the time of acquisition, BEM had an active

research grant under the SBIR Program for a project entitled "EndoPulse System for Endoscopic Ultrasound-Guided Therapy of Pancreatic Carcinoma." The research project was completed during the year ended December 31, 2015. During the nine-month period ended September 30, 2015, the Company received research grant funding of \$340,000 that was recorded as an offset to research and development expenses. The Company has not subsequently received additional grants.

#### **Sponsored Research Agreement**

The Company entered into a Sponsored Research Agreement ("SRA") with the Old Dominion University Research Foundation ("ODURF") during 2014 pursuant to which the Company sponsors research activities performed by ODURF's Frank Reidy Center. ODURF is compensated by the Company for its conduct of each study in accordance with the budget and payment terms set forth in the applicable task order. During the first quarter of 2015, the Company agreed to sponsor \$1.2 million in research during the subsequent 12-month period to be funded through monthly payments made upon ODURF certifying, to the Company's reasonable satisfaction, that ODURF has met its obligations pursuant to the specified task order and statement of work. The principal investigator may transfer funds with the budget as needed without the Company's approval so long as the obligations of ODURF under the task order and statement of work remain unchanged and unimpaired. During April 2016, the Company agreed to sponsor additional research under the SRA from April 2016 to March 2017 totaling \$1.0 million.

During the three-month periods ended September 30, 2016 and 2015, the Company paid and incurred costs relating to the SRA equal to \$250,000 and \$246,000, respectively, relating to the amount agreed to during 2015. During the nine-month periods ended September 30, 2016 and 2015, the Company paid and incurred costs relating to the SRA equal to \$664,000 and \$791,000, respectively.

#### 8. Related Party Transactions

MDB Capital Group, LLC ("MDB") provides investment banking, executive recruiting and intellectual property management services to the Company. The Company's Chairman, Robert Levande, is a Senior Managing Director of MDB.

During the three and nine-month periods ended September 30, 2016, the Company incurred non-financing related expenses charged by MDB of \$0 and \$100,000, respectively, for services rendered with respect to intellectual property related services.

In connection with the IPO, the underwriting syndicate led by MDB received \$1,800,000 in underwriting discounts, \$160,000 in unaccountable expense reimbursement and warrants valued in the aggregate of \$1,443,000.

Gary Schuman, the Chief Financial Officer of MDB, served as the acting Chief Financial Officer of the Company and was compensated at a monthly rate of \$4,000 from November 1, 2014 to December 31, 2015. Mr. Schuman's compensation of \$12,000 and \$36,000 is reflected in general and administrative expenses for the three and nine-month periods ended September 30, 2015.

At September 30, 2016 and December 31, 2015, \$0 and \$58,000, respectively, was included in accounts payable to MDB for patent related services and their expenses incurred relating to the Company's planned IPO, which were recorded as offering costs in stockholders' equity and deferred offering costs, respectively.

Information with respect to payments under the Company's SRA with ODURF, a greater-than 10% stockholder of the Company, is described in Note 7.

#### 9. Commitments and Contingencies

# **Operating Lease**

The Company leases corporate offices and research facilities in Burlingame, California. In July 2016, the Company's lease was amended to extend the term to March 31, 2017, at a monthly cost of approximately \$19,000.

# 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 Registration Statement on Form S-1, as amended. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our products, plans and strategy for our business and related financing, contains forward-looking statements that involve risks and uncertainties, including statements regarding our expected financial results in future periods. The words "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. 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 in the following discussion and analysis. We do not assume any obligation to update any forward-looking statements.

#### Overview

We are a medical technologies company developing commercial clinical applications for proprietary Nano-Pulse Stimulation ("NPS") technology. NPS is a novel patented technology which leverages nano-second duration energy pulses that have demonstrated effective local tumor control and the initiation of an adaptive immune response in pre-clinical studies. We are pursuing a number clinical applications for NPS, including human oncology, dermatology, aesthetics and other minimally invasive applications where NPS is believed to provide greater benefits compared to current therapies and treatments. We are currently conducting research and development activities in pursuit of commercial applications for our NPS technology, but have not yet commercialized or recognized revenue from our technology. Our corporate office and research facility are located in Burlingame, California.

#### **Plan of Operation**

We plan to create a leading market position as a medical technology company that is able to produce a drugless, localized cell death by a process of cell signaling that induces a targeted adaptive immune stimulation response through the following key elements:

- Improving our technology by continuing our research and product development efforts. We expect to develop different devices to target different treatments that will leverage the novel treatments offered by our technology platform.
- Further explore and understand the benefits of NPS with the objective of broadening the currently-identified cosmetic and therapeutic applications and identifying new applications. We anticipate that the clinical studies will enable us to recognize the advantages and efficacy of our technology for certain unmet medical needs and to identify new applications.
- Continuing to protect and dominate the intellectual property landscape with respect to NPS technology, which we expect will increase our ability to deter competitors and position our company for favorable licensing and partnering opportunities.
- · Partnering with medical or biomedical device companies for certain applications which we anticipate may accelerate product acceptance into target market areas and allow us to gain the sales and marketing advantages of the distribution infrastructure.

#### **Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations are based upon our unaudited financial statements, which have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission ("SEC"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our critical accounting policies and estimates. 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.

There have been no material changes to the critical accounting policies and estimates discussed in our Registration Statement on Form S-1, as amended, other than the policies noted below.

# Cash, Cash Equivalents, Investments and Credit Risk

We consider all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents.

Financial instruments that potentially subject us to a concentration of credit risk consist of cash and cash equivalents and investments. We place our cash equivalents and investments with high credit quality financial institutions and, by policy, limit the amounts invested with any one financial institution or issuer. Deposits held with banks may exceed the amount of insurance provided on such deposits. We have not experienced any losses on its deposits of cash and cash equivalents.

