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

Form 10-K

(Mark One)

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

For the fiscal year ended December 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)**

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

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 LLC**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

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, 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 ☒

Aggregate market value of registrant's common stock held by non-affiliates of the registrant on June 28, 2019, the last business day of the registrant's most recently completed second fiscal quarter, based upon the closing price of the registrant's common stock on such date as reported by Nasdaq Capital Market, was approximately $154,277,812. Shares of voting stock held by each officer and director have been excluded in that such persons may be deemed to be affiliates. This assumption regarding affiliate status is not necessarily a conclusive determination for other purposes.

Number of shares outstanding of the registrant's common stock as of February 28, 2020: 20,825,469

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant's definitive Proxy Statement relating to its 2020 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K where indicated. The Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after December 31, 2019.

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SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains certain "forward-looking statements" that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the following words: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements relate to future events or our future financial performance or condition and involve known and unknown risks, uncertainties and other factors that could cause our actual results, levels of activity, performance or achievement to differ materially from those expressed or implied by these forward-looking statements.

You should read this Annual Report and the documents that we reference elsewhere in this Annual Report completely and with the understanding that our actual results may differ materially from what we expect as expressed or implied by our forward-looking statements. In light of the significant risks and uncertainties to which our forward-looking statements are subject, you should not place undue reliance on or regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all. We discuss many of these risks and uncertainties in greater detail in this Annual Report, particularly in Part I. Item 1A. "Risk Factors." These forward-looking statements represent our estimates and assumptions only as of the date of this Annual Report regardless of the time of delivery of this Annual Report. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this Annual Report.

Part I

Item 1. Business

In this Annual Report on Form 10-K, 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. Pulse Biosciences, Pulse TX, CellFX, Nano-Pulse Stimulation, NPS and the stylized logos are among the trademarks and/or registered trademarks of Pulse Biosciences, Inc. in the United States (U.S.) and other countries.

Overview

Pulse Biosciences, Inc. is a novel bioelectric medicine company committed to developing innovative health products that improve and potentially extend the lives of patients. We are pursuing regulatory clearance from the U.S. Food and Drug Administration (FDA) to market our first product, our proprietary CellFX™ System (CellFX). The CellFX System utilizes its patented Nano-Pulse Stimulation™ (NPS) technology to treat a variety of applications for which an optimal solution remains unfulfilled. NPS is a proprietary technology that delivers nanosecond duration pulses of high amplitude electrical energy to non-thermally clear targeted cells while sparing adjacent non-cellular tissue. The Company is working to validate the cell-specific effects of NPS technology in a series of completed and ongoing clinical studies.

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 a tunable nanosecond pulsed energy system designed for use in human medicine. 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 and are conducting several clinical studies, including studies in Seborrheic Keratosis, the most common benign raised pigmented lesion, Sebaceous Hyperplasia, a common but difficult to treat facial lesion, Basal Cell Carcinoma, 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 clinical indications cleared or approved by the FDA.** During February 2019 we submitted a Pre-Market Notification 510(k) to the FDA seeking clearance to commercialize our CellFX System. However, in February 2020, we received a Not Substantially Equivalent (NSE) letter from the FDA, indicating that based on the data provided, we had not demonstrated that the CellFX System is substantially equivalent to the predicate device, concluding the 510(k) review process without clearance. We will continue to work with the FDA in pursuit of a clearance via a new 510(k) submission. Pending regulatory clearance, we plan to launch our CellFX System in the U.S.

Our Proprietary Nano-Pulse Stimulation Technology Platform

Our proprietary CellFX System leverages our patented NPS technology platform. NPS technology is characterized by ultrafast electrical energy pulses, with pulse durations from billionths up to a millionth of a second. When applied to targeted tissue, our NPS technology is designed to send energy pulses to cells in order to alter the function of the internal cellular organelles, including the mitochondria and endoplasmic reticulum, without disrupting extracellular tissue, leading to regulated cell death (RCD), a process exhibited by cells in the human body when they undergo stress and are unable to restore cellular homeostasis.

