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 March 31, 2019

Or

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

For the transition period from to

Commission File Number 001-34899

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

Delaware	**46-5696597**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3957 Point Eden Way Hayward, CA	**94545**
(Address of principal executive offices)	**(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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
Emerging growth company	☒		

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**PLSE**	**The Nasdaq Stock Market**

Number of shares outstanding of the issuer's common stock as of April 29, 2019: 20,710,406

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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)	March 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,536	$ 51,103
Investments	44,265	8,480
Prepaid expenses and other current assets	550	779
Total current assets	53,351	60,362
Property and equipment, net	2,056	2,173
Intangible assets, net	5,046	5,213
Goodwill	2,791	2,791
Other asset	208	101
Total assets	$ 63,452	$ 70,640
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,200	$ 1,272
Accrued expenses	1,519	1,421
Deferred rent, current	—	415
Lease liability, current	396	—
Total current liabilities	3,115	3,108
Deferred rent, less current	—	1,198
Lease liability, less current	1,223	—
Total liabilities	4,338	4,306
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.001 par value; authorized – 50,000 shares; no shares issued and outstanding	—	—
Common stock, $0.001 par value: authorized – 500,000 shares; issued and outstanding – 20,710 shares and 20,593 shares at March 31, 2019 and December 31, 2018, respectively	21	21
Additional paid-in capital	144,887	142,032
Accumulated other comprehensive income (loss)	2	(1)
Accumulated deficit	(85,796)	(75,718)
Total stockholders' equity	59,114	66,334
Total liabilities and stockholders' equity	$ 63,452	$ 70,640

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 March 31, 2019	2018
Revenue	$ —	$ —
Operating expenses:		
General and administrative	4,401	5,383
Research and development	5,842	3,175
Amortization of intangible assets	167	166
Total operating expenses	10,410	8,724
Other income:		
Interest income	332	56
Total other income	332	56
Net loss	(10,078)	(8,668)
Other comprehensive loss:		
Unrealized gain on available-for-sale securities	3	48
Comprehensive loss	$ (10,075)	$ (8,620)
Net loss per share:		
Basic and diluted net loss per share	$ (0.49)	$ (0.51)
Weighted average shares used to compute net loss per common share — basic and diluted	20,679	16,842

See accompanying notes to the condensed consolidated financial statements.

PULSE BIOSCIENCES, INC.

Condensed Consolidated Statements of Cash Flows
(Unaudited)

(in thousands)	Three-Month Periods Ended March 31, 2019	2018
Cash flows from operating activities:		
Net loss	$ (10,078)	$ (8,668)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	162	153
Amortization of intangible assets	167	166
Stock-based compensation	2,361	3,420
Net premium amortization and discount on available-for-sale securities	(96)	(10)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	229	44
Other long-term assets	(107)	—
Accounts payable	(72)	162
Accrued expenses	98	(188)
Other current and long-term liabilities	6	(97)
Net cash used in operating activities	(7,330)	(5,018)
Cash flows from investing activities:		
Purchases of property and equipment	(45)	(34)
Purchases of investments	(44,186)	(19,157)
Maturities of investments	8,500	6,315
Sales of investments	—	24,875
Net cash provided by (used) in investing activities	(35,731)	11,999
Cash flows from financing activities:		
Proceeds from issuance of common stock under employee stock purchase plan	272	188
Proceeds from exercises of stock options	222	112
Net cash provided by financing activities	494	300
Net increase (decrease) in cash	(42,567)	7,281
Cash and cash equivalents at beginning of period	51,103	3,386
Cash and cash equivalents at end of period	$ 8,536	$ 10,667
Supplemental disclosure of noncash investing and financing activities:		
Change in unrealized gains on available-for-sale securities	$ 3	$ 48

See accompanying notes to the condensed consolidated financial statements.

PULSE BIOSCIENCES, INC.

Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

(in thousands, except per share amount)	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance, December 31, 2018	20,593	$ 21	$ 142,032	$ (1)	$ (75,718)	$ 66,334
Issuance of shares upon exercise of stock options	99	—	272	—	—	272
Issuance of shares under employee stock purchase plan	18	—	222	—	—	222
Stock-based compensation expense	—	—	2,361	—	—	2,361
Unrealized gain on available-for-sale securities	—	—	—	3	—	3
Net loss	—	—	—	—	(10,078)	(10,078)
Balance, March 31, 2019	20,710	$ 21	144,887	$ 2	$ (85,796)	$ 59,114

(in thousands, except per share amount)	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance, December 31, 2017	16,819	$ 17	$ 84,202	$ (51)	$ (38,173)	$ 45,995
Issuance of shares upon exercise of stock options	38	—	112	—	—	112
Issuance of shares under employee stock purchase plan	12	—	188	—	—	188
Stock-based compensation expense	—	—	3,420	—	—	3,420
Unrealized gain on available-for-sale securities	—	—	—	48	—	48
Net loss	—	—	—	—	(8,668)	(8,668)
Balance, March 31, 2018	16,869	$ 17	$ 87,922	$ (3)	$ (46,841)	$ 41,095

See accompanying notes to the condensed consolidated financial statements.

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

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

1. Description of the Business

Pulse Biosciences, Inc., is a bioelectric medicine company pursuing commercial introduction of its proprietary CellFX™ System utilizing the Company's proprietary Nano-Pulse Stimulation™ (NPS™) platform technology. The Company's NPS technology provides a novel, precise, non-thermal cellular treatment technology delivering nanosecond pulses of high amplitude electrical energy that clear targeted cells while sparing adjacent non-cellular tissue. The novel characteristics of the Company's NPS mechanism of action has the potential to significantly benefit patients across multiple medical applications, including dermatology, the Company's first planned commercial application.

The Company was incorporated in Nevada on May 19, 2014. On June 18, 2018, the Company reincorporated from the State of Nevada to the State of Delaware. The Company'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 revenue-generating operations, does not have cash flows from operations, and will need to raise additional capital to finance its operations. There can be no assurances that the Company will be able to obtain additional financing on acceptable terms and in the amounts necessary to fully fund its operating requirements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements ("Financial Statements") have been prepared on a basis consistent with the Company's December 31, 2018 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 of America ("U.S. GAAP"). The condensed consolidated balance sheet as of December 31, 2018 was derived from the audited consolidated financial statements as of that date, but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. These Financial Statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018. The results of operations for the three-month period ended March 31, 2019 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. The Company evaluates its estimates and assumptions based on historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ materially from these estimates.