#### Investments

We have designated all investments as available-for-sale and therefore, such investments are reported at fair value, with unrealized gains and losses recognized in accumulated other comprehensive income (loss) in stockholders' equity. The cost of marketable securities is adjusted for the amortization of premiums and discounts to expected maturity. Premium and discount amortization is included in other income. Realized gains and losses, as well as interest income, on available-for-sale securities are also included in other income. The cost of securities sold is based on the specific identification method. We include all of our available-for-sale securities in current assets.

All of our investments are subject to a periodic impairment review. We recognize an impairment charge when a decline in the fair value of our investments below the cost basis is judged to be other-than-temporary. Factors considered in determining whether a loss is temporary include the length of time and extent to which the investment's fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, extent of the loss related to credit of the issuer, the expected cash flows from the security, our intent to sell the security and whether or not we will be required to sell the security before the recovery of its amortized cost.

#### **Results of Operations**

#### Comparison of the three-month periods ended September 30, 2016 and 2015

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

	Three-Month Periods Ended September 30,		
(in thousands)	2016	2015	\$ Change
Revenue	\$	\$	\$ —
Operating expenses:			
General and administrative	893	408	485
Research and development	1,739	659	1,080
Amortization of intangible assets	166	167	(1)
Total operating expenses	2,798	1,234	1,564
Other income:			
Interest income	31	_	31
Total other income	31		31
Loss from operations, before income taxes	(2,767)	(1,234)	1,533
Income tax benefit		483	(483)
Net loss	\$ (2,767)	<u>\$ (751)</u>	\$ 2,016

#### Overview

The operating results for the year ended December 31, 2015 reflect the first full year of operational activities and the increasing pace and expenditures of development activities involving our proprietary technology, including sponsored research costs, in combination with the establishment and expansion of general and administrative functions during the year. We expect both research and development and general and administrative expenses to increase during 2016 as compared to 2015 reflecting continuation and expansion of activities that commenced during 2015.

#### **General and Administrative**

General and administrative expenses for the three-month period ended September 30, 2016 increased by \$485,000 compared to the same period in 2015 due primarily to \$265,000 of increased compensation costs, \$102,000 of increased insurance costs, \$78,000 of increased stock-based compensation expense, \$21,000 of increased supplies and \$13,000 of increased travel costs. Compensation, including stock-based compensation costs, increased due to increased headcount. Insurance, supplies and travel costs increased primarily as a result of fees incurred as part of operating as a public company. General and administrative expenses are expected to increase substantially during 2016 reflecting the increasing operational activities that commenced during 2015 and the additional costs of operating as a public company.

#### **Research and Development**

Research and development expenses for the three-month period ended September 30, 2016 increased by \$1,080,000 compared to the same period in 2015 due primarily to \$397,000 of increased consulting and outside services, \$284,000 of increased compensation costs, \$186,000 of increased lab supplies and equipment, \$130,000 of increased intellectual property-related legal costs, \$55,000 of increased stock-based compensation expense and \$13,000 of increased travel costs. Consultant and outside services and lab supplies and equipment costs increased due to increased product development activities and the costs associated with manufacturing pre-production prototypes. Intellectual property-related legal costs and travel costs also increased as a result of our ongoing research and development. Compensation, including stock-based compensation costs, increased due to increased headcount. Research and development expenses are expected to increase substantially during 2016 compared to 2015, reflecting the increasing operational activities that commenced during 2015.

#### Comparison of the nine-month periods ended September 30, 2016 and 2015

	Nine-Month Septer		
(in thousands)	2016	2015	\$ Change
Revenue	<u>\$</u>	<u>\$</u>	\$
Operating expenses:			
General and administrative	2,063	807	1,256
Research and development	4,182	1,627	2,555
Amortization of intangible assets	499	499	
Total operating expenses	6,744	2,933	3,811
Other income:			
Interest income	35		35
Total other income	35	_	35
Loss from operations, before income taxes	(6,709)	(2,933)	3,776
Income tax benefit		1,139	(1,139)
Net loss	\$ (6,709)	\$ (1,794)	\$ 4,915

# **General and Administrative**

General and administrative expenses for the nine-month period ended September 30, 2016 increased by \$1,256,000 compared to the same period in 2015 due primarily to \$709,000 of increased compensation costs, \$211,000 of increased stock-based compensation expense, \$141,000 of increased insurance costs, \$73,000 of increased professional and consulting services, \$60,000 of increased supplies and \$44,000 of increased travel costs. Compensation, including stock-based compensation costs and facilities costs, increased due to increased headcount. Insurance, supplies, professional and consulting services and travel costs increased primarily as a result of fees incurred in preparation for and operating as a public company.

#### **Research and Development**

Research and development expenses for the nine-month period ended September 30, 2016 increased by \$2,555,000 compared to the same period in 2015 due primarily to \$755,000 of increased consulting and outside services, \$647,000 of increased prototype and development supplies, \$621,000 of increased compensation costs, \$211,000 of increased sponsored research expenses, net of grant funding received during the period in 2015, \$149,000 of increased stock-based compensation expense, \$86,000 of increased intellectual property-related legal costs, \$33,000 of increased depreciation expense and \$26,000 of increased travel costs. Consultant and outside services and lab supplies and equipment increased due to increased product development activities and the costs associated with manufacturing pre-production prototypes. Compensation, including stock-based compensation costs, increased due to increased headcount. Sponsored research expenses increased due

primarily to research expenses incurred during the nine-month period ended September 30, 2016 related to the sponsored research agreement entered into with Old Dominion University Research Foundation ("ODURF") in March 2015. Intellectual property-related legal costs and travel costs increased as a result of ongoing research and development. Depreciation expense increased as a result of lab equipment purchased and used for research and development purposes.

