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

Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2017

Or

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

For the transition period from to

Commission File Number 001-34899

Pulse Biosciences, Inc.
(Exact name of registrant as specified in its charter)

Nevada **(State or other jurisdiction of incorporation or organization)**	**46-5696597** **(I.R.S. Employer Identification No.)**
3957 Point Eden Way **Hayward, CA** **(Address of principal executive offices)**	**94545** **(Zip Code)**

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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

Number of shares outstanding of the issuer's common stock as of October 31, 2017: 16,341,256

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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, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 32,423	$ 2,089
Investments	9,618	14,306
Prepaid expenses and other current assets	512	268
Total current assets	42,553	16,663
Property and equipment, net of accumulated depreciation	2,635	317
Intangible assets, net of accumulated amortization	6,044	6,543
Goodwill	2,791	2,791
Other asset	101	—
Total assets	$ 54,124	$ 26,314
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 914	$ 265
Accrued expenses	1,168	751
Deferred rent, current	392	—
Total current liabilities	2,474	1,016
Deferred rent	1,715	—
Total liabilities	4,189	1,016
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 – 16,341 shares and 13,315 shares at September 30, 2017 and December 31, 2016, respectively	16	13
Additional paid-in capital	79,391	37,898
Accumulated other comprehensive loss	(2)	(7)
Accumulated deficit	(29,470)	(12,606)
Total stockholders' equity	49,935	25,298
Total liabilities and stockholders' equity	$ 54,124	$ 26,314

See accompanying notes to the condensed consolidated financial statements.

PULSE BIOSCIENCES, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

(in thousands, except per share amounts)	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2017	2016	2017	2016
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
General and administrative	4,159	893	9,151	2,063
Research and development	3,200	1,739	7,333	4,182
Amortization of intangible assets	166	166	499	499
Total operating expenses	7,525	2,798	16,983	6,744
Other income:				
Interest income	39	31	119	35
Total other income	39	31	119	35
Net loss	(7,486)	(2,767)	(16,864)	(6,709)
Other comprehensive loss:				
Unrealized gain on available-for-sale securities, net of tax	4	—	5	—
Comprehensive loss	$ (7,482)	$ (2,767)	$ (16,859)	$ (6,709)
Net loss per share:				
Basic and diluted net loss per share	$ (0.52)	$ (0.21)	$ (1.19)	$ (0.66)
Weighted average shares used to compute net loss per common share — basic and diluted	14,381	13,315	14,141	10,235

See accompanying notes to the condensed consolidated financial statements.

PULSE BIOSCIENCES, INC.

Condensed Consolidated Statements of Cash Flows
(Unaudited)

(in thousands)	Nine-Month Periods Ended September 30, 2017	2016
Cash flows from operating activities:		
Net loss	$ (16,864)	$ (6,709)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	196	70
Amortization of intangible assets	499	499
Stock-based compensation	6,403	627
Net premium amortization on investments	24	3
Landlord incentive for tenant improvements	2,119	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(244)	(463)
Accounts payable	649	184
Accrued expenses	207	56
Other asset	(101)	—
Deferred rent	(12)	—
Net cash used in operating activities	(7,124)	(5,733)
Cash flows from investing activities:		
Purchases of property and equipment	(2,407)	(64)
Purchases of investments	(11,363)	(14,096)
Maturities of investments	16,034	—
Net cash provided by (used) in investing activities	2,264	(14,160)
Cash flows from financing activities:		
Proceeds from issuance of common stock	34,944	20,915
Proceeds from exercise of warrants	50	—
Proceeds from exercises of stock options	200	—
Net cash provided by financing activities	35,194	20,915
Net increase in cash	30,334	1,022
Cash and cash equivalents at beginning of period	2,089	3,606
Cash and cash equivalents at end of period	$ 32,423	$ 4,628
Supplemental disclosure of noncash investing and financing activities:		
Reclassification of deferred offering costs to additional paid-in capital upon initial public offering	$ —	$ 627
Equipment purchased in accrued expenses	109	—
Financing costs not yet paid	101	—

See accompanying notes to the condensed consolidated financial statements.

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

In 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., incorporated in Nevada on May 19, 2014, is a clinical-stage medical technology company developing commercial clinical applications for its proprietary Nano-Pulse Stimulation ("NPS") technology. NPS is a novel patented technology that 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 potential clinical applications for NPS, including oncology, dermatology, aesthetics and other minimally invasive applications where the Company believes NPS may provide greater benefits compared to current therapies and treatments. The Company's headquarters and research facility are located in Hayward, California.

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

2. Summary of Significant Accounting Policies

Basis of Presentation

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, 2016 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 applicable rules and regulations of the Securities and Exchange Commission and, as permitted by such rules and regulations, omit certain information and footnote disclosures necessary to present the financial statements in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). The condensed consolidated balance sheet as of December 31, 2016 was derived from the audited consolidated financial statements as of that date, but does not include all of the information and footnotes required by U.S. GAAP for completed financial statements. These Financial Statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2016 included in the Company's Annual Report on Form 10-K, filed on March 20, 2017. The results of operations for the three-month and nine-month periods ended September 30, 2017 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 and the useful lives assigned to long-lived assets. 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, 2017, as compared to the significant accounting policies described in the Company's Annual Report on Form 10-K for the year ended December 31, 2016.

Principles of Consolidation

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

Net Loss per Share

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

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

The following outstanding stock options, warrants and restricted stock units 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,	
	2017	2016
Common stock warrants	705,121	874,610
Common stock options	2,326,676	1,254,790
Restricted stock units	229,774	—
Total	3,261,571	2,129,400

Reclassification

Certain items in the prior period financial statements have been reclassified to conform to the presentation in the current period financial statements.

Recent Accounting Pronouncements

Recently Adopted Accounting Standards

During March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-09, *Compensation - Stock Compensation (Topic 718): 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 adopted this ASU as of January 1, 2017. The adoption of this ASU did not have a significant impact on the Company's financial position.

Recently Issued Accounting Standards

During May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers*, requiring an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to 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 to periods beginning after December 15, 2017. This updated standard becomes effective for the Company in the first quarter of fiscal year 2018. The Company expects to adopt this standard upon commencing revenue generating activities. Since the Company has not recognized or generated revenue to date, it does not expect the adoption of this pronouncement on January 1, 2018 to have any impact to its financial statements.

During February 2016, the FASB issued ASU No. 2016-02, *Leases*, 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. While the Company is continuing to assess

all potential impacts of this standard, it expects that most of its lease commitments will be subject to the updated standard and recognized as lease liabilities and right-of-use assets upon adoption.

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. The Company is currently evaluating the impact of adopting this standard.

During January 2017, the FASB issued ASU 2017-04, *Intangibles — Goodwill and Other (Topic 350): Simplifying the Accounting for Goodwill Impairment*, which simplifies the accounting for goodwill impairment. This ASU removes Step 2 of the goodwill impairment test, which requires hypothetical purchase price allocation. A goodwill impairment will now be the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. The new guidance also requires disclosure of the amount of goodwill at reporting units with zero or negative carrying amounts. ASU 2017-04 is effective for the Company beginning January 1, 2020. Early adoption is permitted for any impairment tests performed after January 1, 2017. The Company is currently evaluating the impact of adopting such standard.

During May 2017, the FASB issued ASU 2017-09, *Compensation — Stock Compensation (Topic 718)*: Scope of Modification Accounting. This standard provides clarification on when modification accounting should be used for changes to the terms or conditions of a share-based payment award. This standard does not change the accounting for modifications but clarifies that modification accounting guidance should only be applied if there is a change to the value, vesting conditions, or award classification and would not be required if the changes are considered non-substantive. The amendments in this ASU are effective for the Company effective beginning January 1, 2018, with early adoption permitted. This ASU should be applied prospectively on and after the effective date. The Company is currently evaluating the impact of adopting this standard.

3. Fair Value of Financial Instruments

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

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

Level 2 - Inputs, other than quoted prices included within Level 1, which are directly observable for the asset or liability or indirectly observable through corroboration with observable market data. Financial assets and liabilities utilizing Level 2 inputs include fixed income securities, non-exchange based derivatives, mutual funds, and fair-value hedges.