Our proprietary CellFX System is designed to function on the basis of a unique non-toxic and non-thermal mechanism of action that likely results in a biophysical disruption brought about by the tunable speed and amplitude of our NPS pulses interacting with the physical structure of cells. While our CellFX System delivers pulses that directly affect the internal organelles of cells, these pulses should not have significant functional effect on non-cellular tissue, such as collagen, a protein that forms the structural foundation of the skin. In short, with our proprietary CellFX System, we can deliver a more selective, cell-focused effect that we believe leads to RCD while preserving surrounding non-cellular tissue, a combination that may potentially lead to highly differentiated treatment applications. Additionally, in the case of cancer this regulated cell death process may result in immunogenic cell death that stimulates the immune system to mount a systemic immune response against antigens, or markers, in those cancer cells.

Aesthetic Dermatology Procedure Market

We believe our CellFX System has high potential to offer improved clinical outcomes for a broad range of dermatology conditions and aesthetic skin applications for which targeted clearance of cellular lesions or structures is medically or cosmetically desirable. Current dermatology procedures to remove lesions or undesired skin tissue typically involve either excision (e.g. surgery) or the use of heat (e.g. lasers or radiofrequency energy) or cold (e.g. cryoablation). These thermal methods of tissue destruction affect both cellular and non-cellular tissue components indiscriminately, which can lead to collateral damage of the dermal foundation in the skin.

Based on our clinical data demonstrating the unique, non-thermal, cell targeting NPS mechanism, we believe there is a significant opportunity for our CellFX System in aesthetic and medical dermatology in the U.S. According to the 2017 Consumer Survey by the American Society for Dermatologic Surgery the number of consumers considering a cash-pay cosmetic procedure has more than doubled, from 30% in 2013 to 70% in 2017. The survey also highlighted that consumers ranked their dermatologist as the #1 influencer of skin procedure decisions. We have worked closely with top key opinion leaders (KOLs) in the aesthetic and medical dermatology field to identify those procedures and skin conditions in which our CellFX System and its unique NPS mechanism of action would offer a high value proposition.

Initial Aesthetic Dermatology Applications

Sebaceous Hyperplasia

Sebaceous Hyperplasia (SH) is a common, benign condition of sebaceous glands in adults of middle age or older. SH occurs when the sebaceous glands become enlarged, creating small, shiny, yellowish lesions or bumps, usually 2-4 millimeters in diameter and typically on the face. Results from our research have demonstrated that NPS has a unique ability to target cellular structures located within the dermis of the skin, such as the sebaceous gland, without damaging the dermis, making it a potentially unique and highly effective treatment modality for SH lesions and similar targets residing deeper within the dermis of the skin.

During 2018 we conducted a multi-center clinical study evaluating the safety and efficacy of our NPS platform for the treatment of SH. Results from our clinical study, including 73 patients and 222 treated SH lesions, indicate that NPS technology is effective for the treatment of SH. Over 99% of treated SH lesions (221 of 222) were rated clear or mostly clear by investigators at the 60-day post treatment follow-up evaluation. Approximately 92% (n=203) of treated lesions were assessed as clear or mostly clear after a single treatment. Patients in the study rated 77% of lesion outcomes as satisfied or mostly satisfied.

We believe that the successful treatment of SH lesions reflects a valuable commercial opportunity for our CellFX System in an area of unmet need and substantiates the unique ability of NPS pulses to penetrate the dermis and target deeper cellular structures without damaging the surrounding dermis.

Seborrheic Keratosis

Seborrheic Keratosis (SK) is one of the most common non-cancerous skin growths in older adults. SK usually appear as a brown, black or light tan growth on the face, chest, shoulders or back and has a waxy, scaly, slightly elevated appearance. SK are normally painless, and patients often seek to have them removed if they become irritated by clothing or for cosmetic reasons.