#### **Liquidity and Capital Resources**

To date, we have not generated any revenues from product sales, and management does not expect to generate revenues from product sales for the next few years. Since our inception, funding for our business plan has been provided from the issuance of equity securities and grants from governmental agencies. Over the next few years, we intend to invest in research and development to develop commercially viable products and to assess the feasibility of potential future products. Additionally, we expect that our general and administrative expenses will increase as we incur substantial incremental costs associated with being a public company.

In May and June 2016, we completed our initial public offering from which we received total net proceeds of \$20.3 million, including proceeds from the exercise of the overallotment option granted to the underwriters, net of underwriting discounts and commissions and other offering costs.

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

	Nine-Month Periods Ended		
	September 30,		
(in thousands)	2016		2015
Net cash used in operating activities	\$ (5,733)	\$	(1,987)
Net cash used in investing activities	\$ (14,160)	\$	(73)
Net cash provided by financing activities	\$ 20,915	\$	_
Net increase (decrease) in cash	\$ 1,022	\$	(2,060)

At September 30, 2016, we had cash, cash equivalents and investments of \$18.7 million. We believe that the net proceeds from our initial public offering, combined with our existing cash resources, will be sufficient to fund our projected operating requirements for at least the next 12 months. 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 or corporate collaboration and licensing arrangements. Such additional funds may not be available on terms acceptable to us or at all, particularly in light of recent market conditions. If we raise funds by issuing equity securities, the ownership of our stockholders will be diluted and the holders of new equity securities may have priority rights over our existing stockholders.

#### **Operating Activities**

During the nine months ended September 30, 2016, we used cash of \$5.7 million in operating activities. The difference between cash used in operating activities and net loss consisted primarily of depreciation and amortization and stock-based compensation, offset by increased prepaid expenses and other current assets and deferred offering costs and increased accounts payable.

During the nine months ended September 30, 2015, we used cash of \$2.0 million in operating activities. The difference between cash used in operating activities and net loss consisted primarily of depreciation and amortization and stock-based compensation, and a decrease in deferred tax liability.

#### **Investing Activities**

During the nine months ended September 30, 2016, we used cash of \$14.2 million for investing activities for the purchase of investments and office and laboratory equipment.

During the nine months ended September 30, 2015, we used cash of \$73,000 for the purchase of office and laboratory equipment.

#### **Financing Activities**

During the nine months ended September 30, 2016, cash provided from financing activities was \$20.9 million due to the net proceeds received from our initial public offering, after deducting underwriting discounts and commissions and other offering costs.

We did not have any cash flows from financing activities during the nine months ended September 30, 2015.

#### **Contractual Obligations**

There have been no material changes outside the ordinary course of our business to the contractual obligations disclosed in our Registration Statement. We lease corporate offices and research facilities in Burlingame, California. In July 2016, our lease was amended to extend the term to March 31, 2017, at a monthly cost of approximately \$19,000.

#### **Off-Balance Sheet Arrangements**

At September 30, 2016, we did not have any transactions, obligations or relationships that constitute off-balance sheet arrangements.

#### 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 initial public offering in May and June 2016 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 have enough funds to sustain our operations, we will consider other options to continue our path to commercialization of NPS, 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, if necessary, on acceptable terms or at all. If cash resources are insufficient to satisfy our ongoing cash needs, we would be required to scale back or discontinue our technology and product development programs, or obtain funds, if available, although there can be no assurances, through the sale, licensing or strategic alliances that could require us to relinquish rights to our technology and intellectual property, or to 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

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.

#### **Interest Rate and Market Risk**

Our exposure to market risk is confined to our cash, cash equivalents and investments, all of which have maturities of less than three years. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of our cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. The securities in our investment portfolio are not leveraged, are classified as available-for-sale, and are, due to their relatively short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that a hypothetical 10% change in market interest rates would have any material negative impact on the value of our investment portfolio.

#### Foreign Exchange Risk

The majority of our expense and capital purchasing activities are transacted in U.S. dollars. We do not have any international operations. We may incur foreign exchange gains or losses in the future.

#### **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 and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that as of September 30, 2016 our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial 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 that occurred during the three months ended September 30, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act).

#### **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. In addition, third parties may, from time to time, assert claims against us in the form of letters and other communications. We currently believe that these ordinary course matters will not have a material adverse effect on our business; however, the results of litigation and claims are inherently unpredictable. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

#### Item 1A. Risk Factors

You should consider carefully the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q, which could materially affect 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.

#### **Risks Relating to Our Business**

Since we have a limited operating history and have not commenced any revenue producing operations, it is difficult for potential investors to evaluate the future of our business. We formed our corporation in May 2014 as a consolidation vehicle and acquired assets and licenses in our November 2014 business combinations. We are still in the development stage, and we have not yet commenced revenue-producing operations. To date, our operations on a consolidated basis have consisted of the continued development of our technologies and implementation of the early parts of our business plan. 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 may never achieve commercial success and continue to operate in the research and development stage, without having commercially launched any products. 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 for potential investors to evaluate our technology or prospective operations and business prospects. As a development-stage company, we are subject to all the risks inherent in the initial organization, business development, financing, unexpected expenditures, and complications and delays that often occur in a new business. Investors should evaluate an investment in us in light of the uncertainties encountered by developing companies in a competitive environment. There can be no assurance that our efforts will be successful or that we will ultimately be able to attain profitability.