Level 3 - Unobservable inputs in which there is little or no market data for the asset or liability which requires the reporting entity to develop its own assumptions. Financial assets and liabilities utilizing Level 3 inputs include infrequently-traded, non-exchange-based derivatives and commingled investment funds, and are measured using present value pricing models.

The Company determines the level in the fair value hierarchy within which each fair value measurement falls in its entirety, based on the lowest level input that is significant to the fair value measurement in its entirety. In determining the appropriate levels, the Company performs an analysis of the assets and liabilities at each reporting period end.

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, 2017 and December 31, 2016, respectively (in thousands):

		September 30, 2017				December 31, 2016			
Assets	Classification	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Money market funds	Cash and cash equivalents	$ 32,030	$ —	$ —	$ 32,030	$ 1,726	$ —	$ —	$ 1,726
Commercial paper	Investments	—	3,339	—	3,339	—	—	—	—
Corporate bonds	Investments	—	5,779	—	5,779	—	13,289	—	13,289
Asset-backed security	Investments	—	500	—	500	—	1,017	—	1,017
Total assets measured at fair value		$ 32,030	$ 9,618	$ —	$ 41,648	$ 1,726	$ 14,306	$ —	$ 16,032

The Company did not have any financial liabilities measured on a recurring basis as of September 30, 2017 or December 31, 2016.

During the nine-month period ended September 30, 2017, 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.

4. Property and Equipment, Net

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

	September 30, 2017	December 31, 2016
Leasehold improvements	$ 2,228	$ —
Laboratory equipment	486	425
Software	31	20
Furniture, fixtures, and equipment	221	17
	2,966	462
Less: Accumulated depreciation	(331)	(145)
	$ 2,635	$ 317

During June 2017, the Company prepared to move into new office space in Hayward, California, and its landlord provided $2.1 million for leasehold improvements pursuant to the tenant allowance clause in the lease agreement between the Company and its landlord which has been capitalized and amortized over the shorter of the lease term or estimated useful life.

Depreciation and amortization expense was $147,000 and $25,000 for the three-month periods ended September 30, 2017 and 2016, respectively. Depreciation and amortization expense was $196,000 and $70,000 for the nine-month periods ended September 30, 2017 and 2016, respectively.

5. Intangible Assets, Net

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

	September 30, 2017	December 31, 2016
Acquired patents and licenses	$ 7,985	$ 7,985
Less: Accumulated amortization	(1,941)	(1,442)
	$ 6,044	$ 6,543

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2017	December 31, 2016
Professional fees	$ 254	$ 285
Compensation expense	538	261
Financing costs	101	—
Clinical trials	45	—
Other	230	205
	$ 1,168	$ 751

7. Stockholders' Equity and Stock-Based Compensation

Private Placements

On February 7, 2017, the Company entered into a securities purchase agreement with Robert W. Duggan and Maky Zanganeh (the "Investors"), pursuant to which the Company, in a private placement, issued and sold to the Investors an aggregate of 819,673 shares of the Company's common stock, par value $0.001 per share, at a price per share of $6.10, for net proceeds of approximately $4,965,000.

On September 24, 2017, the Company entered into a securities purchase agreement with Robert W. Duggan, pursuant to which the Company, in a private placement, issued and sold to Robert W. Duggan an aggregate of 2,000,000 shares of the Company's common stock, par value $0.001 per share, at a price per share of $15.02, for net proceeds of approximately $29,876,000. In connection with this private placement, the Company granted certain registration rights to Robert W. Duggan, pursuant to which, among other things, the Company is obligated to prepare and file with the Securities and Exchange Commission a registration statement to register for resale of these shares no earlier than January 2, 2018.

Warrants

During the nine-months ended September 30, 2017, warrants to purchase 169,489 shares of common stock were either cash or net exercised, resulting in the issuance of approximately 136,552 shares of common stock. As of September 30, 2017, 705,121 warrants remained outstanding.

Equity Plans

2017 Equity Incentive Plan

The Board of Directors (the "Board") of the Company previously adopted, subject to stockholder approval, the Company's 2017 Equity Incentive Plan (the "2017 Plan"). The Company's stockholders approved the 2017 Plan at the annual meeting of stockholders held on May 16, 2017 (the "Annual Meeting").

The 2017 Plan has a 10-year term, and provides for the grant of stock options, stock appreciation rights, restricted stock, restricted stock units, performance units, and performance shares to employees, directors and consultants of the Company and any parent or subsidiary of the Company, as the Compensation Committee of the Board of Directors may determine. Subject to an annual evergreen increase and adjustment in the case of certain capitalization events, 1,500,000 shares of the Company's common stock are authorized for issuance pursuant to awards under the 2017 Plan. In addition, shares remaining available under the Company's 2015 Equity Incentive Plan, as amended (the "2015 Plan"), and shares reserved but not issued pursuant to outstanding equity awards that expire or terminate without being exercised or that are forfeited or repurchased by the Company will be added to the shares of common stock available for issuance under the 2017 Plan. The 2017 Plan is administered by the Board's Compensation Committee.

2017 Employee Stock Purchase Plan

The Board of the Company previously adopted, subject to stockholder approval, the Company's 2017 Employee Stock Purchase Plan (the "2017 ESPP"). At the Annual Meeting, the stockholders approved the 2017 ESPP.

The 2017 ESPP is a broad-based plan that provides employees of the Company and its designated affiliates with the

opportunity to become stockholders through periodic payroll deductions that are applied towards the purchase of Company common shares at a discount from the then-current market price. Subject to adjustment in the case of certain capitalization events, a total of 250,000 common shares of the Company are available for purchase under the 2017 ESPP.

As of September 30, 2017, the Company had three active equity compensation plans, the outstanding shares under the 2015 Plan, the 2017 Plan and the 2017 ESPP.

The following table summarizes stock option activity for the 2015 Plan and the 2017 Plan for the nine-month period ended September 30, 2017 (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, 2016	1,229	$ 3.82	7.6
Options granted	1,180	26.36	
Options exercised	(70)	3.16	
Options canceled	(12)	4.13	
Options expired	—	—	
Balances — September 30, 2017	2,327	$ 15.27	8.4
Exercisable	721		

The Company did not issue any common stock under the 2017 ESPP during the nine-month period ended September 30, 2017.

Stock-based Compensation

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

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2017	2016	2017	2016
General and administrative	$ 2,778	$ 183	$ 5,287	$ 478
Research and development	572	55	1,116	149
Total stock-based compensation expense	$ 3,350	$ 238	$ 6,403	$ 627

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 Company reviews, and when deemed appropriate, updates the assumptions used on a periodic basis. Due to the limited trading history of the Company's common stock, the Company utilizes a portfolio of comparable companies to estimate volatility. 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,	
	2017	2016	2017	2016
Expected term in years	6.1	6.1	5.3 - 6.1	6.1
Expected volatility	80%	80%	80%	80%
Risk-free interest rate	1.8%	1.2%	1.8 - 2.1%	1.3%
Dividend yield	—	—	—	—

The Company granted stock options to a non-employee during the nine-month period ended September 30, 2017. The Company uses the Black-Scholes option-pricing model to estimate the fair value of awards granted to nonemployees. The measurement of stock-based compensation for nonemployees is subject to periodic adjustments as the underlying equity instruments vest, and the resulting change in value, if any, is recognized in the Company's consolidated statements of operations during the period the related services are rendered. The fair value of a nonemployee stock option during the nine-month period ended September 30, 2017 was estimated using the following assumptions: expected term: 9.4 years; expected

volatility: 80%; risk-free interest rate: 2.3%; and dividend yield: none. The Company did not grant any stock options to non-employees during the three-month period ended September 30, 2017.

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

	Three-Month Periods Ended September 30,		Nine-Month Periods Ended September 30,	
	2017	2016	2017	2016
Expected term in years	0.5 - 1.0	N/A	0.8 - 1.3	N/A
Expected volatility	95%	N/A	95%	N/A
Risk-free interest rate	1.1 - 1.2%	N/A	1.1 - 1.2%	N/A
Dividend yield	—	N/A	—	N/A

The fair value of restricted stock unit (“RSUs”) awards is determined based on the number of units granted and the closing price of the Company’s common stock as of the grant date. The estimated fair value of RSUs is recognized on a straight-line basis over the requisite service period. During June 2017, the Company granted 160,974 RSUs to an officer, with a cliff vest in June 2018. The stock-based compensation expense related to these RSUs was approximately $1,275,000 and $1,607,000 for the three-month and nine-month periods ended September 30, 2017, respectively.