Recently Adopted Accounting Pronouncement

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842)* ("Topic 842"), which amended prior accounting standards for leases. The Company adopted Topic 842 on January 1, 2019, using the transition method per ASU No. 2018-11 issued on July 2018 wherein entities were allowed to initially apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Accordingly, all periods prior to January 1, 2019 were presented in accordance with the previous ASC 840, Leases, and no retrospective adjustments were made to the

comparative periods presented. The adoption of ASC 842 resulted in an increase to total assets and liabilities due to the recording of operating lease right-of-use assets ("ROU") presented within other assets and operating lease liabilities of approximately $0.1 million as of January 1, 2019. The adoption did not materially impact the Company's Consolidated Statement of Stockholders' Equity or Cash Flows.

Significant Accounting Policies

There have been no material changes to the Company's significant accounting policies during the three-month period ended March 31, 2019, as compared to the significant accounting policies described in the Company's Annual Report on Form 10-K for the year ended December 31, 2018, except for the adoption of ASU No. 2016-02, *Leases*, as of January 1, 2019.

Principles of Consolidation

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

Net Loss per Share

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

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:

	Three-Month Periods Ended March 31,	
	2019	2018
Common stock warrants	213,485	249,709
Common stock options	2,871,770	2,598,754
Restricted stock units	222,606	229,774
Total	3,307,861	3,078,237

Reclassification

Certain items in prior period financial statements have been reclassified to conform to the presentation in the current period financial statements. Such reclassifications did not impact the Company's previously reported net loss or financial position.

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 of financial instruments into three levels, and requires that assets and liabilities carried at fair value be classified and disclosed in one of three categories, as presented below.

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

Level 2 - Inputs, other than quoted prices included within Level 1, which are directly observable for the asset or liability or indirectly observable through corroboration with observable market data. Financial assets and liabilities utilizing Level 2 inputs include commercial paper, corporate bonds, and asset-backed securities.

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

The following table sets forth the fair value of the Company's financial assets measured on a recurring basis as of March 31, 2019 and December 31, 2018, respectively (in thousands):

		March 31, 2019				December 31, 2018			
Assets	Classification	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Money market funds	Cash and cash equivalents	$ 7,773	—	—	$ 7,773	$ 50,703	$ —	$ —	$ 50,703
U.S. Treasury Securities	Investments	—	44,265	—	44,265	—	8,480	—	8,480
Total assets measured at fair value		$ 7,773	$ 44,265	$ —	$ 52,038	$ 50,703	$ 8,480	$ —	$ 59,183

The Company did not have any financial liabilities measured on a recurring basis as of March 31, 2019 or December 31, 2018.

During the three-month period ended March 31, 2019, 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):

	March 31, 2019	December 31, 2018
Leasehold improvements	$ 2,248	$ 2,248
Laboratory equipment	589	518
Furniture, fixtures, and equipment	256	248
Software	117	118
Construction in progress	—	33
	3,210	3,165
Less: Accumulated depreciation	(1,154)	(992)
	$ 2,056	$ 2,173

Depreciation expense was $0.2 million and $0.2 million for the three-month periods ended March 31, 2019 and 2018, respectively.

5. Intangible Assets, Net

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

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

	March 31, 2019	December 31, 2018
Acquired patents and licenses	$ 7,985	$ 7,985
Less: Accumulated amortization	(2,939)	(2,772)
	$ 5,046	$ 5,213

A schedule of the amortization of intangible assets for the remainder of 2019 and the succeeding five fiscal years and thereafter is as follows (in thousands):

Year Ending December 31:	
2019 (remaining 9 months)	$ 499
2020	665
2021	665
2022	665
2023	665
2024	665
Thereafter	1,222
	$ 5,046

6. Goodwill

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

The Company reviews goodwill for impairment at least annually or whenever changes in circumstances indicate that the carrying amount of goodwill may not be recoverable. Based on the Company's annual impairment test as of December 31, 2018 the Company determined that no impairment of goodwill existed and was not aware of any indicators of impairment at such date. In addition, there were no indicators of impairment at March 31, 2019.

7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2019	December 31, 2018
Compensation expense	$ 672	$ 938
Accrued clinical	429	156
Professional fees	315	274
Supplies	28	53
Other	75	—
	$ 1,519	$ 1,421

8. Stockholders' Equity and Stock-Based Compensation

Rights Offering

On October 25, 2018, the Company commenced a rights offering pursuant to which stockholders of record as of November 19, 2018, were issued, at no charge, one subscription right for each share of common stock then outstanding. Each right entitled the holder to purchase 0.19860755 share of the Company's common stock for $12.57 per share (the "Rights Offering").

Stockholders who exercised their rights in full were also permitted an over-subscription right to purchase additional shares of common stock that remained unsubscribed at the expiration of the Rights Offering, subject to the availability of shares and a pro rata allocation of shares among persons exercising the oversubscription right.

Upon the closing of the Rights Offering on December 6, 2018, the Rights Offering was oversubscribed. A total of 3,581,148 shares of the Company's common stock were issued and sold in the Rights Offering for net proceeds of approximately $44.8 million. Robert W. Duggan, the Company's Chairman of the Board of Directors and the beneficial owner of approximately 35% of the Company's outstanding common stock prior to the Rights Offering, participated in the Rights Offering and purchased an aggregate of 3,146,226 shares for an additional investment of approximately $39.5 million.

Common Stock Warrants

In connection with a private placement offering of the Company's common stock, par value $0.001 per share in 2014, the Company issued warrants as compensation to the placement agent to purchase a total of 299,625 shares of its common stock at a price of $2.67 per share (the "Private Placement Warrants"). The Private Placement Warrants are exercisable for a period of seven years. As of March 31, 2019, there were a total of 91,876 Private Placement Warrants outstanding. In connection with the closing of the Company's initial public offering in 2016, the Company issued warrants as compensation to its underwriters to purchase a total of 574,985 shares of its common stock at a price of $5.00 per share ("the IPO Warrants"). The IPO Warrants are exercisable for a period of five years. As of March 31, 2019, there were a total of 121,609 of the IPO Warrants outstanding.