Because we are in the development stage, we have been using our available capital resources for research and development, and we have not generated any revenues; therefore we may not be able to continue as a going concern. Our ability to continue as a going concern ultimately is dependent upon our generating cash flow from sales that are sufficient to fund operations or finding adequate financing to support our operations. To date, we have had no revenues and relied on equity-based financing from the sale of securities. Our research and development plans may not be successful in creating a marketable product, and our business plan may not be successful in achieving a sustainable business and revenues. Currently, we have no arrangements in place for all the anticipated, required financing to be able to fully implement our business plan. If we are unable to continue as planned currently, we may have to curtail some or all of our business plan and operations. In such case, investors will lose all or a portion of their investment.

We anticipate needing additional financing over the longer term to execute our business plan and fund operations, which additional financing may not be available on reasonable terms or at all. Our cash and investments are sufficient to provide capital to further develop our technologies and fund the earlier stages of our overall business plan for at least the next 12 months, but we believe we will require additional capital in the future to fully develop our technologies and potential products to the stage of a commercial launch. We cannot give any assurance that we will be able to obtain all the necessary funding that we may need. We may pursue additional funding through various financing sources, including the private sale of our equity and debt securities, licensing fees for our technology, joint ventures with capital partners and project type financing. 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. If financing is not available on satisfactory terms, we may be unable to further pursue our business plan we may be unable to continue operations, in which case you may lose your entire investment. Alternatively, we may consider changes in our business plan that might enable us to achieve aspects of our business objectives and lead to some commercial success with a smaller amount of capital, but we cannot assure that changes in our business plan will result in revenues or maintain any value in your investment.

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 on our financial statements. A significant portion of our total assets are comprised of goodwill and intangibles that arose from our 2014 business acquisitions. The company reviews goodwill for impairment at least annually or whenever changes in circumstances indicate that the carrying value of the goodwill may not be recoverable. The company also reviews its 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 the company takes 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.

Our efforts may never demonstrate the feasibility of our technology. Our research and development efforts remain subject to all of the risks associated with the development of new devices and treatment modalities and related products based on the emergence of sub-microsecond electric field technology. Nano-Pulse Stimulation, or NPS, technology for biomedical applications is not yet fully developed. Development of the underlying technology, including the development of the PulseTx system, may be affected by unanticipated technical or other problems, among other development and research issues, and the possible insufficiency of funds needed in order to complete development of these products or devices. Safety, regulatory and efficacy issues, clinical hurdles or challenges also may result in delays and cause us to incur additional expenses that will increase our need for capital and result in additional losses. If we cannot complete, or if we experience significant delays in developing our medical devices or products for use in potential commercial applications, particularly after incurring significant expenditures, our business may fail and investors may lose the entirety of their investment.

**As an investor, you may lose all of your investment**. Investing in our common stock involves a high degree of risk. As an investor you may never recoup all, or even part of, your investment, and you may never realize any return on your investment.

We cannot assure you that we will generate revenue or become profitable in the future. We are a development-stage medical device company, and do not expect to generate any revenues until we successfully complete development of our PulseTx system and our first potential commercial devices and products and regulatory approval is obtained and/or commercialization commenced. Our technology is still in development and products are only proposed. We are incurring significant operating losses, and we cannot assure you that we will generate revenue or be profitable in the future. Our future products may never be approved or become commercially viable or accepted for use. Even if we find commercially viable applications for our technology, which may include licensing, we may never recover our research and development expenses.

We anticipate future losses and negative cash flow, and we are unsure when we will become profitable. We have not yet demonstrated our ability to generate revenue, and we may never be able to produce material revenues or operate on a profitable basis. We have incurred significant losses since our inception and expect to experience operating losses and negative cash flow for the foreseeable future. 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, marketing and promotion, 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, science and other operational personnel, and the continued development of relationships with strategic partners. We anticipate our losses will continue to increase from the current levels during our development stages.

We currently do not have, and may never develop, any FDA approved or commercialized products. We currently do not have any FDA or other jurisdiction approved products or any commercialized products. To date, we have invested a substantial amount of time and capital to research and develop the foundations of our technology and potential applications. For us to develop any products that might ultimately be commercialized, we will have to invest further time and capital in research and product development, medical and other regulatory compliance, and market development. Therefore, we may never develop any products that can be commercialized. All of our development efforts will require substantial additional investment, which may never result in any revenue. Our efforts may not lead to approved or commercially successful products for a number of reasons, including:

- we may not be able to complete the science and develop any potential products for NPS;
- we may not be able to obtain regulatory approvals for our proposed products, or the approved indications may be narrower than we seek;
- we may experience delays in our development program, clinical trials and the regulatory approval process;
- our NPS technology may not prove to be safe and effective in clinical trials;
- physicians may not receive any reimbursement from third-party payers, or the level of reimbursement may be insufficient to support widespread adoption of any of our products;
- any products that are approved may not be accepted in the marketplace by physicians or patients;
- we may not be able to manufacture our products in commercial quantities or at an acceptable cost; and
- rapid technological change or the appearance of a new competitive technology may make our technology and products obsolete.

Laboratory conditions differ from commercial conditions and field conditions, which could affect the effectiveness of our potential products. Failures to effectively move from laboratory to the field would harm our business. 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 the proposed products in the field. The failure of our proposed products under development or other future products to be able to be tested, approved and manufactured in available manufacturing facilities or to be able to meet the demands of users in the field would harm our business.