During the three-month period ended September 30, 2017, the Company granted 68,800 RSUs to certain employees which vest 50% on June 1, 2019 with the remaining 50% vesting on June 1, 2021. In the event of a change in control, these RSUs vest 100%. The stock-based compensation expense related to these RSUs was approximately $34,000 for both the three-month and nine-month periods ended September 30, 2017.

8. Research Grants and Agreements

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 second quarters of 2017 and 2016, the Company agreed to sponsor $740,000 and $1.0 million, respectively, 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. In addition, during 2017, the Company agreed to provide $300,000 in research funding to researchers affiliated with ODURF and Eastern Virginia Medical School matching funds made available to those researchers by the Virginia Biosciences Health Research Corporation. The Company’s sponsorship affords access to certain intellectual property, if any, developed during the project. As of September 30, 2017, there was approximately $150,000 remaining available under this sponsorship.

During the three-month periods ended September 30, 2017 and 2016, the Company paid and incurred costs relating to the SRA equal to $260,000 and $250,000, respectively. During the nine-month periods ended September 30, 2017 and 2016, the Company paid and incurred costs relating to the SRA equal to $585,000 and $664,000, respectively.

9. Commitments and Contingencies

Operating Leases

The Company leased approximately 4,300 square feet of corporate offices and research facilities in Burlingame, California, at a monthly cost of approximately $21,000. This lease expired on June 30, 2017.

During January 2017, the Company entered into a new lease agreement (the “Lease”) for premises consisting of approximately 15,700 rentable square feet located in Hayward, California (the “Premises”).

The Company moved into the Premises in July 2017. The Premises is being used for the Company's corporate headquarters and principal operating facility. The term of the Lease is sixty-two (62) months, which commenced on July 1, 2017. Base rent was abated for the first two (2) months of the Lease term and thereafter is $42,400 per month during the first year of the Lease term, with specified annual increases thereafter until reaching approximately $50,300 per month during the last two (2) months of the Lease term. The Company paid a refundable security deposit of approximately $101,000 and is required to reimburse the landlord for certain expenses during the Lease term.

The landlord provided the Company with improvement allowances in the amount of approximately $135.00 per rentable square foot of the Premises that were applied towards the costs of construction of the initial improvements in the Premises. The Company remains responsible for any improvement costs in excess of the foregoing allowances. During the nine-month period ended September 30, 2017, the landlord incurred approximately $2.1 million related to the initial tenant leasehold improvements and the Company capitalized these leasehold improvements to property and equipment and a corresponding deferred rent liability on its balance sheet.

The Company has the right to extend the Lease term by five (5) years upon written notice not more than twelve (12) months nor less than nine (9) months prior to the expiration of the original Lease term, with monthly payments equal to the "Fair Rental Value" as defined in the Lease. As of December 31, 2016, the lease obligations for less than one year, one to three years, three to five years and more than five years is approximately $0.3 million, $1.1 million, $1.1 million and $0.3 million, respectively.

During the three-month periods ended September 30, 2017 and 2016, rent expense, including common area maintenance charges, was approximately $101,000 and $56,000, respectively. During the nine-month periods ended September 30, 2017 and 2016, rent expense, including common area maintenance charges, was approximately $239,000 and $155,000, respectively.

10. Related Party Transactions

MDB Capital Group, LLC ("MDB") provided investment banking, executive recruiting and intellectual property management services to the Company. The Company's former Chairman of the Board, Robert Levande, was a Senior Managing Director of MDB throughout his tenure on the Company's Board of Directors.

During the three-month and nine-month periods ended September 30, 2016, the Company incurred $0 and $100,000, respectively, for services rendered by MDB with respect to intellectual property management.

In connection with the initial public offering during May 2016, the underwriting syndicate led by MDB received $1,800,000 in underwriting discounts, $160,000 in unaccountable expense reimbursement and warrants valued in aggregate of $1,443,000.

During September 2017, the Company entered into a securities purchase agreement with Robert W. Duggan, a significant stockholder of the Company and Chairman of the Board effective November 2, 2017, pursuant to which the Company issued and sold to Robert W. Duggan an aggregate of 2,000,000 shares of the Company's common stock, par value $0.001 per share, at a price per share of $15.02. At the time of the transaction, Mr. Duggan owned approximately 27% of the Company's then outstanding securities and approximately 36% upon completion of the transaction.

On November 2, 2017, the Company appointed Ken Clark to the Board of Directors. Mr. Clark is a member of the law firm of Wilson Sonsini Goodrich and Rosati ("WSGR"), which is also outside corporate counsel to the Company. During the three-month and nine-month periods ended September 30, 2017, the Company incurred expenses for legal services rendered by WSGR totaling approximately $233,000 and $525,000, respectively.

11. Subsequent Events

On November 2, 2017, the Company's board of directors accepted the resignations of Robert J. Greenberg, M.D., Ph.D., Robert M. Levande, Mitchell E. Levinson and Thierry B. Thaure as directors, including the resignation of Mr. Levande as Chairman of the Board and the resignations of Dr. Greenberg, Mr. Levinson and Mr. Thaure from the Audit Committee, the Compensation Committee, and the Nominating and Corporate Governance Committee of the Board. In connection with their resignations, Dr. Greenberg, Mr. Levande, Mr. Levinson and Mr. Thaure will each receive a lump sum cash stipend equivalent to their annual retainer, prorated for the remainder of their respective term, and all equity awards held by each individual were fully vested.

On November 2, 2017, the Company's board of directors elected Kenneth A. Clark, Robert W. Duggan, Thomas J. Fogarty, M.D. and Manmeet S. Soni as directors. Mr. Clark, Mr. Duggan, Dr. Fogarty and Mr. Soni will serve until their respective terms expire at the annual meeting of stockholders to be held in 2018 and until their successors are duly elected and qualified or until their earlier death, resignation or removal. In addition, to fill in the vacancies created by the departures of Dr. Greenberg, Mr. Levande, Levinson and Mr. Thaure, the Company's board of directors appointed (i) Mr. Duggan to serve as Chairman of the Board; (ii) Dr. Fogarty, Mr. Soni and Maky Zanganeh to serve as members of the Audit Committee, with Mr. Soni serving as Chair of the Audit Committee; (iii) Mr. Soni and Dr. Zanganeh to serve as members of the Compensation Committee, with Dr. Zanganeh serving as Chair of the Compensation Committee; and (iv) Mr. Clark, Mr. Duggan and Dr. Fogarty to serve as members of the Nominating and Corporate Governance Committee, with Mr. Clark serving as Chair of the Nominating and Corporate Governance Committee.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and the related notes included in this Quarterly Report and those in our Annual Report on Form 10-K. 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 on Form 10-Q 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 clinical-stage medical technology company developing a non-thermal tissue treatment platform technology based upon our proprietary Nano-Pulse Stimulation ("NPS") technology and pursuing applications in oncology, dermatology, general tissue treatment and veterinary medicine. 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 of clinical applications for NPS, including oncology, dermatology, aesthetics and other minimally invasive applications where we believe NPS has the potential to compare favorably with current therapies and treatments. We are currently conducting research and development activities in pursuit of commercial applications for our NPS technology, but we have not yet commercialized or recognized revenue from our technology.

Plan of Operation

We plan to establish ourselves as a medical technology company with a local, non-thermal, and drug-free treatment platform that initiates cell death in targeted tissue by a process of cell signaling and also induces a systemic adaptive immune response to the targeted tissue. In order to accomplish this, we plan to:

- Improve our technology by continuing our research and product development efforts. We expect to develop different devices to target different tissue types that will leverage the novel characteristics of our technology platform.
- Further explore and understand the benefits of NPS with the objectives of broadening the currently planned cosmetic and therapeutic applications and identifying new applications. We anticipate that results of our pre-clinical and clinical studies will enable us to recognize certain unmet medical needs that may be addressed by our technology.
- Continue to protect and expand our intellectual property portfolio 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.
- Partner with medical or biomedical device companies for certain applications which we anticipate may accelerate product development and 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 Annual Report on Form 10-K as of and for the year ended December 31, 2016.