During 2017 and 2018 we conducted a multi-center clinical study evaluating the safety and efficacy of NPS technology for the treatment of SK. Results from our clinical study, including 58 patients and 174 treated SK lesions, indicate that a single NPS treatment is effective for the treatment of SK. 82% of treated SK lesions (143 of 174) were rated clear or mostly clear by investigators at the 106-day post treatment follow-up evaluation. Patients in the study rated 78% of treatment outcomes as satisfied or mostly satisfied.

We believe that the results of this clinical study provide support to pursue commercial opportunities for the CellFX System in the treatment of SK.

Future Dermatology Application Feasibility Studies

We expect to conduct clinical studies on an ongoing basis to continue to evaluate clinical opportunities for and demonstrate the value of our CellFX System across a growing list of valuable indications, including:

Cutaneous Warts

During 2018 we initiated a 20-patient, multi-center clinical feasibility study evaluating the safety and effectiveness of our CellFX System for the treatment of non-genital cutaneous warts. Non-genital cutaneous warts are benign grainy skin growths that are typically caused by the human papillomavirus. Results from this study will inform decisions regarding opportunities for future clinical studies for the treatment of warts.

Acne

During early 2019 we initiated a multi-center clinical feasibility study evaluating the safety and effectiveness of our CellFX System for the treatment of acne on the back. Back acne is characterized by eruptions of pimples, pustules, blackheads and/or cysts, often on the upper back, and is generally caused by the same factors that trigger facial acne, namely overactive sebaceous glands that lead to the proliferation of acne related bacteria. Our unique ability to target the sebaceous gland, as evidenced by the impressive results from our sebaceous hyperplasia study, led our dermatology advisory board to encourage us to pursue a feasibility study in acne, based on the role of the sebaceous glands in chronic acne eruptions.

Nano-Pulse Stimulation Initiated Immunogenic Cell Death

In previously published pre-clinical models of cancerous lesions, NPS treatment has been shown to induce immunogenic cell death, a process that leads to the exposure of the unique cancer cell antigens to the immune system, resulting in the generation of cytotoxic T-cells and the mounting of an adaptive immune response targeted against those cells, without any observed toxic side effects. Based on this foundation of pre-clinical evidence, we believe NPS technology has the potential to play a role in immuno-oncology. Applications in immuno-oncology are a longer-term potential opportunity and may require the use of adjuvants or other agents in combination with NPS. We continue to evaluate NPS technology and our CellFX System in clinical and pre-clinical studies.

During 2018 we commenced a clinical biomarker study to evaluate the CellFX System and NPS technology in Basal Cell Carcinoma (BCC), the most prevalent form of skin cancer. We believe BCC represents a bridge between our developments in dermatology and those in oncology. This is our first human study in cancer and it will allow us to look at both the ability of CellFX System and NPS pulses to treat BCC lesion cells and the immune response changes as a result of treatment. This is not a therapeutic endpoint study, but it is an important first step that enables us to move quickly to demonstrate safety and NPS technology effect in treating skin cancer while providing necessary information to inform decisions relative to next steps towards a follow-on study aimed at a therapeutic endpoint.

Our CellFX System

We have developed and plan to commercialize our proprietary CellFX System into the large and growing aesthetic procedure market as our first commercial market. The CellFX System is a platform, designed to support a wide array of

applications in aesthetic dermatology and potentially in other medical disciplines. We believe our CellFX System is an ideal tunable nanosecond pulsed energy delivery system designed and used in human medicine. Our CellFX System allows for the adjustment of four key treatment parameters: pulse duration, pulse amplitude, pulse frequency, and the number of pulses, depending on the target tissue, application and desired treatment outcome.

The CellFX System currently includes a multi-use handpiece and an initial family of five (5) single-patient use dermatology treatment tips. The system is designed to operate in a variety of medical environments, including a physician's office or clinic, as well as outpatient surgery centers or hospitals. The system is a mobile cart-based system that can easily be transported from room to room and plugs into a standard wall outlet adaptable to either U.S. or international power sources.