Equity Plans

2017 Equity Incentive Plan and 2017 Inducement Equity Incentive Plan

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

The 2017 Plan has a 10-year term, and provides for the grant of stock options, stock appreciation rights, restricted stock, 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 may determine. Subject to an annual evergreen increase and adjustment in the case of certain capitalization events, the Company initially reserved 1,500,000 shares of the Company's common stock for issuance pursuant to awards under the 2017 Plan. In addition, shares remaining under the Company's 2015 Equity Incentive Plan, as amended (the "2015 Plan"), and shares reserved but not issued pursuant to outstanding equity awards that expire or terminate without being exercised or that are forfeited or repurchased by the Company will be added to the shares of common stock available for issuance under the 2017 Plan. The 2017 Plan is administered by the Board's Compensation Committee. Effective January 1, 2019, the Company's Board authorized an increase in the number of shares of common stock available under the 2017 Plan by 823,716 shares pursuant to the evergreen provision of the 2017 Plan. Pursuant to the 2017 Plan, the 2019 share increase is determined based on the least of (i) 1,200,000 shares, (ii) 4% of the Company's common stock outstanding at December 31 of the immediately preceding year, or (iii) such number of shares as determined by the Board. As of March 31, 2019, 1,375,516 shares of common stock were available for issuance under the 2017 Plan.

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

The Inducement Plan has a 10-year term, and provides for the grant of equity-based awards, including nonstatutory stock options, restricted stock units, restricted stock, stock appreciation rights, performance shares and performance units, and its terms are substantially similar to the 2017 Plan, including with respect to treatment of equity awards in the event of a "merger" or "change in control" as defined under the Inducement Plan. Options issued under the Inducement Plan may have a term up to ten years and have variable vesting provisions. New hire grants generally vest 25% upon the first anniversary of the grant and 1/48th monthly thereafter, over the subsequent 36 months. Equity-based awards issued under the Inducement Plan are only issuable to individuals not previously engaged as employees or non-employee directors of the Company prior to the Inducement Plan's adoption date. As of March 31, 2019, 515,250 shares of common stock were available for issuance under the Inducement Plan.

2017 Employee Stock Purchase Plan

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

The 2017 ESPP is a broad-based plan that provides employees of the Company and its designated affiliates with the opportunity to become stockholders through periodic payroll deductions that are applied towards the purchase of Company common shares at a discount from the then-current market price. Subject to adjustment in the case of certain capitalization events, a total of 250,000 common shares of the Company were available for purchase at adoption of the 2017 ESPP. Pursuant to the 2017 ESPP, the annual share increase pursuant to the evergreen provision is determined based on the least of (i) 450,000 shares, (ii) 1.5% of the Company's common stock outstanding at December 31 of the immediately preceding year, or (iii) such number of shares as determined by the Board. In January 2019, the Board determined not to increase the

number of shares of common stock available under the 2017 ESPP pursuant to the evergreen provision of the 2017 ESPP. During the three-month period ended March 31, 2019, the Company issued 18,574 shares of common stock under the 2017 ESPP. As of March 31, 2019, 459,900 shares of common stock were available for issuance under the 2017 ESPP.

A summary of stock option activity under the 2015 Plan, 2017 Plan and Inducement Plan for the three-months ended March 31, 2019 is presented below:

	Stock Options Outstanding	
	Number of shares	Weighted average exercise price
Balances — December 31, 2018	2,956,687	$ 17.04
Options granted	174,303	
Options exercised	(98,928)	
Options canceled	(9,667)	
Options expired	(150,625)	
Balances — March 31, 2019	2,871,770	$ 17.22
Exercisable — March 31, 2019	1,446,422	$ 16.06

The table above excludes 42,500 performance stock options granted during the year ended December 31, 2018 for which the performance criteria had not been established as of March 31, 2019.

Stock-based Compensation

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

	Three-Month Periods Ended March 31,	
	2019	2018
General and administrative	$ 1,485	$ 2,699
Research and development	876	721
Total stock-based compensation expense	$ 2,361	$ 3,420

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 March 31,	
	2019	2018
Expected term in years	0.4 - 6.1	6.1
Expected volatility	70%	70%
Risk-free interest rate	2.4 - 2.7%	2.7%
Dividend yield	—	—

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 March 31,	
	2019	2018
Expected term in years	0.5 - 1.0	0.5 - 1.0
Expected volatility	70%	70%
Risk-free interest rate	2.5% - 2.6%	1.9% - 2.1%
Dividend yield	—	—

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. In the three-month period ended June 30, 2017, the Company granted 160,974 RSUs all of which vested pursuant to which no shares were issued, during June 2018. Additional paid in capital was reduced by $0.1 million during 2018 for tax payments related to shares withheld in connection with the vesting of the RSUs. As of March 31, 2019, there was no unrecognized compensation expense related to these RSUs.

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 $0.1 million and $0.1 million for the three-month periods ended March 31, 2019 and March 31, 2018, respectively.

9. Research Grants and Agreements

Sponsored Research Agreement

The Company may annually sponsor research activities performed by ODURF’s Frank Reidy Research Center for Bioelectrics. During the year ended December 31, 2018, the Company agreed to sponsor $0.8 million in research during the subsequent 12-month period to be funded through monthly payments made upon ODURF certifying, to the Company’s reasonable satisfaction, that ODURF has met its obligations pursuant to the specified task order and statement of work. The principal investigator may transfer funds with the budget as needed without the Company’s approval so long as the obligations of ODURF under the task order and statement of work remain unchanged and unimpaired. As of March 31, 2019, approximately $0.4 million remained payable under this sponsorship.

In addition, during 2017, the Company agreed to provide $0.3 million 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 March 31, 2019, approximately $0.1 million remained payable under this sponsorship.

During the three-month periods ended March 31, 2019 and 2018, the Company paid and incurred costs relating to the sponsored research agreements equal to $0.2 million and $0.3 million, respectively.

10. Commitments and Contingencies

Operating Leases

During January 2017, the Company entered into a new lease agreement for premises consisting of approximately 15,700 rentable square feet located in Hayward, California. The lease commenced on July 1, 2017 and expires in August 2022, with an option to extend the lease term for an additional five years.

The Company adopted Topic 842 on January 1, 2019, using the transition method per ASU No. 2018-11 issued on July 2018 wherein entities were allowed to initially apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Accordingly, all periods prior to January 1, 2019 were presented in accordance with the previous ASC 840, Leases, and no retrospective adjustments were made to the comparative periods presented. The adoption of ASC 842 resulted in an increase to total assets and liabilities due to the recording of operating lease right-of-use assets (“ROU”) presented within other assets and operating lease liabilities of

approximately $0.1 million as of January 1, 2019. Because the rate implicit in each lease is not readily determinable, the Company uses its incremental borrowing rate to determine the present value of the lease payments.