We are subject to regulation in respect of our research and federal funding. Because we and our subsidiaries and licensors have conducted research under federal grants and we may conduct further research under federal grants, we will be subject to federal regulation in how we conduct our research and the license terms relating to those grants. There are also ethical guidelines promulgated by various governments and research institutions that we are to follow in respect of our research. These are orientated to ethical standards and protections of humans and animals in research and experimentation activities. We also follow good scientific practices. Failure to follow the regulations, agreement terms and science standards would jeopardize our grants and our results and the use of the results in further research and approval circumstances.

Because we and one of our licensors have used federal funding in the development of certain aspects of our technology, the federal government retains 'march-in' rights in connection with results derived from these grants. March-in rights give the federal government the right to grant to other entities, which may include competitors, licenses or to take a license for itself if the government funded the development of a patent. The march-in right applies to patents that have been issued. The march-in right is intended to be used only if there is a threat to public health and safety that the owner of the patent is not equipped to handle. The march-in right may also be used to remove the exclusive rights belonging to a patent holder if the patent for which the government provided funding is not suitable for public use. If march-in rights are used by the government, the entities using the patent are required to pay royalties to the patent holder, which amount would be subject to negotiation. Because federal funding was used for some aspects of the company's technology that will be the subject of some of our patents, the company could be subject to the march-in right and lose its exclusivity of those patents, and may suffer direct competition if any license is granted by the government under the march-in right to a competitor.

We have not yet sought, and may never receive, regulatory approval, including that from the FDA, for any of our proposed products. We have not yet sought to obtain any regulatory approvals for any potential devices or products in the United States or in any foreign market. Therefore, it is highly speculative as to any timing for our potential products to be commercialized. We are not familiar with any currently approved devices that deploy our type of technology that might make our seeking regulatory approval more assured or potentially faster than currently contemplated. Investors need to take a long term approach to an investment in our securities, as the commercial realization of our technology is speculative and well in the future.

We will be subject to stringent domestic and foreign regulation in respect of any potential devices and products. Any unfavorable regulatory action may materially and adversely affect our future financial condition and business operations and prospects. Our potential devices and products, further development activities and manufacturing and distribution, once developed and determined, will be subject to extensive, rigorous and ongoing regulation by numerous government agencies, including the FDA and comparable foreign agencies. 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 devices. The process of obtaining and maintaining marketing approval or clearance from the FDA and comparable foreign bodies 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 pre-clinical 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 we seek.

If we experience any of these occurrences, our operations may suffer, we might experience harm to our competitive standing and result in further losses that adversely affect our financial condition. We will have ongoing responsibilities under FDA and international regulations, both before and after a product is approved 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 medical devices are ineffective or pose an unreasonable health risk, the FDA or comparable foreign agency could ban such medical

devices or products, detain or seize such medical 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 devices or products present unreasonable risks of substantial harm to the public health. Additionally, the FDA or comparable foreign agency may impose other operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices and products and assess civil or criminal penalties against our officers, employees, or us. The FDA and comparable foreign agencies have been increasing its scrutiny of the medical device industry and the government is 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. 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.

We will have to comply with complex statutes prohibiting fraud and abuse, and both we and physicians utilizing our potential products could be subject to significant penalties for noncompliance. 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 federal laws include: the anti-kickback statutes which prohibit certain business practices and relationships, including the payment or receipt of remuneration for the referral of patients whose care will be paid by Medicare or other federal healthcare programs; the physician self-referral prohibition, commonly referred to as the Stark Law; the anti-inducement law, which prohibits providers from offering anything to a Medicare or Medicaid beneficiary to induce that beneficiary to use items or services covered by either program; the Civil False Claims Act, which prohibits any person from knowingly presenting or causing to be presented false or fraudulent claims for payment by the federal government, including the Medicare and Medicaid programs and the Civil Monetary Penalties Law, which authorizes the imposition of civil penalties administratively for fraudulent or abusive acts.

Sanctions for violating these federal laws include criminal and civil penalties that range from punitive sanctions, damage assessments, money penalties, imprisonment, denial of Medicare and Medicaid payments, or exclusion from the Medicare and Medicaid programs, or both. As federal and state budget pressures continue, federal and state administrative agencies may also continue to escalate investigation and enforcement efforts to root out waste and to control fraud and abuse in governmental healthcare programs. Private enforcement of healthcare fraud has also increased, due in large part to amendments to the Civil False Claims Act in 1986 that were designed to encourage private persons to sue on behalf of the government. A violation of any of these federal and state fraud and abuse laws and regulations could have a material adverse effect on our liquidity and financial condition

To obtain the necessary device and marketing and manufacturing approval, as a pre-condition, we will have to conduct various preclinical and clinical tests, all of which will be costly and time consuming, and may not provide results that will allow us to seek regulatory approval. The number of preclinical and clinical tests that will be required for regulatory 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 and the applicable regulations. Regulatory agencies, including those in the United States, Canada, Europe and other countries 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 medical device to be safe or effective;
- · may interpret data from preclinical and clinical testing differently than we do;
- may not approve our manufacturing processes;
- may conclude that our device does not meet quality standards for durability, long-term reliability, biocompatibility, electromagnetic compatibility, or electrical safety; and
- · may change their approval policies or adopt new regulations.

The FDA may make requests or suggestions regarding conduct of our clinical trials, resulting in an increased risk of difficulties or delays in obtaining regulatory approval in the US. Any of these occurrences could prove materially harmful to our operations and business.

Even if a potential device or product ultimately is approved by the different regulatory authorities, it may be approved only for narrow indications which may render it commercially less viable. Even if a potential device or product of ours is approved, it may not be approved for the indications that are necessary or desirable for a successful commercialization. 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 classification may be more limited than we originally seek. The 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.