The treatment tips enable treatment of a variety of lesion sizes, from 1.5mm to 10mm square, and wirelessly connect to our CellFX System when they are plugged into the handpiece. This enables the use of automated treatment settings based on the treatment tip being utilized.

The CellFX System and its component parts are engineered for volume manufacturing and the use of outsourced contract manufacturing partners to ensure our ability to meet anticipated demand while effectively managing underlying system costs that support a profitable sale of the CellFX System at competitive price points.

Safety Profile of Our NPS Technology Platform

During the course of conducting human clinical studies in dermatology with the NPS platform to support an FDA filing at leading dermatology research centers across the U.S., no serious adverse events have been reported and patient tolerance to the procedure has been very high. A histological study of treated human tissue examined by experts in dermatopathology revealed a unique and consistent cell-specific mechanism of action and a predictable healing response that spared non-cellular dermal tissue across a wide range of skin types and patient demographics.

Commercialization Strategy

During February 2019, we submitted a Pre-Market Notification 510(k) to the FDA seeking clearance to commercialize our CellFX System. However, in February 2020, we received a NSE letter from the FDA, indicating that based on the data provided, we had not demonstrated that the CellFX System is substantially equivalent to the predicate device, concluding the 510(k) review process without clearance. We will continue to work with the FDA in pursuit of a clearance via a new 510(k) submission. Pending regulatory clearance, we plan to launch our CellFX System in the U.S. The commercialization strategy for our CellFX System is comprised of three primary elements:

- We are in the process of building a sales and marketing team comprised of professionals with experience in delivering products and applications into the aesthetic dermatology market and have long-standing relationships with the key opinion leaders, clinics and customers. We plan to scale our sales and marketing infrastructure along with the growth of the business;

- We intend to leverage and expand our existing relationships with our KOL advisors. These opinion leaders have significant influence on their peers and on the adoption of new technologies and treatment modalities through podium presentations at major meetings and media exposure in major markets; and

- We will continue to conduct clinical studies and work with our KOLs to pursue additional applications for which our cell specific mechanism of action is enabling. We have already started our evaluation for the treatment of warts, acne and basal cell carcinoma. Our application development pipeline continues to reveal additional targets that have potential to add to the utilization potential of our future growing installed base.

We believe knowledgeable salespersons who can convey and assist the clinician in delivering the value of our CellFX System to patients, success of early adopter KOLs, and the increasing utility of our CellFX System with meaningful clinical data greatly enhances our ability to attract customers and promote ongoing utilization of installed systems.

Intellectual Property

We maintain a portfolio of intellectual property surrounding our CellFX System and our NPS technology platform. As a medical technology company our current patents and ongoing intellectual property development are, and will continue to be, a priority for our business. We believe our intellectual property is an important competitive advantage for us. We also rely on trade secrets, know-how, continuing technological innovations and licensing opportunities to further develop, maintain and

strengthen our competitive position. We actively protect our intellectual property through a combination of patent registrations, trademarks, and copyright protections; confidentiality agreements with our employees, consultants and other parties; and access control to sensitive information.

We own or have a license to 95 issued patents worldwide and have 94 patent applications pending worldwide, with the earliest expiration of nine U.S.-issued licensed patents in 2020 and the latest in 2037. As in the past, we plan to continue to file new patent applications to protect our systems, algorithms, applicators, methods, and designs of our technologies and products as they evolve. Medical technologies such as ours may be utilized in many different applications and incorporate several patentable features, and our strategy will be to always strive to protect our products and technologies with multiple patents directed to the variety of features and applications, in order to establish a strong defense against competitors and such that an expiration of a single patent does not lessen our overall comprehensive coverage. We believe our NPS platform and current CellFX System are protected by several issued patents covered, as well as pending applications.