Recent Accounting Pronouncements

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

Results of Operations

Comparison of the three-month periods ended September 30, 2017 and 2016

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

	Three-Month Periods Ended September 30,		
(in thousands)	2017	2016	$ Change
Revenue	$ —	$ —	$ —
Operating expenses:			
General and administrative	4,159	893	3,266
Research and development	3,200	1,739	1,461
Amortization of intangible assets	166	166	—
Total operating expenses	7,525	2,798	4,727
Other income:			
Interest income	39	31	8
Total other income	39	31	8
Net loss	$ (7,486)	$ (2,767)	$ 4,719

General and Administrative

General and administrative expenses increased by $3,266,000 to $4,159,000 for the three-month period ended September 30, 2017, from $893,000 during the same period in 2016 primarily due to $2,596,000 of increased stock-based compensation expense, $264,000 of increased compensation costs, $211,000 of increased professional and consulting costs, and $46,000 of increased insurance costs. Stock-based compensation increased principally due to the higher Black-Scholes values and grant date intrinsic value ascribed to options and restricted stock units, respectively, granted during 2017. These higher values can be attributed to the increase in the fair market value of our common stock which is a primary component in valuing equity grants leading to stock-based compensation. Headcount increases during 2017 also contributed to increased stock-based compensation as well as compensation costs more broadly. General and administrative expenses are expected to increase substantially during 2017 compared to 2016 and this growth is expected to continue into and through 2018 reflecting the buildout of additional operational infrastructure to support the increased level of clinical and development activities, in addition to increased operational compliance activities.

Research and Development

Research and development expenses increased by $1,461,000 to $3,200,000 for the three-month period ended September 30, 2017, from $1,739,000 during the same period in 2016 due primarily to $517,000 of increased stock-based compensation costs, $337,000 of increased clinical trial costs, $303,000 of increased compensation costs, $112,000 of increased prototype and development supplies costs and $88,000 of increased depreciation expense. Stock-based compensation increased principally due to the higher Black-Scholes values and grant date intrinsic value ascribed to options and restricted stock units, respectively, granted during 2017. Headcount increases during 2017 also contributed to increased stock-based compensation as well as compensation costs more broadly. Clinical trial costs increased due to the Company's clinical study of NPS for the treatment of seborrheic keratosis. This study was initiated and conducted during 2017. Prototype and development supplies increased due to timing of component part acquisitions as additional clinical systems we assembled for current and planned clinical trials and next generation systems were being designed. Increases in depreciation expense are primarily attributable to the depreciation of leasehold improvements recorded to property and equipment in the second quarter of 2017. Research and development expenses are expected to continue to increase substantially during 2017

compared to 2016 and into and through 2018 as we expand our clinical study activities by initiating additional studies, continue development and enhancement of our PulseTx system in preparation for additional clinical trials and commercialization, and pursue regulatory clearance for our technology.

Comparison of the nine-month periods ended September 30, 2017 and 2016

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

	Nine-Month Periods Ended September 30,		
(in thousands)	2017	2016	$ Change
Revenue	$ —	$ —	$ —
Operating expenses:			
General and administrative	9,151	2,063	7,088
Research and development	7,333	4,182	3,151
Amortization of intangible assets	499	499	—
Total operating expenses	16,983	6,744	10,239
Other income:			
Interest income	119	35	84
Total other income	119	35	84
Net loss	$ (16,864)	$ (6,709)	$ 10,155

General and Administrative

General and administrative expenses increased by $7,088,000 to $9,151,000 in the nine-month period ended September 30, 2017, from $2,063,000 in the same period in 2016 due primarily to $4,809,000 of increased stock-based compensation expense, $1,000,000 of increased professional and consulting costs, $744,000 of increased compensation costs, $168,000 of increased insurance costs, $94,000 of increased office supplies costs and $92,000 of increased travel expenses. Stock-based compensation increased principally due to the higher Black-Scholes values and grant date intrinsic value ascribed to options and restricted stock units, respectively, granted during 2017. Headcount increases during 2017 also contributed to increased stock-based compensation as well as compensation costs more broadly. Professional, consulting and insurance costs increased primarily as a result of increased costs incurred due to operations and reporting obligations as a public company. The increase in office supplies costs was due to the Company's move to new office space in the third quarter of 2017.

Research and Development

Research and development expenses increased by $3,151,000 to $7,333,000 in the nine-month period ended September 30, 2017, from $4,182,000 in the same period in 2016 due primarily to $967,000 of increased stock-based compensation costs, $692,000 of increased consulting and outside services costs, $674,000 of increased compensation costs, $558,000 of increased clinical trial expense, $93,000 of increased depreciation expense and $99,000 of increased other expenses, partially offset by $79,000 of decreased sponsored research expenses. Stock-based compensation increased principally due to the higher Black-Scholes values and grant date intrinsic value ascribed to options and restricted stock units, respectively, granted during 2017. Headcount increases during 2017 also contributed to increased stock-based compensation as well as compensation costs more broadly. Consulting and outside services increased due to increased product development activities, including those around the 510(k) submission to the FDA. Clinical trial costs increased due to the Company's clinical study of NPS for the treatment of seborrheic keratosis that was initiated and conducted during 2017. Increases in depreciation expense are primarily due to the depreciation of leasehold improvements recorded to property and equipment in the second quarter of 2017.

Sponsored research expenses decreased mainly due to the timing of sponsored research activities conducted by Old Dominion University Research Foundation ("ODURF") during the nine-month period ended September 30, 2017 compared to the corresponding period in 2016. Prototype and development supplies increased due to timing of component part acquisitions as additional clinical systems we assembled for current and planned clinical trials and next generation systems were being designed.

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 inception, we have funded our business through 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 operating as a public company.

During February 2017, we entered into a securities purchase agreement with Robert W. Duggan and Maky Zanganeh (the "Investors"), pursuant to which we, in a private placement, issued and sold to the Investors an aggregate of 819,673 shares of our common stock, par value $0.001 per share, at a price per share of $6.10, for net proceeds of approximately $4,965,000.

During September 2017, we entered into a securities purchase agreement with Robert W. Duggan, pursuant to which we, in a private placement, issued and sold to Robert W. Duggan an aggregate of 2,000,000 shares of our common stock, par value $0.001 per share, at a price per share of $15.02, for net proceeds of approximately $29,876,000.

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

	Nine-Month Periods Ended September 30,	
(in thousands)	2017	2016
Net cash used in operating activities	$ (7,124)	$ (5,733)
Net cash provided by (used) in investing activities	2,264	(14,160)
Net cash provided by financing activities	35,194	20,915
Net increase in cash	30,334	1,022

At September 30, 2017, we had cash, cash equivalents and investments of $42.0 million. We believe that our existing cash, cash equivalents and investments will be sufficient to fund our projected operating requirements through the next twelve months; however, we plan to raise additional capital in the future. 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. If we raise funds by issuing equity or equity-linked securities, our stockholders will be diluted and the holders of new equity securities may have priority rights over our existing stockholders. If adequate funds are not available, we may be required to curtail operations significantly or to obtain funds by entering into agreements on unattractive terms. Our inability to raise capital could have a material adverse effect on our business, financial condition and results of operations.

Operating Activities

Our primary uses of cash in operating activities are for ongoing product development.

During the nine-month period ended September 30, 2017, we used cash of $7.1 million in operating activities. The difference between cash used in operating activities and net loss consisted primarily of stock-based compensation and depreciation and amortization, cash received from our landlord for tenant improvements, a net increase in accounts payable and accrued expenses, partially offset by increased prepaid expenses and other current assets and other assets.

During the nine-month period 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.

Investing Activities

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

During the nine-month period ended September 30, 2017, $4.7 million of cash was provided by net maturities of investments, partially offset by $2.4 million of cash used for leasehold improvement and equipment purchases.

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

Financing Activities

During the nine-month period ended September 30, 2017, cash provided from financing activities was $35.2 million primarily due to private placements in February 2017 and September 2017, as well as cash received from stock option and warrant exercises.

During the nine-month period 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.