Information related to the Company's right-of-use assets and related lease liabilities were as follows:

Cash paid for operating lease liabilities	$	132
Right-of-use assets recognized in exchange for new lease obligations		107
Current operating lease liabilities		396
Non-current operating lease liabilities		1,223
Total lease liabilities	$	1,619
Weighted average remaining lease term		3.42 years
Weighted average discount rate		10%

Maturities of lease liabilities as of March 31, 2019 were as follows (in thousands):

Year Ending December 31:		
2019 (remaining 9 months)	$	404
2020		554
2021		574
2022		392
Total lease payments		1,924
Less imputed interest		(305)
Total operating lease liabilities	$	1,619

During the three-month periods ended March 31, 2019 and 2018, rent expense, including common area maintenance charges, was approximately $59,000 and $57,000, respectively.

Legal Proceedings

The Company maintains indemnification agreements with its directors and officers that may require the Company to indemnify them against liabilities that arise by reason of their status or service as directors or officers, except as prohibited by applicable law.

From time to time, the Company may be involved in a variety of claims, lawsuits, investigations and proceedings relating to securities laws, product liability, patent infringement, contract disputes and other matters relating to various claims that arise in the normal course of our business in addition to governmental and other regulatory investigations and proceedings. In addition, third parties may, from time to time, assert claims against the Company in the form of letters and other communications. The Company currently believes 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 the Company because of defense and settlement costs, diversion of management resources and other factors.

11. Related Party Transactions

Kenneth A. Clark, a director of the Company since November 2017, is a member of the law firm of Wilson Sonsini Goodrich and Rosati (“WSGR”), which also serves as the outside corporate counsel to the Company. During the three-month periods ended March 31, 2019 and 2018, the Company incurred expenses reported in general and administrative expenses in the consolidated statement of operations for legal services rendered by WSGR totaling approximately $0.2 million and $0.3 million, respectively.

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 bioelectric medicine company pursuing commercial introduction of our proprietary CellFX™ System utilizing our patented Nano-Pulse Stimulation™ (NPS™) platform technology. With our proprietary NPS technology, we can deliver nano-second pulses of high amplitude electrical energy to non-thermally clear targeted cells while sparing adjacent non-cellular tissue. The cell-specific effect of our NPS technology has been demonstrated through a series of clinical trials. In addition, early pre-clinical evidence suggests that the NPS technology may have future applications in immuno-oncology by demonstrating an ability to induce immunogenic cell death. 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 intend to commercialize novel, proprietary, and differentiated products that have the potential to significantly improve patient outcomes in the markets we intend to serve. To achieve this plan, we intend to:

- **Demonstrate the unique benefits of our proprietary CellFX System and its unique mechanism of action across a number of compelling indications.** The CellFX System is the only tunable nanosecond pulsed energy system designed for use in human medicine of which we are aware. Our proprietary CellFX System allows for the adjustment of four key pulsing parameters: pulse duration, pulse amplitude, pulse frequency, and the number of pulses, depending on the tissue and desired treatment outcome. We have conducted or are conducting several clinical studies, including studies in Seborrheic Keratosis (SK), the most common benign raised pigmented lesion, Sebaceous Hyperplasia (SH), a common but difficult to treat facial lesion, Basal Cell Carcinoma (BCC), the most common form of skin cancer, cutaneous non-genital warts, and acne. We expect to conduct clinical studies on an ongoing basis to continue to demonstrate the value of our CellFX System across a growing list of valuable applications;

- **Commercialize our proprietary CellFX System and applications for its use across a broad array of clinical indications.** During February 2019, we submitted a Pre-Market Notification 510(k) to the U.S. Food and Drug Administration (FDA) seeking clearance to commercialize our CellFX System. Our FDA filing requests clearance of the CellFX System for commercial use in common dermatologic procedures to remove general benign lesions including SH and SK. On April 30, 2019, we received an additional information (AI) letter request from the FDA that, among other things, questioned the appropriateness of our selected predicate device provided in the 510(k). responding to this request is likely to add time and is likely to require additional testing, including clinical trials. In consideration of the above, we are reviewing options and alternatives to pursue clearance for our CellFX System, including the option of making a De Novo Request to the FDA. Pending regulatory clearance, we plan to launch our CellFX System in the United States.

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, 2018, except for the adoption of the lease accounting standard as of January 1, 2019 as disclosed in Note 2.

Recent Accounting Pronouncements

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

Segment and Geographical Information

We operate and manage our business as one reportable and operating segment. Our Chief Executive Officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. All of our long-lived assets are primarily based in the United States.

Results of Operations

Comparison of the three-month periods ended March 31, 2019 and 2018

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

	Three-Month Periods Ended March 31,		
(in thousands)	2019	2018	$ Change
Revenue	$ —	$ —	$ —
Operating expenses:			
General and administrative	4,401	5,383	(982)
Research and development	5,842	3,175	2,667
Amortization of intangible assets	167	166	1
Total operating expenses	10,410	8,724	1,686
Other income:			
Interest income	332	56	276
Total other income	332	56	276
Net loss	$ (10,078)	$ (8,668)	$ 1,410

Reclassification

Certain items in prior period financial statements have been reclassified to conform to the presentation in the current period financial statements. Such reclassifications did not impact the Company's previously reported net loss or financial position.

General and Administrative

General and administrative expenses consist of compensation and related expenses for executives, finance, legal, human resources, information technology and administrative personnel, professional fees, patent fees and costs, insurance costs and other general corporate expenses. General and administrative expenses decreased by $1.0 million to $4.4 million for the three-month period ended March 31, 2019, from $5.4 million during the same period in 2018 primarily due to $1.2 million of decreased stock-based compensation expenses and $0.2 million of decreased professional and consulting expenses, partially offset by $0.2 million of increased compensation costs and $0.1 million of increased corporate insurance costs. Stock-based compensation decreased principally due to timing of vesting of certain awards and options granted. Professional and consulting costs decreased primarily due to decreased legal costs related to corporate matters. Compensation costs

increased primarily due to increased headcount. Corporate insurance costs increased primarily due to higher insurance rates. General and administrative expenses are expected to substantially increase during 2019 in connection with the buildout of additional operational commercial and infrastructure to support the anticipated commercialization of our CellFX System in the aesthetic dermatology market.