Even if we obtain clearance or approval to sell a potential product, 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 collaborative partners such as manufacturers and distributors, will be required to adhere to applicable FDA regulations regarding good manufacturing practice, which include testing, control, and documentation requirements. We will be subject to similar regulations in foreign countries. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Ongoing compliance with good manufacturing practice 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 previously obtained, and criminal prosecution. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements will limit our ability to operate and could increase our costs.

Any failure or delay in completing clinical trials or studies for our devices and products and the expense of those trials may adversely affect our business. Preclinical studies, clinical trials and post-clinical monitoring and trials required to demonstrate the safety and efficacy of our potential devices and products will be time consuming and expensive. If we must conduct additional clinical trials or other studies with respect to any of our proposed product candidates to those that are initially contemplated, if we are unable to successfully complete any clinical trials or other studies, or if the results of these trials or studies are not positive or are only modestly positive, we may be delayed in obtaining marketing approval for the proposed products, we may not be able to obtain marketing approval, or we may obtain approval for indications that are not as broad as we seek. Our research and product development costs also will increase if we experience delays in testing or approvals. The completion of clinical trials for our proposed devices and products could be delayed because of our inability to manufacture or obtain from third-parties materials sufficient for use in preclinical studies and clinical trials; delays in patient enrollment and variability in the number and types of patients available for clinical trials; difficulty in maintaining contact with patients after treatment, resulting in incomplete data; poor effectiveness of proposed devices and products during clinical trials; unforeseen safety issues or side effects; and governmental or regulatory delays and changes in regulatory requirements and guidelines. If we incur significant delays in our clinical trials, our competitors may be able to bring their products to market before we do, which could result in harming our ability to commercialize our potential products. If we experience any of these occurrences our business will be materially harmed.

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 our potential devices and products and related treatments, and therefore our commercial success as a company, will be affected by the availability of government reimbursement and medical insurance coverage and reimbursement for newly approved medical devices. Insurance coverage and reimbursement is granted at all. In the United States and other jurisdictions in Europe and other regions, 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 proposed 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 devices and products, and as a result, they may not cover or provide adequate payment for the use of our proposed products. In order to obtain satisfactory reimbursement arrangements, we may have to agree to a fee or sales price lower than the fee or sales price we might otherwise charge. Even if Medicare and other third-party payers decide to cover procedures involving our proposed devices and products, we cannot be certain that the reimbursement levels will be adequate. Accordingly, even if our proposed products are approved for commercial sale, unless government and other third-party payers provide adequate coverage and reimbursement for our devices and products, some physicians may be discouraged from using them, and our sales would suffer.

Medicare reimburses for medical devices and products in a variety of ways, depending on where and how the item is used. However, Medicare only provides reimbursement if Centers for Medicare & Medicaid Services, or 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 new provisions will be implemented and it is not possible to indicate how they might apply to any of our proposed devices and products, as they are still in the development stages. Coverage presupposes that the device or product has been cleared or approved by the FDA and further, that the coverage will be no broader than 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. 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 United States 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.

We expect to operate in a highly competitive market, we may face competition from large, well-established medical device and product manufacturers with significant resources, and we may not be able to compete effectively. We do not know of any directly competitive devices or products that our proposed products would compete against on a direct basis. There may be companies that are working in the area of sub-microsecond pulsed electric devices, of which we are not aware. The broader market for devices that provide the health benefits of electricity field technology is becoming more focused and potentially more competitive. Over time, we believe this field will become subject to more rapid change and new devices and products will emerge. We may find ourselves in competition with companies that have competitive advantages over us, such as:

- · significantly greater name recognition;
- · established relations with healthcare professionals, customers and third-party payers;
- · 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 conducting research and development, manufacturing, clinical trials, obtaining regulatory approval for products, and marketing approved products; and
- greater financial and human resources for product development, sales and marketing, and patent litigation.

As a result, we may not be able to compete effectively against these companies or their devices and products.

We do not have any sales, marketing, manufacturing and distribution capabilities or arrangements, and will need to create these as we move towards commercialization of our products. We do not yet have sales, marketing, manufacturing and distribution capabilities or arrangements. To be able to commercialize our potential products, we will need to develop all of the foregoing. We do not have any corporate experience in establishing these capabilities, and therefore, we may be unsuccessful in achieving commercialization and earning revenues. We believe that setting up 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.

Rapidly changing technology in life sciences could make the products we are developing obsolete. The medical device industry is 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. We also 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 lose key management personnel, or if we fail to recruit additional highly skilled 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 and the members of our scientific team. These persons have significant experience and knowledge with sub-microsecond pulsed electric fields and the loss of any team member could impair our ability to design, identify, and develop new intellectual property and new scientific or product ideas.

We may have difficulty managing growth in our business. Because of our small size, growth in accordance with our business plan, if achieved, will place a significant strain on our financial, technical, operational and management resources. As we expand our activities, there will be additional demands on these resources. The failure to continue to upgrade our technical, administrative, operating and financial control systems or the occurrence of unexpected expansion difficulties, including issues relating to our research and development activities and retention of experienced scientists, managers and engineers, could have a material adverse effect on our business, financial condition and results of operations and our ability to timely execute our business plan. If we are unable to implement these actions in a timely manner, our results may be adversely affected.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired, which would adversely affect our business and our stock price. Ensuring that we have adequate internal financial and accounting controls and procedures in place to produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. We may discover material weaknesses in our internal financial and accounting controls and procedures that need improvement from time to time.

Management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with United States generally accepted accounting principles. Management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within our company will be detected.