Contractual Obligations

There have been no material changes outside the ordinary course of our business to the contractual obligations disclosed in our 2016 Annual Report on Form 10-K.

Frank Reidy Research Center Agreement

As provided for in the license agreement with ODURF and Eastern Virginia Medical School, effective on November 6, 2014, we sponsored certain approved research activities at ODURF's Frank Reidy Research Center under a sponsored research agreement. In June 2017, we agreed to sponsor $740,000 in research from July 1, 2017 to June 30, 2018. During the three-month periods ended September 30, 2017, we paid and incurred costs relating to the sponsored research agreement equal to $260,000. During the nine-month periods ended September 30, 2017, we paid and incurred costs relating to the sponsored research agreement equal to $585,000.

In addition, during 2017, we agreed to provide $300,000 in research funding to researchers affiliated with ODURF and Eastern Virginia Medical School matching funds made available to those researchers by the Virginia Biosciences Health Research Corporation. Our sponsorship affords access to certain intellectual property, if any, developed during the project. As of September 30, 2017, there was approximately $150,000 remaining under this sponsorship.

Operating Leases

We leased approximately 4,300 square feet of corporate offices and research facilities in Burlingame, California, at a monthly cost of approximately $21,000. This lease expired on June 30, 2017.

In January 2017, we entered into a new lease agreement (the "Lease") for premises consisting of approximately 15,697 rentable square feet located in Hayward, California (the "Premises").

We took possession of the Premises in late June 2017 and moved into the Premises in July 2017. The Premises is being used for our corporate headquarters and principal operating facility. The term of the Lease is sixty-two (62) months which commenced on July 1, 2017. Base rent was abated for the first two (2) months of the Lease term and thereafter will be $42,400 per month during the first year of the Lease term, with specified annual increases thereafter until reaching approximately $50,300 per month during the last two (2) months of the Lease term. We paid a refundable security deposit of approximately $101,000. The landlord is obligated to provide us with improvement allowances in the amount of approximately $135.00 per rentable square foot of the Premises, which has and will be applied towards the costs of construction of the initial improvements in the Premises. We will be responsible for any such improvement costs in excess of the foregoing allowances. We may also be required to reimburse the landlord for certain expenses during the Lease term. We have the right to extend the Lease term by five (5) years upon written notice not more than twelve (12) months nor less than nine (9) months prior to the expiration of the original Lease term, with monthly payments equal to the "Fair Rental Value" as defined in the Lease. Our lease obligations as of December 31, 2016 for less than one year, one to three years, three to five years and more than five years is approximately $0.3 million, $1.1 million, $1.1 million and $0.3 million, respectively.

Off-Balance Sheet Arrangements

At September 30, 2017, we did not have any transactions, obligations or relationships that constitute off-balance sheet arrangements.

In the ordinary course of business, we enter into standard indemnification arrangements. Pursuant to these arrangements, we indemnify, hold harmless, and agree to reimburse the indemnified parties for losses suffered or incurred by

the indemnified party in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology, or from claims relating to our performance or non-performance under a contract. The maximum potential amount of future payments we could be required to make under these agreements is not determinable because it involves claims that may be made against us in future periods, but have not yet been made. To date, we have not incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

We also enter and have entered into indemnification agreements with our directors and officers that may require us to indemnify them against liabilities that arise by reason of their status or service as directors or officers, except as prohibited by applicable law. In addition, we may have obligations to hold harmless and indemnify third parties involved with our fundraising efforts and their respective affiliates, directors, officers, employees, agents or other representatives against any and all losses, claims, damages and liabilities related to claims arising against such parties pursuant to the terms of agreements entered into between us and such third parties in connection with such fundraising efforts. No liability associated with such indemnification agreements has been recorded as of September 30, 2017.

JOBS Act Accounting Election

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Trends, Events and Uncertainties

Research and development of new technologies are, by their nature, unpredictable. Although we undertake development efforts with commercially reasonable diligence, there can be no assurance that the net proceeds from our financings will be sufficient to enable us to develop our technology to the extent needed to generate future sales to sustain our operations. If we do not continue to have enough funds to sustain our operations, we will consider other options to continue 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 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 currently 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, including our Chief Executive Officer and our Chief Financial Officer, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934, as amended, as of September 30, 2017. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were not effective at the reasonable level of assurance due to a material weakness in internal control over financial reporting discussed below (a) to ensure that information that we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and (b) to include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

In connection with the audit of our financial statements as of and for the year ended December 31, 2016, we identified a material weakness in our internal control over financial reporting. The material weakness related to a lack of effective controls to adequately restrict access and segregate duties. Specifically, due to the limited number of staff in our accounting function, certain personnel had the ability to prepare and post journal entries without a qualified independent review performed by someone without this ability. Upon identifying this material weakness, we performed additional procedures to evaluate the impact on the financial statements. Based on these procedures, we believe the material weakness did not result in any material misstatements to our financial statements and we believe the consolidated financial statements included in this Quarterly Report present, in all material respects, our financial position, results of operations, comprehensive loss and cash flows for the periods presented in conformity with U.S. generally accepted accounting principles. However, this material weakness could result in a misstatement of our accounts or disclosures that would result in a material misstatement of our financial statements that would not be prevented or detected. We are implementing measures designed to improve our internal control over financial reporting to remediate this material weakness, including the following:

- We are evaluating our accounting system access rights so that there are accounting personnel without journal entry access who can perform review activities.
- We are formalizing our internal control documentation and strengthening supervisory reviews by our management.
- We have added, and are in the process of adding, additional accounting personnel and will be segregating duties amongst accounting personnel.

Our remediation efforts are in process and have not yet been completed. We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weakness in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

Changes in Internal Control over Financial Reporting

Except for the remediation efforts described above, there have been no changes in our internal control over financial reporting that occurred during the nine-month period ended September 30, 2017, 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, employment and other matters 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

Investing in our common stock involves a high degree of risk. 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, including our financial statements and related notes, which could have a material adverse effect on our business, financial condition, results of operations and prospects. The risks described below are not the only risks facing us. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially affect our business, financial condition, results of operations and prospects.

Risks Relating to Our Business, Industry and Financial Condition

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 are a clinical-stage medical technology company and 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. We have incurred significant operating losses in each year since our inception and we expect to continue to incur additional loses for the next several years. In addition, a high percentage of our expenses will continue to be fixed; accordingly, our losses may be greater than expected and our operating results may suffer. We have limited historical financial data upon which we may base our projected revenue and base our planned operating expenses. Our limited operating history makes it difficult for potential investors to evaluate our technology or prospective operations and business prospects.

We currently have no commercial products or product revenue and may never become profitable.

To date, we have not generated revenue and have relied on equity-based financing from the sale of securities to fund our operations. We expect that our future financial results will depend primarily on our success in obtaining approval for, launching, selling and supporting our PulseTx™ System or other products based on Nano Pulse Stimulation, or NPS; however, our technology is still in development. 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, and other operational personnel, and the continued development of relationships with potential partners. We are incurring significant operating losses, we expect to continue to incur additional loses for the next several years, 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.

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

We anticipate needing additional financing to execute our business plan and fund operations, which additional financing may not be available on reasonable terms or at all.

Our ability to continue as a going concern ultimately depends on our ability to generate cash flow from sales that are sufficient to fund operations or to find adequate financing to support our operations. Currently, we have no revenue and we do not have arrangements in place for all the anticipated, required financing to be able to fully implement our business plan.

We cannot give any assurance that we will be able to obtain all the necessary funding that we may need. We believe that we will require additional capital in the future to fully develop our technologies and planned products to the stage of a commercial launch. We have pursued and 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. If we raise funds by issuing equity or equity-linked securities, dilution to our stockholders will result. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings could impose significant restrictions on our operations. We also may seek government based financing, such as development and research grants. There can be no assurance that funds will be available on commercially reasonable terms, if at all.

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

If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, delay clinical trials necessary to market our products, or delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products. If this were to occur, our ability to grow and support our business and to respond to market challenges could be significantly limited or we may be unable to continue operations, in which case you could lose your entire investment.

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

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

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

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

We 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.

The medical technology, medical device, biotechnology and pharmaceutical industries are characterized by intense and dynamic competition to develop new technologies and proprietary therapies. 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.