Research and Development

Research and development expenses consist of compensation and related expenses for research and development personnel, clinical trials and consulting costs related to the design, development and enhancement of our potential future products, prototype material and devices. Research and development expenses increased by $2.7 million to $5.8 million for the three-month period ended March 31, 2019, from $3.2 million during the same period in 2018 primarily due to $0.9 million of increased compensation costs, $0.4 million of increased prototype expenses, $0.3 million of increased clinical trial costs, $0.3 million of increased consulting and outside service costs, $0.2 million of increased stock-based compensation costs, $0.2 million of increased laboratory supply and equipment costs, and $0.1 million of increased travel expenses. Compensation costs increased primarily due to increased headcount during 2018 and 2019. Prototype costs increased primarily due to our production of our CellFX System for clinical use and in preparation for commercialization. Clinical trial costs increased due to our ongoing and recently started clinical trials including, among others, basal cell carcinoma, warts, and acne. Consulting and outside service costs increased due to product development activities. Stock-based compensation expense, laboratory supplies, and equipment expenses and travel expenses increased principally due to headcount increases during 2018 and 2019, respectively. Research and development expenses are expected to continue to increase substantially during 2019 as we expand our clinical study activities by initiating additional studies, continue development and enhancement of our CellFX System in preparation for additional clinical trials.

Interest Income

Interest income increased by approximately $0.3 million to $0.3 million for the three-month period ended March 31, 2019, from $56,000 during the same period in 2018 due primarily to higher cash equivalent and investment balances.

Liquidity and Capital Resources

To date, we have not generated any revenues from product sales. Since inception, we have funded our business primarily through the issuance of equity securities. 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.

In December 2018, we completed a rights offering pursuant to which we sold an aggregate of 3,581,148 shares of our common stock, par value $0.001 per share, at a price per share of $12.57 per share, for net proceeds of approximately $44.8 million.

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

	Three-Month Periods Ended March 31,	
(in thousands)	2019	2018
Net cash used in operating activities	$ (7,329)	$ (5,018)
Net cash provided by (used) in investing activities	(35,732)	11,999
Net cash provided by financing activities	494	300
Net increase (decrease) in cash	(42,567)	7,281

At March 31, 2019, we had cash, cash equivalents and investments of $52.8 million. We believe that our existing cash, cash equivalents and investments will be sufficient to fund our projected operating requirements for at least the next twelve months from the filing date of this Quarterly Report; 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, the ownership of 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 three-month period ended March 31, 2019, we used cash of $7.3 million in operating activities. The difference between cash used in operating activities and net loss consisted primarily of depreciation and amortization and stock-based compensation, and an increase in prepaid expenses.

During the three-month period ended March 31, 2018, we used cash of $5.0 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, an increase in accounts payable, partially offset by increased prepaid expenses and other current assets and decreases in accrued liabilities and deferred rent.

Investing Activities

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

During the three-month period ended March 31, 2019, $35.7 million of cash was used in investing activities, consisting of $44.2 million of cash used to purchase available-for-sale securities partially offset by $8.5 million of cash proceeds from the maturities of investments.

During the three-month period ended March 31, 2018, $12.0 million of cash was provided from the sale of investments of $25.0 million and $6.3 million of cash proceeds from the maturities of investments, partially offset by $19.2 million cash used for the purchase of available-for-sale securities.

Financing Activities

During the three-month period ended March 31, 2019, cash provided from financing activities was $0.5 million primarily due to cash received from stock option exercises and the sale of stock under our employee stock purchase plan.

During the three-month period ended March 31, 2018, cash provided from financing activities was $0.3 million primarily due to cash received from stock option exercises and the sale of stock under our employee stock purchase plan.

Contractual Obligations

There have been no material changes outside the ordinary course of our business to the contractual obligations disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018.

Off-Balance Sheet Arrangements

At March 31, 2019, 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 March 31, 2019.

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 our CellFX System, 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 receive regulatory clearance, 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. Our market risk exposure is primarily a result of fluctuations in interest rates. We do not hold financial instruments for trading purposes.

Interest Rate and Market Risk

As of March 31, 2019 and December 31, 2018, we had cash, cash equivalents and investments totaling $52.8 million and $59.6 million, respectively, all of which have maturities of less than one year. The goal of our investment policy is preservation of capital, fulfillment of liquidity needs and fiduciary control of our cash and investments. To achieve our goal, 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 risks. We currently do not hedge interest rate exposure. A decline in interest rates would reduce our interest income; however, because of the short-term maturities of our investments, we do not believe that a hypothetical 10% change in market interest rates would have a material negative impact on the value of our investment portfolio.

On the other hand, when interest rates rise, our marketable securities purchased at a lower yield would incur a mark-to-market unrealized loss. Under certain circumstances, if we are forced to sell our marketable securities prior to maturity, we may incur realized losses in such investments. However, because of the conservative and short-term nature of the investments in our portfolio, a change in interest rates is not expected to have a material impact on our condensed consolidated financial statements.

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, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, our principal executive and principal financial officers, respectively, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934, as amended, as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of March 31, 2019, our disclosure controls and procedures were effective (a) to ensure that information that we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and (b) to include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act, as amended, that occurred during the quarter ended March 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Internal control over financial reporting means a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.

Inherent Limitations on Effectiveness of Controls

Our disclosure controls and procedures and our internal control over financial reporting are not expected to 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 legal proceedings and claims relating to securities laws, product liability, patent infringement, contract disputes, employment matters and other matters relating to the normal course of our business in addition to governmental and other regulatory investigations and proceedings. In addition, third parties may, from time to time, assert claims against us in the form of letters and other communications.

The results of legal proceedings and claims are inherently unpredictable. We do not believe any currently pending matters will have a material adverse effect on our business based on our current understanding of such matters.

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, 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 to evaluate the future of our business.

We are a bioelectric medicine 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 losses for the next several years. In addition, a high percentage of our expenses will continue to be fixed; accordingly, our losses may be greater than expected and our operating results may suffer. We have limited historical financial data upon which we may base our projected revenue and base our planned operating expenses. Our limited operating history makes it difficult to evaluate our technology 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 financing from the sale of equity 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 therapies and treatments utilizing our CellFX System or other products based on NPS technology; however, our technology is still in development and has not been approved to treat any disease or condition. We expect to expend significant resources on hiring of personnel, continued scientific and product research and development, potential product testing and pre-clinical 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 losses for at least 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 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.

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

We have experienced operating losses, and we expect to continue to incur operating losses for the next several years as we implement our business plan. Currently, we have no revenue and do not have arrangements in place for all the anticipated financing that would be required to fully implement our business plan. Our prior losses combined with expected future losses, have had and will continue to have, for the foreseeable future, an adverse effect on our stockholders' equity and working capital. While we believe we have the resources necessary to fund operations for twelve months from the date of issuance of this Quarterly Report, our inability to raise capital in the future could have a material adverse effect on our business, financial condition and results of operations. We plan to raise additional funds in the near future and intend to finance our operations through equity financings.