Research and Development

Since inception, the majority of our business has focused on the development of our CellFX System and earlier clinical versions of the system, conducting clinical studies, including dermatology studies in SK, SH, warts, acne and BCC, and pre-clinical and basic research into the unique mechanism of action of our NPS technology platform. We continue to conduct research and development activities in pursuit of commercial applications for our CellFX System but have not yet commercialized or recognized revenue from our technology.

The development of our proprietary CellFX System has involved a multi-disciplinary effort including; electrical, mechanical, biomedical, and software engineers to design and integrate the various elements of our CellFX System and its predecessors; clinical research specialists to plan and conduct clinical studies; and research scientists to assess and interpret the focal and systemic biological effects of our technology. We believe we can expand the potential of our CellFX System through ongoing innovation and additional clinical studies demonstrating safety and efficacy in additional dermatologic conditions and additional therapeutic areas.

Competition

The applications we intend to target are subject to intense competition from rapidly evolving companies and new scientific discoveries. We compete against well-established incumbent technologies offering products in oncology, dermatology and aesthetics, minimally invasive procedures, and veterinary applications. Given the broad scope of our technology, we face competition ranging from large manufacturers with multiple business lines to small companies with focused products, as well as providers of other medical therapies and therapeutics for conditions that our products are intended to treat. Some of these companies currently have greater financial, technical, research and/or other resources than we do and have larger and more established manufacturing capabilities and marketing, sales and support functions. Our future success will depend on our ability to establish and maintain a competitive position in current and future technologies. Our technology is unique and differentiated in that NPS technology stimulates primarily intracellular cell death which we believe would be less traumatic to treated tissue and would result in less scarring or collateral damage to surrounding tissues.

Government Regulation

The CellFX System is a medical device subject to extensive and ongoing regulation by the FDA under the Federal Food, Drug, and Cosmetic Act and its implementing regulations, as well as other federal and state regulatory bodies in the U.S. The laws and regulations govern, among other things, product design and development, pre-clinical and clinical testing, manufacturing, packaging, labeling, storage, recordkeeping and reporting, clearance or approval, marketing, distribution, promotion, import and export, and post-marketing surveillance.

The FDA regulates the medical device market to ensure the safety and efficacy of these products. For medical devices that require pre-market review, the FDA allows for three clearance/approval pathways for a medical device to be commercialized: approval via a Pre-market Approval Application (PMA), clearance of a 510(k) submission, or submission of a de novo application. The FDA has established three different classes of medical devices, based on the level of risk associated with using a device and consequent degree of regulatory controls needed to govern its safety and efficacy, as well as the appropriate clearance/approval pathway needed to obtain authorization to legally market a medical device in the U.S.

Class I and Class II devices are considered low and moderate risk devices. Most Class I devices are exempt from premarket notification. Most Class II devices require 510(k) clearance from the FDA in order to be marketed in the U.S. A 510(k) Premarket Notification is a premarket submission made to the FDA to demonstrate that the device to be marketed is

substantially equivalent to a legally marketed Class II device, or a predicate. Companies making a 510(k) submission must compare their 510(k) candidate device to a predicate device, and establish substantial equivalence to the satisfaction of FDA. A device previously cleared under 510(k) or a device approved through a de novo application can be used as a predicate device for later developed substantially equivalent medical devices. However, establishing substantial equivalence in a 510(k) submission requires the candidate device to have the same intended use and the same technological characteristics as a predicate device. The FDA has a 90-calendar day review goal from the date of receipt of the 510(k) to either authorize or decline commercial distribution of the device, but clearance generally takes longer than 90 days. During the review process, the FDA may also request additional information which extends the review process. If the FDA decides that the product is not substantially equivalent to a predicate device, a clearance will not be granted and the device cannot be commercialized. If a 510(k) submission is rejected by FDA, the applicant may be required to seek premarket authorization through the de novo pathway or the premarket approval pathway, which are more costly and will generally take longer for FDA approval.