We may also face increased competition in the future as new companies enter our markets and as scientific developments surrounding electro-signaling therapeutics continue to accelerate. While we will seek to expand our technological capabilities to remain competitive, research and development by others may render our technology or product candidates obsolete or noncompetitive or result in treatments or cures superior to any therapy developed by us. As a result, we may not be able to compete effectively against current and potential future competitors or their devices and products.

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

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

We 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.

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

Any growth that we experience in the future could provide challenges to our organization, requiring us to expand our sales personnel and manufacturing operations and general and administrative infrastructure. Future growth will impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. Rapid expansion in personnel could mean that less experienced people carry out our research and development activities, manufacture our PulseTx System devices and market and sell our NPS technology, therapies and treatments, which could result in inefficiencies and unanticipated costs, reduced quality and disruptions to our operations. In addition, rapid and significant growth may strain our administrative and operational infrastructure, and the failure to continue to upgrade our

technical, administrative, operating and financial control systems or the occurrence of unexpected expansion difficulties could have a material adverse effect on our business, financial condition and results of operations and our ability to timely execute our business plan. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

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

The life sciences industries are characterized by rapid and significant technological changes, frequent new product introductions and enhancements and evolving industry standards. Our future success will depend on our ability to continually develop and then improve the products that we design and to develop and introduce new products that address the evolving needs of our customers on a timely and cost-effective basis. 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.

Security breaches, loss of data and other disruptions to us or our third-party service providers could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we, and our third-party service providers may collect and store sensitive data, including legally protected health information, personally identifiable information about our patients, information related to our trials, intellectual property, and our proprietary business and financial information. We manage and maintain our applications and data utilizing a combination of on-site and vendor-owned systems. We face a number of risks related to our protection of, and our service providers' protection of, this critical information, including loss of access, unauthorized disclosure and unauthorized access, as well as risks associated with our ability to identify and audit such events.

Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or otherwise breached due to employee error, malfeasance or other activities. While we have not experienced any such attack or breach, if such an event were to occur, our networks would be compromised and the information we store on those networks could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to process tests, provide test results, provide services, conduct research and development activities, collect, process and prepare company financial information, provide information about our product candidates and manage the administrative aspects of our business and could damage our reputation, any of which could adversely affect our business.

In addition, the interpretation and application of federal and state consumer, health-related and data protection laws in the United States are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices, systems and compliance procedures in a manner adverse to our business.

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

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

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

For example, if we pursue clinical trials in the field of oncology, patients with the types and stages of cancer targeted by our NPS technology may already be in severe and advanced stages of disease, may have worsened conditions despite traditional therapies, may not be surgical candidates, and/or may have both known and unknown significant pre-existing and potentially life-threatening conditions. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to our NPS Technology or our PulseTx System. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market those products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our product, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval processes, or impact and limit the type of regulatory approvals our products could receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could harm our business.

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

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

We have incurred net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. If not utilized, the federal and state NOL carryforwards will begin to expire in various years beginning after 2032. Under the Internal Revenue Code of 1986, as amended, or the Code, and certain similar state tax provisions, a corporation is generally allowed a deduction for net operating losses, or NOLs, carried over from a prior taxable year. Under those provisions, we can carry forward our NOLs to offset our future taxable income, if any, until such NOLs are used or expire. The same is true of other unused tax attributes, such as tax credits.

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

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

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

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

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our second annual report following our initial public offering, which will be the year ending December 31, 2017, provide a management report on internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

In connection with the audit of our financial statements as of and for the year ended December 31, 2016, we identified a material weakness in our internal control over financial reporting. The material weakness related to a lack of effective controls to adequately restrict access and segregate duties. Specifically, due to the limited number of staff in our accounting function, certain personnel had the ability to prepare and post journal entries without a qualified independent review performed by someone without this ability. Upon identifying this material weakness, we performed additional procedures to evaluate the impact on the financial statements. Based on these procedures, we believe the material weakness did not result in any material misstatements to our financial statements. However, this material weakness could result in a misstatement of our accounts or disclosures that would result in a material misstatement of our financial statements that would not be prevented or detected. We are implementing measures designed to improve our internal control over financial reporting to remediate this material weakness, including the following:

- We are evaluating our accounting system access rights so that there are accounting personnel without journal entry access who can perform review activities.
- We are formalizing our internal control documentation and strengthening supervisory reviews by our management.
- We have added, and are in the process of adding, additional accounting personnel and will be segregating duties amongst accounting personnel.

We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weakness in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

In addition to the remediation efforts related to the material weakness described above, we are in the process of designing and implementing internal control over financial reporting required to comply with Section 404 of the Sarbanes Oxley Act. This process will be time consuming, costly and complicated. If during the evaluation and testing process, we identify one or more other material weaknesses in our internal control over financial reporting, our management will be unable to assert that our internal control over financial reporting is effective. Even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may conclude that

there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed. If we are unable to assert that our internal control over financial reporting is effective, or when required in the future, if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

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 Product Development

We currently do not have any products approved or cleared by the FDA or other similar foreign regulatory authorities for commercial sale 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 planned products for NPS;
- we may not be able to obtain regulatory approvals for our planned 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 or 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.

If we fail to obtain and maintain necessary regulatory clearances or approvals for our devices, or if clearances or approvals for future devices and indications are delayed or not issued, our commercial operations would be harmed.

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

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

Before a new medical device, or a new intended use for, an existing device can be marketed in the United States, a company must first submit and receive either 510(k) clearance or premarketing approval, or PMA from the FDA, unless an exemption applies. In the 510(k) clearance process, the FDA will determine that a proposed device is “substantially equivalent” to a device legally on the market, known as a “predicate” device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-

supporting or implantable devices. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). Either process can be expensive, lengthy and unpredictable. We may not be able to obtain the necessary clearances or approvals or may be unduly delayed in doing so, which could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the device, which may limit the market for the device. For example, during September 2017, the FDA requested that we submit additional data in connection with our application seeking clearance of our PulseTx System for soft tissue ablation. Subsequent to this FDA request, we chose to withdraw our application, so as to enable us to collect additional data and with the intent of submitting the data in a subsequent application.

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

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

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

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

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 therapies, devices, treatment modalities, and related products based on our NPS technology. NPS applications are 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 may increase our need for capital and result in additional losses. In addition, the potential indications for NPS are numerous, and we may fail to pursue the most optimal indications. If we cannot complete, or if we experience significant delays in developing our technology, applications 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.

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

The exact mechanism(s) of action(s) of NPS is not fully understood, and data is still being gathered regarding its use. Furthermore, there are only a relatively small number of scientists and researchers who can be considered experts in the use of this emerging technology. A full understanding of a future product’s mechanism of action and a large stable of scientific experts are typically believed to make product development less risky. The FDA or similar foreign regulatory authorities may view this as increasing the potential risks, and diminishing the potential benefits, of products based on NPS technology. In addition, potential partners may view this as a limitation of the program, and it may be more challenging for us to obtain a partnership on favorable terms as a result.

NPS or our planned products may cause serious adverse side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial desirability of an approved label or result in significant negative consequences following any marketing approval.

The risk of failure of clinical development is high. For example, the vast majority of our *in vivo* data has been a result of animal testing, and we have only recently begun our first pilot study in humans. It is impossible to predict when or if this or any planned products will prove safe enough to receive regulatory approval. Undesirable side effects caused by NPS or any of our planned products could cause us or regulatory authorities to interrupt, delay or halt clinical trials. They could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority.

Additionally, if NPS or any of our planned products receive marketing approval but, we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- we may be forced to recall such product and suspend the marketing of such product;
- regulatory authorities may withdraw their approvals of such product;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such products;
- the FDA or other regulatory authorities may issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- the FDA may require the establishment or modification of Risk Evaluation Mitigation Strategies or a comparable foreign regulatory authority may require the establishment or modification of a similar strategy that may, for instance, restrict distribution of our products and impose burdensome implementation requirements on us;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to subjects or patients;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

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

Our business is dependent upon physicians adopting our NPS technology, and if we fail to obtain broad adoption, our business would be adversely affected.