We cannot give any assurance that we will be able to obtain all the necessary funding that we may need. In addition, we believe that we will require additional capital in the future to fully develop 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.

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

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

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

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

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

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 sales, marketing, scientific and engineering teams. These persons have significant experience and knowledge with sub-microsecond pulsed electric fields and more broadly in aesthetics, dermatology, 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.

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.

We expect to operate in a highly competitive market, we may face competition from large, well-established medical technology, 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 face competition from a number of sources, such as pharmaceutical companies, medical device companies, generic drug companies, biotechnology companies and academic and research institutions. 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;
- greater efficacy or better safety profiles;
- established distribution networks;
- additional lines of products, and the ability to offer rebates, higher discounts or incentives to gain a competitive advantage;
- greater experience in obtaining patents and regulatory approvals for product candidates and other resources;
- 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. In addition, certain of our product candidates, if approved, may compete with other dermatological products, including over-the-counter, or OTC, treatments, for a share of some patients' discretionary budgets and for physicians' attention within their clinical practices. Even if a generic product or an OTC product is less effective than our product candidates, a less effective generic or OTC product may be more quickly adopted by physicians and patients than our competing product candidates based upon

cost or convenience. 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, large-scale 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.

We have experienced and continue to experience rapid growth in our business. Recent and future growth imposes significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. Rapid expansion in personnel could mean that less experienced people carry out our research and development activities, manufacture, market and sell CellFX System, 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.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Furthermore, the market for aesthetic medical procedures may be particularly vulnerable to unfavorable economic conditions. In particular, insurance coverage and reimbursement for aesthetic dermatology procedures using CellFX System may not be available, and, as a result, demand for this product will be tied to discretionary spending levels of our targeted patient population. A global financial crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets. A severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including weakened demand for our lead product candidates or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

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 or the California Consumer Privacy Act of 2018 (the "CCPA"), which was enacted in June 2018 and will become effective in January 2020. 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, for our 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 CellFX System or our NPS technology. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market those products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our product, the investigation into the

circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval processes, or impact and limit the type of regulatory approvals our products could receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could harm our business.

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

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

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

Our 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 2034. 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.

Further, in December 2017, the Tax Cuts and Jobs Act (the "TCJA") was enacted into law. The change in the tax law was partially effective in 2017 and fully effective in 2018. The primary impacts to us include a decrease of the corporate income tax rate structure and NOL limitations. These changes may have a material impact to the value of deferred tax assets and liabilities and our future taxable income and effective tax rate. We are assessing the TCJA with professional advisers, and believe that the impact of the TCJA on our business may not be fully known for some time, and until such analysis is complete, the full impact of the new tax law on us in future periods is uncertain, and no assurances can be made by us on any potential impacts.

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.

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

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

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. We implemented measures and remediated the material weakness in 2017; however, we cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to avoid potential future material weaknesses. The existence of one or more material weaknesses could preclude a conclusion that we maintain effective internal control over financial reporting. Accordingly, there could be a possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

We are required to disclose changes made in our internal control and procedures on a quarterly basis. However, our independent registered public accounting firm will not be required to report on the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act until we are no longer an “emerging growth company” as defined in the Jumpstart Our Business Startups Act, or JOBS Act if we continue to take advantage of the exemptions contained in the JOBS Act. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. Our remediation efforts may not enable us to avoid a material weakness in the future. If we are unable to assert that our internal control over financial reporting is effective, or when required in the future, if our independent registered public accounting firm is unable to express an 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, obtaining regulatory approval or clearance, implementing regulatory compliance standards, 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 development of any planned products;
- we may not be able to obtain regulatory approvals or clearances for our planned products, or the approved or cleared indications may be narrower than we seek;
- we may experience delays in our development program, clinical trials and the regulatory approval or clearance 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 or cleared by regulatory authorities 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.

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

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure or delay can occur at any time during the clinical trial process. Success in nonclinical studies and early feasibility clinical studies does not ensure that expanded clinical trials that will be used to support regulatory submissions will be successful. These setbacks have been caused by, among other things, nonclinical findings made while clinical trials were underway, and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval or clearance for our product candidates.

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

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

If we fail to obtain and maintain necessary regulatory clearances or approvals for our planned products, or if clearances or approvals for future devices and indications are delayed or not issued, our commercial operations would be harmed. Additionally, changes in methods of product candidate manufacturing may result in additional costs or delay.

Our product candidates under development 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, pre-clinical 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 with reasonable scientific data the safety and effectiveness of the device based on extensive data, including, but not limited to, technical, pre-clinical, 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. For example, during February 2019, we submitted a 510(k) to the FDA seeking clearance to commercialize our CellFX System. During April 2019, we received an additional information (AI) letter request from the FDA that, among other things, questioned the appropriateness of our selected predicate device provided in the 510(k). Responding to this request is likely to add time and is likely to require additional testing, including clinical trials. In consideration of the above, we are reviewing options and alternatives to pursue clearance for our CellFX System, including the option of making a De Novo request to the FDA, which is also likely to require additional time, testing, and clinical studies. 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.

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 technology. CellFX System and NPS applications are not yet fully developed. Development of the underlying technology, including the development of our CellFX 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. Regulatory and 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 our NPS technology 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 technology platform has not been fully determined or validated.

The exact mechanism(s) of action(s) of the NPS technology platform 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 scale 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.

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 completed a limited number of feasibility studies in humans. It is difficult to predict when or if this or any planned products will prove safe enough to receive regulatory approval or clearance. Undesirable side effects caused by our CellFX System, 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 any of our planned products receive marketing approval or clearance 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 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 CellFX System and NPS technology, and if we fail to obtain broad adoption, our business would be adversely affected.