Medical devices regarded as the highest risk by the FDA are typically designated Class III and generally require the submission of a PMA application for approval. Class III devices generally include life-sustaining, life-supporting, or implantable devices or devices without a known predicate technology already approved by the FDA. A PMA application must be accompanied by substantial data that supports the reasonable safety and efficacy of the device, which includes the provision of pre-clinical, clinical, technical, manufacturing and labeling information. After the FDA determines the application is sufficiently complete to commence a substantive review, it has 180 days to review the submission, but it can typically take longer (up to several years) as this regulatory body can request additional data, including clinical data or clarifications. The FDA may also impose additional regulatory scrutiny for a PMA, including the institution of an outside advisory committee (panel review) to assess the application or provide recommendations as to whether to approve the device. Although the FDA is not required to follow the recommendation of an advisory panel, it generally does. As part of the review, the FDA will also inspect the manufacturing operations of the company requesting approval to verify compliance with Quality System regulations.

If a new medical device does not qualify for the 510(k) premarket notification process because no predicate device to which it is substantially equivalent can be identified, the device is automatically classified into Class III. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the “Request for Evaluation of Automatic Class III Designation,” or the de novo classification process. This process allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. The FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk and requires PMA or that general controls would be inadequate to control the risks and special controls cannot be developed.

After a device receives 510(k) clearance or PMA approval, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or PMA Supplemental approval. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer’s determination. If the FDA disagrees with the determination not to seek a new 510(k) clearance or PMA Supplement, the FDA may retroactively require a new 510(k) clearance or PMA Supplements to be submitted. The FDA could also require a manufacturer to cease marketing and distribution and/or recall the modified device until clearance or approval is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines, penalties, and possible warning letters.

Pervasive and Continuing Regulation

After a device is placed on the market after FDA clearance or approval, numerous FDA regulatory requirements continue to apply. These include:

- the FDA’s Quality System Regulation (QSR) which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;

- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses;

- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur; and

- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

The FDA has broad post-market and regulatory enforcement powers. We may be subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Public Health to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our suppliers.

Failure to comply with applicable regulatory requirements can result in enforcement action by FDA, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;

- repair, replacement, refunds, recall or seizure of our products;

- operating restrictions, partial suspension or total shutdown of production;

- refusing our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products;

- withdrawing 510(k) clearance or premarket approval that has already been granted; and

- criminal prosecution.

Regulatory System for Medical Devices in Europe

The European Union (EU) consists of 28-member states and has a coordinated system for the authorization of medical devices. Marketing medical devices in the EU is subject to compliance with the Medical Devices Directive 93/92/EEC (MDD) and the European Medical Device Regulation (MDR), which becomes effective in May 2020. A medical device may be placed on the market within the EU only if it conforms to certain “essential requirements” and bears the CE Mark. The most fundamental and essential requirement is that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the essential performance(s) intended by the manufacturer and be designed, manufactured and packaged in a suitable manner.

Manufacturers must demonstrate that their devices conform to the relevant essential requirements through a conformity assessment procedure. The nature of the assessment depends upon the classification of the device. The classification rules are mainly based on three criteria: the length of time the device is in contact with the body, the degree of invasiveness and the extent to which the device affects the anatomy. Conformity assessment procedures for all but the lowest risk classification of device involve a notified body. Notified bodies are often private entities and are authorized or licensed to perform such assessments by government authorities. Manufacturers usually have some flexibility to select a notified body for the conformity assessment procedures for a particular class of device and to reflect their circumstances, e.g., the likelihood that the manufacturer will make frequent modifications to its products. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product and post-market experience in respect of similar products already marketed. Notified bodies also may review the manufacturer’s quality systems. If satisfied that the product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity and application of the CE Mark. Application of the CE Mark allows the general commercializing of a product in the EU. The product can also be subjected to local registration requirements depending on the country.