If we obtain regulatory approval for an NPS application or product, our success will depend on our ability to educate physicians regarding the benefits of NPS, such as our PulseTx System, over existing treatment modalities and to persuade them to prescribe PulseTx System treatments for their patients. We do not know if NPS will be successful over the long term, and market acceptance may be hindered if physicians are not presented with compelling data demonstrating the efficacy of our service compared to alternative treatments. Any studies we, or third parties, may conduct comparing our NPS technology with alternative treatments may be expensive, time consuming or may not yield positive results. Additionally, adoption will be directly influenced by a number of financial factors, including the ability of providers to attract cash reimbursement from patients or to obtain sufficient reimbursement from third party commercial payors, and the Centers for Medicare & Medicaid Services, or CMS, for the professional services they provide in administering NPS treatments. The efficacy, safety, performance and cost-effectiveness of our NPS technology, PulseTx System or other potential products based on NPS technology, on a stand-alone basis and relative to competing services, will determine the availability and level of reimbursement received by us and providers. If physicians do not adopt and prescribe our future products, we may never become profitable.

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

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

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

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

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

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

We may encounter manufacturing problems or delays that could result in lost revenue. Additionally, we currently rely on third-party suppliers for critical materials needed to manufacture NPS devices such as the PulseTx System and related applicators and, if we obtain regulatory approval, our planned products. Any problems experienced by these suppliers could result in a delay or interruption of their supply to us, and as a result, we may face delays in the development and commercialization of planned products.

We perform final assembly of our devices to support our current research and development activities at our facility in California. We believe we have adequate manufacturing capacity for these purposes. However, if demand for our planned products increases significantly, we will need to either expand our manufacturing capabilities or outsource to other manufacturers. We have no corporate experience in commercial-scale manufacturing of our planned products, and we currently rely upon third-party suppliers to manufacture and supply components for our NPS devices. The manufacture of these products in compliance with the FDA's regulations requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medical device products often encounter difficulties in production, including difficulties with production costs and yields, quality control, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced FDA requirements, other federal and state regulatory requirements, and foreign regulations.

We currently purchase components for our NPS devices under purchase orders and do not have long-term contracts with most of the suppliers of these materials. If suppliers were to delay or stop producing our components, or if the prices

they charge us were to increase significantly, or if they elected not to sell to us, we would need to identify other suppliers. We could experience delays in manufacturing the devices while finding another acceptable supplier, which could impact our results of operations.

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 therapies, technologies and devices. Insurance coverage and reimbursement is not assured. It typically takes a period of use in the market place before coverage and reimbursement is granted, if it 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 planned products, we would expect to earn only diminished revenues, if any revenues are earned.

Medicare, Medicaid, health maintenance organizations and other third-party payers are increasingly attempting to contain healthcare costs by limiting both the scope of coverage and the level of reimbursement of new medical technologies and products, and as a result, they may not cover or provide adequate payment for the use of our planned 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 planned 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 technologies and products in a variety of ways, depending on where and how the item is used. However, Medicare only provides reimbursement if CMS determines that the item should be covered and that the use of the device or product is consistent with the coverage criteria. A coverage determination can be made at the local level by the Medicare administrative contractor, a private contractor that processes and pays claims on behalf of CMS for the geographic area where the services were rendered, or at the national level by CMS through a national coverage determination. There are statutory provisions intended to facilitate coverage determinations for new technologies, but it is unclear how these 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 technology, 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 work with outside scientists and their institutions in developing product candidates. These scientists may have other commitments or conflicts of interest, which could limit our access to their expertise and harm our ability to leverage our discovery platforms.

We work with scientific advisors and collaborators at academic research institutions in connection with our product development. These scientists and collaborators are not our employees, but they serve as either independent contractors or researchers under research agreements that we have with their sponsoring clinic, academic institution or research institution. Such scientists and collaborators may have other commitments that would limit their availability to us. Although our scientific advisors generally agree not to do competing work, if an actual or potential conflict of interest between their work for us and their work for another entity arises, we may lose their services. It is also possible that some of our valuable proprietary knowledge may become publicly known through these scientific advisors if they breach their confidentiality agreements with us, which would cause competitive harm to our business.

Risks Related to Intellectual Property

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 must 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. Generally, the loss of any one of our current licenses, or any other license we may acquire in the future, could harm our business, prospects, financial condition and results of operation.

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

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

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

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

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

In addition to patented technology, we rely upon, among other things, unpatented proprietary technology, processes, trade secrets and know-how. Any involuntary disclosure to or misappropriation by third-parties of our confidential or proprietary information could enable competitors to duplicate or surpass our technological achievements, potentially eroding our competitive position in our market. We seek to protect confidential 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 or our licensors 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. If we or any current licensors or future licensees or licensors with rights to prosecute, assert or defend patents related to our product candidates fail to appropriately prosecute and maintain patent protection for patents covering any of our product candidates, or if patents covering any of our product candidates are asserted against infringers or defended against claims of invalidity or unenforceability in a manner which adversely affects such coverage, our ability to develop and commercialize any such product candidate may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. 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.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information, which would harm our competitive position.

In addition to patents, we rely on trade secrets, technical know-how and proprietary information concerning our business strategy and product candidates in order to protect our competitive position, which are difficult to protect. As we collaborate with various third parties on the research and development of our planned products, we must, at times, share trade secrets with them. In the course of our research and development activities and our business activities, we rely on confidentiality agreements to protect our proprietary information. Such confidentiality agreements are used, for example, when we talk to vendors or potential strategic collaborators. In addition, each of our employees and consultants is required to sign a confidentiality agreement and invention assignment agreement upon joining our company. Our employees, consultants, contractors, business partners or outside scientific collaborators might intentionally or inadvertently disclose our trade secret information in breach of these confidentiality agreements or our trade secrets may otherwise be misappropriated. Our collaborators might also have rights to publish data, and we might fail to apply for patent protection prior to such publication. It is possible that a competitor will make use of such information, and that our competitive position will be compromised. In addition, to the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States sometimes are less willing than U.S. courts to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how, and our trade secrets cannot be enforced against such independently developed knowledge. If we cannot maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information would be jeopardized, which would adversely affect our competitive position.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our independent contractors, collaborators and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our

product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could harm our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. We believe this is caused by both the technical nature of the subject matter and a general enthusiasm for generic competition in developing countries, and is not a concern that is specific to any particular foreign jurisdiction. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We have not yet registered some of our trademarks in all of our potential markets, and failure to secure those registrations could adversely affect our business.

If we apply to register our trademarks in all of our potential markets, our applications may not be allowed for registration, and our registered trademarks may not be maintained or enforced. In addition, in the U.S. Patent and Trademark Office and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also may affect patent litigation. These also include provisions that switched the United States from a “first-to-invent” system to a “first-to-file” system, allow third party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the

enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

Risks Related to Government Regulation

We may never receive regulatory approval, including that from the FDA, for any of our planned products.

We may never receive regulatory approvals, including from the FDA, for any potential therapies, devices or products in the United States or in any foreign market. For example, during September 2017, the FDA requested that we submit additional data in connection with our application seeking clearance of our PulseTx System for soft tissue ablation. Subsequent to this FDA request, we chose to withdraw our application, so as to enable us to collect additional data and with the intent of submitting the data in a subsequent application. As such, it is highly speculative as to any timing for our planned products to be approved or commercialized. 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 therapies, devices and products. Any unfavorable regulatory action may materially and adversely affect our future financial condition and business operations and prospects.

Our potential therapies, 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 similar foreign regulatory authorities. To varying degrees, each of these agencies monitors and enforces our compliance with laws and regulations governing the development, testing, manufacturing, labeling, marketing, distribution, and the safety and effectiveness of our medical technology. The process of obtaining and maintaining marketing approval or clearance from the FDA and similar foreign regulatory authorities for new therapies, 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 therapies or devices are ineffective or pose an unreasonable health risk, the FDA or similar foreign regulatory authorities could ban such medical therapies, devices or products, detain or seize such devices or products, order a recall, repair, replacement, or refund of such devices or products, or require us to notify health professionals and others that the therapies, devices or products present unreasonable risks of substantial harm to the public health. Additionally, the FDA or similar foreign regulatory authorities may impose other operating restrictions, enjoin and restrain certain violations of applicable law pertaining to therapies, devices and products and assess civil or criminal penalties against our officers, employees, or us. The FDA and similar foreign regulatory authorities have been increasing its scrutiny of the 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 therapies, 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 planned 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 clearance or approval, as a pre-condition, we will have to conduct various preclinical and clinical tests, which may be costly and time consuming, and may not provide results that will allow us to seek regulatory approval.