If we obtain regulatory approval or clearance for our CellFX System, our success will depend on our ability to educate physicians regarding the benefits of CellFX procedures over existing treatment modalities and to persuade them to prescribe CellFX procedures for their patients. We do not know if the CellFX System or NPS technology will be successful over the long term, and market acceptance may be hindered if physicians are not presented with compelling data demonstrating the efficacy and safety of our products compared to alternative treatments. Any studies we, or third parties, may conduct comparing our CellFX System or 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 payments 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 CellFX procedures. The efficacy, safety, performance and cost-effectiveness of our CellFX System, NPS technology, 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 or clearance of planned products may be delayed. If there are delays in accumulating the required patients and patient data, there may be delays in completing the trial. Further, if any of our clinical trial sites fail to comply with required good clinical practices, or GCPs, 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, CellFX procedures 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 CellFX procedures 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 our CellFX System and related applicators. Any problems experienced by these suppliers could result in a delay or interruption of their supply to us, and as a result, we may face delays in the development and commercialization of 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 CellFX System. 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 do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, and if our contract manufacturers cannot successfully manufacture our product candidates that conform to our specifications and the strict regulatory requirements of the FDA or comparable regulatory authorities in foreign jurisdictions, we may not be able to rely on their manufacturing facilities for the manufacture of our product candidates. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds these facilities inadequate for the manufacture of our product candidates or if such facilities are subject to enforcement action in the future or are otherwise inadequate, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates.

We currently purchase components for our CellFX System 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, may be affected by the availability of government reimbursement and medical insurance coverage and reimbursement for newly approved medical therapies, technologies and devices. Insurance coverage and reimbursement 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. Each plan may separately require us to provide scientific and clinical support for the use of our products and, as a result, the coverage determination process is often a time-consuming and costly process with no assurance that coverage and adequate reimbursement will be applied consistently or obtained at all. Even if Medicare and other third-party payers decide to cover procedures involving 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 or clearance. The Medicare statutory framework is also subject to administrative rulings, interpretations and discretion that affect the amount and timing of reimbursement made under Medicare. Medicaid coverage determinations and reimbursement levels are determined on a state by state basis, because Medicaid, unlike Medicare, is administered by the states under a state plan filed with the Secretary of the 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, harm our ability to leverage our discovery platforms, or negatively impact our clinical trials.

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. To the extent these scientists and collaborators may receive cash or equity compensation in connection with such services from time to time, these relationships and any related compensation may result in perceived or actual conflicts of interest, or a regulatory authority to conclude that the financial relationship may have affected the interpretation of the trial, such that the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of the marketing application we submit.

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 Old Dominion University Research Foundation (“ODURF”) and Eastern Virginia Medical School (“EVMS”) and from Alfred E. Mann Institute for Biomedical Engineering at the University of Southern California (“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, we 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. In addition, some of our licenses from third parties limit the field in which we can use the licensed technology. Therefore, in order for us to use such licensed technology in potential future applications that are outside the licensed field of use, we may be required to negotiate new licenses with our licensors or expand our rights under our existing licenses. We cannot assure you that we will be able to obtain such licenses or expanded rights on reasonable terms or at all. In the event a dispute with our licensors were to occur, our licensors may seek to renegotiate the terms of our licenses, increase the royalty rates that we pay to obtain and maintain those licenses, limit the field or scope of the licenses, or terminate the license agreements. In addition, we have limited rights to participate in the prosecution and enforcement of the patents and patent applications that we have licensed. As a result, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. Further, because of the rapid pace of technological change in our industry, we may need to rely on key technologies developed or licensed by third parties, and we may not be able to obtain licenses and technologies from these third parties at all or on reasonable terms. The occurrence of these events may have a material adverse effect on our business, financial condition or results of operations.

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 on our intellectual property rights;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we may obtain patents for certain products many years before we obtain marketing approval for products utilizing such patents, and because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of our patents may be limited;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may fail to develop additional proprietary technologies that are patentable;
- the laws of certain foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, or we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and
- the patents of others may have an adverse effect on our business, for example by preventing us from marketing one or more of our product candidates for one or more indications.

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

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

In addition to patented technology, we rely upon, among other things, unpatented proprietary technology, processes, trade secrets and know-how. Any involuntary disclosure to or misappropriation by third-parties of our confidential or proprietary information could enable competitors to duplicate or surpass our technological achievements, potentially eroding our competitive position in our market. We seek to protect confidential 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 our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or conflict with third-party rights. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. Additionally, 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. In such cases, over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then our marketing abilities may be impacted.

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

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 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 or clearance, including that from the FDA, for any of our planned products.

We may never receive regulatory approval or clearance, including from the FDA, for any potential devices or products in the United States or in any foreign market. For example, during September 2017, we withdrew our application seeking clearance of our system for soft tissue ablation. As such, it is highly speculative as to any timing for our planned products to be approved or cleared 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 into the future.

We will be subject to stringent domestic and foreign regulation in respect of any potential devices and products. Any unfavorable regulatory action may materially and adversely affect our future financial condition and business operations and prospects.

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

- take a significant, indeterminate amount of time;
- require the expenditure of substantial resources;
- involve rigorous 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 or clearance 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. For example, in connection with the Pre-Market Notification 510(k) we submitted to the FDA seeking clearance to commercialize our CellFX System, during April 2019, we received an additional information (AI) letter request from the FDA that, among other things, questioned the appropriateness of our selected predicate device provided in the 510(k). Responding to this request is likely to add time and is likely to require additional testing, including clinical trials.

We will have ongoing responsibilities under FDA and international regulations, both before and after a product is approved or cleared and commercially released. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections. If an inspection were to conclude that we are not in compliance with applicable laws or regulations, or that any of our devices are ineffective or pose an unreasonable health risk, the FDA or similar foreign regulatory authorities could ban such devices or products, detain or seize such devices or products, order a recall, repair, replacement, or refund of such devices or products, or require us to notify health professionals and others that the therapies, devices or products present unreasonable risks of substantial harm to the public health. Additionally, the FDA or similar foreign regulatory authorities may impose other operating restrictions, enjoin and restrain certain violations of applicable law pertaining to our devices and products 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 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.

The continuing development of our CellFX™ System and other products depends upon maintaining strong working relationships with physicians.

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

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

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

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a U.S. healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the U.S. federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

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

- the U.S. Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;

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

- the CCPA will, among other things, require covered companies to provide new disclosures to California consumers and afford such consumers new abilities to opt-out of certain sales of personal information. Legislators have stated that they intend to propose amendments to the CCPA before it goes into effect in January 2020 and it remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted. We cannot yet predict the impact of the CCPA on our business or operations, but it may require us to modify our data processing practices and policies to incur substantial costs and expenses in an effort to comply;

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

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

We have implemented a comprehensive compliance program to identify and deter healthcare violations by employees and other third-parties that perform services for us. Notwithstanding our compliance program, it is possible that governmental authorities may conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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 and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the above occur, it could have a material adverse effect on our liquidity and financial condition.