We are required to comply with Section 404 of the Sarbanes-Oxley Act in connection with our future annual and quarterly reports on Form 10-K and Form 10-Q. We expect to expend significant resources in developing the necessary documentation and testing procedures required by Section 404. We cannot be certain that the actions we will be taking to improve our internal controls over financial reporting will be sufficient, or that we will be able to implement our planned processes and procedures in a timely manner. In addition, if we are unable to produce accurate financial statements on a timely basis, investors could lose confidence in the reliability of our financial statements, which could cause the market price of our common stock to decline and make it more difficult for us to finance our operations and growth.

The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified board members. As a public company, we will incur accounting, legal, director and officer liability insurance and other expenses that are generally greater than those applicable to a private company. Generally these costs will be associated with meeting our disclosure requirements to our stockholders and will be associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002, and the rules and regulations of the SEC for public reporting companies and The NASDAQ Stock Market. We expect these rules and regulations also to make some activities more time-consuming and costly. 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 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.

New laws and regulations as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Protection Act, and rules adopted by the SEC and NASDAQ, will likely result in increased costs to us as we respond to their requirements.

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 the San Francisco Bay Area 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 cause significant delays in our research programs and commercial activities and make it difficult for us to recover from a 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.

#### Risks Related to Intellectual Property and Other Legal Matters

If we or our licensors are unable to protect our/their 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. 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, and our licensors, 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 or our licensors may fail to maintain these patents, may determine not to pursue litigation against entities that are infringing upon these patents, or may pursue such enforcement less aggressively than we ordinarily would for our own 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 third parties 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, those claims could result in our having to pay substantial damages or could prevent us from developing one or more 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.

If we fail to comply with our obligations in the agreements under which we license development or commercialization rights to products or technology from third-parties, we could lose license rights that are important to our business. We hold licenses from ODURF and EVMS and from AMI-USC to intellectual property relating to the sub-microsecond electric field technology, as well as applicator design and configuration, and pulse generators in addition to the intellectual property that we own for these things. For the continuance of the license with ODURF and EVMS, Pulse Biosciences needs to commence pursuing one or more applications with the FDA by December 15, 2018 and continue to comply with the various obligations set forth in the license. If we fail to meet these obligations, the licensor will have the right to terminate the applicable license or modify certain terms of the license agreement.

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 or proprietary information in part by confidentiality agreements with our employees, consultants and third-parties. While we require all of our employees, consultants, advisors and any third-parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. These 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. To the extent that any of our staff were previously employed by other pharmaceutical, medical technology or biotechnology companies, those employers may allege violations of trade secrets and other similar claims in relation to their medical device development activities for us.

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. The strength of our patents involves complex legal and scientific questions and can be uncertain. Our patents or patent applications may be challenged or our patent applications may fail to result in issued patents and our existing or 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. Further, the patent applications that we license or have filed may fail to result in issued patents. The claims may need to be amended. Even after amendment, a patent may not issue and in that event we may not obtain the use of the intellectual property that we seek and may lose competitive advantage which could result in harm to our business.

We may become involved in future lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful. Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or of our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

The United States Patent and Trademark Office may initiate interference proceedings to determine the priority of inventions described in or otherwise affecting our patents and patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

#### Risks Related to Owning Our Common Stock

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

- · 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;
- · overall conditions in our industry and market;
- · changes in laws or regulations applicable to our planned products;
- 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;
- · announcement or expectation 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; and
- · general economic and market conditions.

If any of the forgoing occurs, it 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. 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. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Control by our principal stockholders may limit your ability to influence the outcome of director elections and other transactions requiring stockholder approval. A significant percentage of our outstanding stock is held by a limited number of investors. As a result, such persons will have significant influence 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 articles 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.

Such persons' stock ownership 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.

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

We agreed in the underwriting agreement for our May 2016 initial public offering to conduct a rights offering as a precondition to certain future offers and sales of our common stock, which may hinder our ability to raise capital during the term of the provision and because of the exceptions stockholders may not be offered the right to participate in future offerings. We agreed with one of the underwriters of our May 2016 initial public offering that for a period of up to five years after it is completed, the company will conduct offerings of its common stock so as to give the holders of its common stock

the ability to participate through a rights offering. There are several exceptions to this obligation, including (i) stock dividends and splits, (ii) exercises and conversions of outstanding securities, (iii) equity awards under a stockholder approved plan which are authorized by the board of directors, (iv) merger, consolidation and combination transactions and business and asset acquisition transactions, (v) equity financings in any 12 month period that do not exceed both \$2,500,000 in gross proceeds and 5% of the then issued and outstanding shares of common stock, and (vi) transactions which are approved by MDB Capital Group, LLC, one of the underwriters of the May 2016 offering. Should any one of these exceptions be applicable to an offering, the company would be able to proceed with the offering without first giving its current stockholders the right to participate. Although a rights offering may provide to the current stockholders the opportunity to maintain their ownership percentage, it may slow an offering of common stock or securities related to common stock by the company. Rights offerings are typically held open for a period of 16 to 30 days, after the required corporate actions and documentation, including a registration statement, are completed, which may range from a few weeks to several months. Because a rights offering may not raise all the capital sought by a company, the company may have to structure the offering with over-subscription rights, standby purchasers, private placement agents and/or underwriters in order to sell the offered and any additional securities in order to obtain the sought amount of capital.

We are an "emerging growth company" under the JOBS Act of 2012 and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors. We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"), and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will 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.

We will remain an "emerging growth company" for up to five years, although we will lose that status sooner if our revenues exceed \$1 billion, if we issue more than \$1 billion in non-convertible debt in a three-year period, or if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of any June 30.

Our status as an "emerging growth company" under the JOBS Act may make it more difficult to raise capital as and when we need it. Because of the exemptions from various reporting requirements provided to us as an "emerging growth company," we may be less attractive to investors as an investment opportunity 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.