The number of preclinical and clinical tests that will be required for regulatory clearance or approval varies depending on the disease or condition to be treated, the method of treatment, the nature of the device, the jurisdiction in which we are seeking approval 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 therapy, technology or 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. As part of the process for regulatory approval, we may, from time to time, elect to withdraw an application. For example, during September 2017, the FDA requested that we submit additional data in connection with our application seeking clearance of our PulseTx System for soft tissue ablation. Subsequent to this FDA request, we chose to withdraw our application, so as to enable us to collect additional data and with the intent of submitting the data in a subsequent application.

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

Even if a potential device or product of ours is cleared or approved, it may not be cleared or approved for the indications that are necessary or desirable for a successful commercialization. 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 therapies, 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 planned 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 therapies, 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 planned products. If we experience any of these occurrences our business will be materially harmed.

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.

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

We are exposed to the risk of fraud or other misconduct by our employees, collaborators, vendors, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and similar foreign regulatory authorities, provide accurate information to the FDA and similar foreign regulatory authorities, comply with data privacy and security and healthcare fraud and abuse laws and

regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. Additionally, laws regarding data privacy and security, including HIPAA, as amended by HITECH, as well as comparable laws in non-U.S. jurisdictions, may impose obligations with respect to safeguarding the privacy, use, security and transmission of individually identifiable health information such as genetic material.

Various laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Any misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause harm to our reputation. We adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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:

- results of clinical trials of our planned products or those of our competitors;
- actions by regulatory bodies, such as the FDA, that have the effect of delaying or rejecting approvals of our planned products;
- actual or anticipated fluctuations in our financial condition and operating results;
- announcements by our customers, partners or suppliers relating directly or indirectly to our products, services or technologies;
- announcements of technological innovations by us or our competitors;
- 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;
- announcements or expectations of additional financing efforts;
- sales of our common stock by us or our stockholders;
- stock price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- reports, guidance and ratings issued by securities or industry analysts; and
- general economic and market conditions.

If any of the foregoing 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.

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

If we or our stockholders, particularly our directors, executive officers and significant stockholders, sell or purchase, register for sale, or indicate an intent to sell or purchase, shares of our common stock in the public market, it may have a material adverse effect on the market price of our common stock.

We maintain a shelf registration statement on Form S-3 pursuant to which we may, from time to time, sell up to an aggregate of $150 million of our common stock, preferred stock, depositary shares, warrants, debt securities or units. We may also issue shares of common stock or securities convertible into or exercisable for our common stock from time to time in connection with financings, acquisitions, investments or otherwise. Any such issuances would result in dilution to our existing stockholders and could cause our stock price to fall.

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

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

Ownership of large numbers of shares 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, including Robert W. Duggan. Mr. Duggan, who was appointed Chairman of the Board effective November 2, 2017, beneficially owns approximately 36% of our outstanding common stock. 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 or officers, and the restriction on the stockholders being able to call a special meeting limited to holders of 10% or more of the outstanding shares of common stock, our management will not be able to greatly influence corporate actions requiring stockholder approval.

Robert W. Duggan's significant ownership position may deter or prevent efforts by other companies to acquire us, which could prevent our stockholders from realizing a control premium.

Robert W. Duggan, who was appointed Chairman of the Board effective November 2, 2017, beneficially owns approximately 36% of our outstanding common stock. As a result of Robert W. Duggan's significant ownership and position as Chairman of the Board, other companies may be less inclined to pursue an acquisition of us and therefore we may not have the opportunity to be acquired in a transaction that stockholders might otherwise deem favorable, including transactions in which our stockholders might realize a substantial premium for their shares.

Robert W. Duggan could sell or transfer a substantial number of shares of our common stock, which could depress the price of our securities or result in a change in control of our company.

Robert W. Duggan is not subject to any contractual restrictions with us on its ability to sell or transfer our common stock on the open market, in privately negotiated transactions or otherwise, and these sales or transfers could create substantial declines in the price of our securities or, if these sales or transfers were made to a single buyer or group of buyers, could contribute to a transfer of control of our company to a third party. Sales by Robert W. Duggan of a substantial number of shares, or the expectation of such sales, could cause a significant reduction in the market price of our common stock.

Four of our directors resigned in November 2017 and we added four new directors to our board of directors at such time, which may lead to changes in our operations.

Four new directors were elected to our board of directors, and four existing directors resigned from our board of directors, on November 2, 2017. One of the new directors, Robert W. Duggan, who was appointed Chairman of the Board, beneficially owns approximately 36% of our outstanding common stock. Because of these recent additions and resignations, our board of directors has not worked together as a group for an extended period of time. This change in the composition of our board of directors may lead to changes in our operations as these new directors analyze our business and contribute to the formulation of business strategies and objectives. Our operating results could be adversely affected as we adjust to new business strategies and objectives.

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

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

Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact, in ways we cannot currently anticipate, the manner in which we operate our business. Our management and other personnel have and will continue to devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations and, as a result of the new corporate governance and executive compensation related rules, regulations, and guidelines prompted by the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, and further regulations and disclosure obligations expected in the future, we will likely need to devote additional time and costs to comply with such compliance programs and rules. New laws and regulations as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002, the Dodd-Frank Act, and rules adopted by the SEC and NASDAQ, will likely result in increased costs to us as we respond to their requirements. We are currently evaluating and monitoring developments with respect to these rules and regulations, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

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

We are 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, or the 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.

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.

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

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

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

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.

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;
- stockholders may not vote by written consent;
- special meetings require a member of the board of directors or a 10% or greater stockholder to call;
- advance notice provisions for director nominations, or other business to be brought, by a stockholder at a meeting of the Company's 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.

These provisions may have the effect of entrenching our board of directors and management team or make it more difficult for stockholders to take other corporate actions, 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

Private Placements

On February 7, 2017, we entered into a securities purchase agreement with Robert W. Duggan and Maky Zanganeh (the "Investors"), pursuant to which we agreed to issue and sell to the Investors an aggregate of 819,673 shares of our common stock at a price per share of $6.10, for gross proceeds of approximately $5 million.

On September 24, 2017, we entered into a securities purchase agreement with Robert W. Duggan, pursuant to which we agreed to issue and sell to Robert W. Duggan an aggregate of 2,000,000 shares of our common stock at a price per share of $15.02, for gross proceeds of approximately $30 million (collectively with the sale of shares to the Investors on February 7, 2017, the "Private Placements").

Pursuant to these Private Placements we sold shares of our common stock to "accredited investors," as that term is defined in the Securities Act of 1933, in reliance on the exemption from registration afforded by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act and corresponding provisions of state securities or "blue sky" laws. The investors represented that they were acquiring the shares of our common stock for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof. Pursuant to each purchase agreement, we agreed to file registration statements to cover the resale of such shares of common stock and to keep such registration statement effective until the date on which all of the shares of our common stock are either sold pursuant to the registration statement or can be sold publicly without restriction or limitation under Rule 144 under the Securities Act of 1933. On June 30, 2017, we filed a registration statement on Form S-3 covering the resale of the shares of our common stock in satisfaction of such requirement with respect to the February Private Placement. With respect to the September Private Placement, we must satisfy such requirement when commercially reasonable, but in any event no earlier than January 2, 2018.

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 prospectus filed with the SEC on May 17, 2016 pursuant to Rule 424(b).

Item 3. Default Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description
3.1(1)	Amended and Restated Corporate Bylaws of the Company
10.1(2)	Securities Purchase Agreement, dated September 24, 2017, by and between the Company and Robert W. Duggan
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

(1) Incorporated by reference to Exhibit 3.1 to Registrant's Current Report on Form 8-K filed with the SEC on October 2, 2017
(2) Incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed with the SEC on September 25, 2017

* 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.

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 8, 2017

By: /s/ BRIAN B. DOW

Brian B. Dow
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

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 8, 2017

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

Exhibit 31.2

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 8, 2017

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

Exhibit 32.1

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, 2017 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:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 8, 2017

/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.