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

The number of pre-clinical and clinical tests that will be required for regulatory clearance or approval varies depending on the disease or condition to be treated, the method of treatment, the nature of the device, the jurisdiction in which we are seeking approval or clearance and the applicable regulations. Regulatory agencies, including those in the United States, Canada, Europe and other 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 technology or device to be reasonably safe or effective for any intended use or indication;

- may interpret data from pre-clinical and clinical testing differently than we do;

- may determine our manufacturing facility or processes do not comply with Quality System regulations;

- may conclude that our device does not meet quality standards for durability, long-term reliability, biocompatibility, electromagnetic compatibility, or electrical safety; and
- may change their approval or clearance 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 or clearance in the U.S. and increased costs. For example, during April 2019, we received an additional information (AI) letter request from the FDA that, among other things, questioned the appropriateness of our selected predicate device provided in the 510(k). Responding to this request is likely to require additional testing, including clinical trials. As part of the process for regulatory approval or clearance, 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 system for soft tissue ablation. Subsequent to this FDA request, we chose to withdraw our 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 we complete clinical testing and a potential device or product of ours is cleared or approved, it may not be cleared or approved for the indications that are necessary or desirable for a successful commercialization. The FDA may grant marketing authorization contingent on the performance of costly additional clinical trials which may be required after approval or clearance. The FDA also may approve or clear our lead product candidates for a more limited indication or a narrower patient population than we originally requested. Our preference will be to obtain as broad an indication as possible for use in connection with the particular disease or treatment for which it is designed. However, the final 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 third-party manufacturer, will be required to adhere to FDA Quality System, which include testing, control, and documentation requirements. We will be subject to similar regulations in foreign countries. Even if regulatory approval or clearance of a product is granted, the approval or clearance may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or clearance, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Ongoing compliance with Quality System regulations and other applicable regulatory requirements is strictly enforced in the United States through periodic inspections by state and federal agencies, including the FDA, and in international jurisdictions by comparable agencies. Failure to comply with regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure to obtain premarket clearance or premarket approval for devices, withdrawal of approvals previously obtained, and criminal prosecution. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements will limit our ability to operate and could increase our costs.

Any failure or delay in completing clinical trials or studies for our devices and products and the expense of those trials may adversely affect our business.

Pre-clinical studies, clinical trials and post-clinical monitoring and trials required to demonstrate the reasonable safety and efficacy of our potential devices and products are and 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 pre-clinical 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 report financial information or data accurately or disclose unauthorized activities to us. See also "–We may be subject to healthcare laws and regulations relating to our business and could face substantial penalties if we are determined not to have fully complied with such laws, which would have an adverse impact on our business." 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.

Healthcare policy changes, including recent federal legislation to reform the U.S. healthcare system, may have a material adverse effect on us.

Our operations may be impacted by the Patient Protection and Affordable Care Act (PPACA). For example, the PPACA imposed, among other things, a 2.3% federal excise tax, with limited exceptions, on any entity that manufactures or imports Class I, II and III medical devices offered for sale in the United States that began on January 1, 2013. The excise tax was suspended for a two year period beginning January 1, 2016 and was further suspended through December 31, 2019, and will be reinstated on medical device sales starting January 1, 2020. The current administration has expressed an intention to repeal the PPACA and replace it with alternative reforms. The details and timing of any further such actions are unknown at this time, and it is possible that these changes could adversely affect our business.

On January 2, 2013, the American Taxpayer Relief Act of 2012, or the ATRA, came into effect, which, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare devices and services, which could result in reduced demand for our devices or additional pricing pressures.

We face uncertainties that might result from modification or repeal of any of the provisions of the PPACA, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the medical device industry as a whole is currently unknown. Any changes to the PPACA are likely to have an impact on our results of operations, and may have a material adverse effect on our results of operations. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may have on our business.

Risks Related to Owning Our Common Stock

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

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

- results of clinical trials of our planned products or those of our competitors;
- actions by regulatory bodies, such as the FDA, that effect our business or have the effect of delaying or rejecting approval or clearance of our planned products;
- actual or anticipated fluctuations in our financial condition and operating results;
- announcements by our customers, partners or suppliers relating directly or indirectly to our products, services or technologies;
- announcements of technological innovations by us or our competitors;
- changes in laws or regulations applicable to 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;
- overall conditions in our industry and market; 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 and adversely impact our ability to raise capital to fund our operations, which could seriously harm our business.

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

If we or our stockholders, particularly our directors, executive officers and significant stockholders, sell or purchase, register for sale, or indicate an intent to sell or purchase, shares of our common stock in the public market, it may have a material adverse effect on the market price of our common stock. In particular, Robert W. Duggan is not subject to any contractual restrictions with us on his ability to sell or transfer our common stock, 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.

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 $150.0 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, exchangeable 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 may also sell shares or other securities at a price per share that is less than the price per share paid by existing investors, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders.

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

Prior to our initial public offering in May 2016, there was no public market for our common stock. Although our common stock is listed on The Nasdaq Capital Market, 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 harm our ability to raise capital by selling additional common stock and may harm our ability to enter into strategic collaborations or acquire companies or products by using our common stock as consideration.

Concentration of ownership by our principal 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, Chairman of our Board, beneficially owns approximately 44% of our common stock outstanding as of the date of this Quarterly Report. 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 certificate of incorporation or bylaws;
- to effect or prevent a merger, sale of assets or other corporate transaction; and
- to control the outcome of any other matter submitted to our stockholders for vote.

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 15% or more of the outstanding shares of common stock, our management will not be able to greatly influence corporate actions requiring stockholder approval.

Robert W. Duggan's 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, is the Chairman of our Board, beneficially owns approximately 44% of our common stock outstanding as of the date of this Quarterly Report. 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.

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 as well as a "smaller reporting company"; as a result, we cannot be certain if the applicable reduced disclosure requirements 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 also qualify as a "smaller reporting company," as defined in the Exchange Act, and so long as we remain a smaller reporting company, we benefit from and may take advantage of scaled disclosure requirements.

We cannot 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 and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our reporting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected. We will remain an "emerging growth company" for up to five years, although we will lose that status sooner if our revenues exceed $1.07 billion, if we issue more than $1.0 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 June 30.

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

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

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

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.

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

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

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

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to engage in certain types of transactions with us.

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

None.

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
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

* 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: May 2, 2019

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: May 2, 2019

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: May 2, 2019

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 March 31, 2019 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: May 2, 2019

/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.