We have not paid dividends in the past and have no plans to pay dividends. We plan to reinvest all of our earnings, to the extent we have earnings, into our product research and development. We do not plan to pay any cash dividends with respect to our securities in the foreseeable future. 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.

Shares eligible for future sale may adversely affect the market for our common stock. Starting in November 2016, certain of our stockholders become eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act, subject to certain limitations and lock-up agreements that run for six or 12 months. In general, pursuant to Rule 144, non-affiliate stockholders may sell freely after six months subject only to the current public information requirement (which ends after one year).

In addition, in connection with the November 2014 private placement, we have granted piggy-back and demand registration rights to the purchasers of common stock. These rights commence on the six-month anniversary of the completion of the May 2016 offering, when the lock-up with respect to these shares expires.

We have also granted piggy-back and demand registration rights to MDB Capital Group, LLC for the 299,625 shares of common stock underlying the warrant issued as compensation for the November 2014 private placement. These rights commence six months after the consummation of the May 2016 offering, subject to a six-month lock up.

In connection with the May 2016 initial public offering we granted seven-year piggy-back and five-year demand registration rights to the underwriters in respect to their underwriter warrants to acquire 574,985 shares. These rights commenced on May 17, 2016. The common shares underlying the underwriter warrants are subject to a six-month lock-up ending in November 2016.

Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our common stock.

Our charter documents and Nevada law may inhibit a takeover that stockholders consider favorable. Provisions of our articles of incorporation and bylaws and applicable provisions of Nevada law may delay or discourage transactions involving an actual or potential change in control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Some of the following provisions in our articles and bylaws that implement these are:

- 5,000,000 shares of "blank check" preferred stock, which may be issued at the discretion of the board of directors, without further approval of the stockholders;
- · no cumulative voting rights for the holders of common stock in the election of directors; and
- · vacancies in the board of directors may be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum.

The Revised Nevada Statutes also provide for restrictions on voting our equity securities in connection with unapproved business combinations and control shares, which we have not opted out of.

These provisions may have the effect of entrenching our management team and may deprive you of the opportunity to sell your shares to potential acquirers at a premium over prevailing prices.

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

#### (a) Sales of Unregistered Securities

#### Warrants

During the nine-month period ended September 30, 2016, in connection with the closing of our initial public offering, we issued warrants as compensation to the underwriters of our initial public offering to purchase a total 574,985 shares of our common stock at a price of \$5.00 per share. The warrants become exercisable 180 days after issuance and are exercisable for a period of five years.

#### Stock Options

During the nine-month period ended September 30, 2016, we issued 405.132 stock options at a weighted average exercise price of \$4.44 under our 2015 Stock Incentive Plan which was adopted in August 2015.

These issuances were undertaken in reliance upon the exemptions from registration requirements available under Rule 701 and Section 4(a)(2) of the Securities Act of 1933, as amended.

#### (b) Use of Proceeds from Public Offerings of Common Stock

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-208694), as amended, which was declared effective on May 13, 2016. Our initial public offering closed on May 23, 2016 and resulted in net proceeds of approximately \$20.3 million, including proceeds from the exercise of the overallotment option granted to the underwriters, net of underwriting discounts and commissions and other offering costs. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectuses filed with the SEC on May 17, 2016 pursuant to Rule 424(b). Pending the uses described, we have invested the net proceeds in short-term, investment-grade interest-bearing securities and obligations, such as money market accounts, corporate bonds and asset-backed securities.

#### Item 3. Default Upon Senior Securities

Not applicable.

#### Item 4. Mine Safety Disclosures

Not applicable.

#### Item 5. Other Information

Not applicable.

#### Item 6. Exhibits

The exhibits listed in the Exhibit Index immediately preceding the exhibits, other than Exhibit 32.1 are filed as part of this Quarterly Report and such Exhibit Index is incorporated herein by reference.

# **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: November 14, 2016

/s/ BRIAN B. DOW
Brian B. Dow
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

#### **Exhibit Index**

Exhibit Number	Exhibit Description
10.1	Amendment to Employment Agreement by and between Darrin R. Uecker and Pulse Biosciences, Inc. dated October 5, 2016 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-37744) filed on October 11, 2016)
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of the Chief Executive and Chief Financial Officers pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

<sup>\*</sup> The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q 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 on Form 10-Q, irrespective of any general incorporation language contained in such filing.

# CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECURITIES EXCHANGE ACT RULES 13a-14(a) and 15d-14(a), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

- I, Darrin R. Uecker, President and Chief Executive Officer, certify that:
- 1. I have reviewed this Quarterly Report on Form 10- Q of Pulse Biosciences, Inc.;
- 2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b)Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c)Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2016 By: /s/ Darrin R. Uecker

Darrin R. Uecker President and Chief Executive Officer (Principal Executive Officer)

# CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECURITIES EXCHANGE ACT RULES 13a-14(a) and 15d-14(a), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

- I, Brian B. Dow, Chief Financial Officer, certify that:
- 1. I have reviewed this Quarterly Report on Form 10-Q of Pulse Biosciences, Inc.;
- 2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a)Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b)Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c)Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2016 By: /s/ Brian B. Dow

Brian B. Dow

Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)

#### **CERTIFICATIONS PURSUANT TO** 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Pulse Biosciences, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

- The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- The information contained in the Report fairly presents, in all material respects, the financial condition and results of (2) operations of the Company.

Date: November 14, 2016

/s/ Darrin R. Uecker Darrin R. Uecker President and Chief Executive Officer (Principal Executive Officer)

/s/ Brian B. Dow Brian B. Dow

Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)

This certification 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 report, irrespective of any general incorporation language contained in such filing.