In May 2017, the EU adopted MDR, which will repeal and replace the MDD with effect from May 26, 2020. The MDR clearly envisages, among other things, stricter controls of medical devices, including strengthening of the conformity assessment procedures, increased expectations with respect to clinical data for devices and pre-market regulatory review of high-risk devices. The MDR also envisages greater control over notified bodies and their standards, increased transparency, more robust device vigilance requirements and clarification of the rules for clinical investigations. Under transitional

provisions, medical devices with notified body certificates issued under the MDD prior to May 26, 2020, and which have not been significantly changed, may continue to be placed on the market for the remaining validity of the certificate, until May 27, 2024 at the latest. After the expiry of any applicable transitional period, only devices that have been CE marked under the MDR may be placed on the market in the EU.

Health Insurance Portability and Accountability Act

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) impacts the transmission, maintenance, use and disclosure of certain individually identifiable health information (referred to as protected health information, or PHI). Since HIPAA was enacted in 1996, numerous implementing regulations have been issued, including, but not limited to: (1) standards for the privacy of individually identifiable health information (the Privacy Rule), (2) standards to protect the confidentiality, integrity and security of electronic protected health information (the Security Rule), (3) standards for electronic transactions, (4) a standard unique national provider identifier for providers and health plans, and (5) the HHS Breach Notification Rule. We refer to these rules, as well as similar state laws applicable to our operations, as the HIPAA Rules. The U.S. Department of Health and Human Services (HHS) has also issued regulations governing the enforcement of the HIPAA Rules, the violation of which potentially includes significant criminal and civil penalties. Furthermore, many states have similar laws and regulations applicable to our operations, including but not limited to state data security breach requirements.

The HIPAA Rules apply to "covered entities," which includes healthcare providers who conduct certain transactions electronically, including but not limited to the electronic submission of health care claims to an insurance carrier. We also provide services to customers that are directly regulated entities under HIPAA and the HIPAA Rules, and we are required to provide satisfactory written assurances to these customers through our written agreements that we will provide our services in accordance with HIPAA and the HIPAA Rules. As such, HIPAA and the HIPAA Rules apply to various aspects of our business.

On February 17, 2009, Congress enacted Subtitle D of the Health Information Technology for Economic and Clinical Health Act (HITECH) provisions of the American Recovery and Reinvestment Act of 2009. This law includes strengthened federal privacy and security provisions to protect PHI, such as the notification requirements set forth in the Breach Notification Rule. On January 25, 2013, the Office for Civil Rights (OCR) of the HHS published its final rule to modify the HIPAA Privacy, Security, Breach and Enforcement Rules, including most revisions/additions made by the HITECH. The rule became effective on March 23, 2013, and entities and business associates covered by the rule were required to comply with most of the applicable requirements by September 23, 2013.

We are currently subject to HIPAA and the HIPAA rules. We are subject to audit under the HHS, HITECH-mandated audit program. We may also be audited in connection with a privacy complaint. We are subject to prosecution and/or administrative enforcement and increased civil and criminal penalties for non-compliance, including a new, four-tiered system of monetary penalties adopted under HITECH. We are also subject to enforcement by state attorneys general who were given authority to enforce HIPAA under HITECH. To avoid penalties under the HITECH breach notification provisions, we must ensure that breaches of protected health information are promptly detected and reported within the company, so that we can make all required notifications on a timely basis. However, even if we make required reports on a timely basis, we may still be subject to penalties for the underlying breach.

In addition to the federal privacy regulations, there are a number of state laws regarding the privacy and security of health information and personal data that are applicable to clinical laboratories. The compliance requirements of these laws, including additional breach reporting requirements, and the penalties for violation vary widely and new privacy and security laws in this area are evolving. Requirements of these laws and penalties for violations vary widely, and new laws and regulations governing privacy and data security may be adopted in the future. We have taken steps to comply with health information privacy and security statutes and regulations in all jurisdictions, both state and federal, that apply to us. However, we may not be able to maintain compliance in all jurisdictions where we do business, and even if we are compliant, we may face allegations that we are not. Any actual or alleged failure to maintain compliance, or changes in state or federal laws regarding privacy or security, could result in regulatory investigations, enforcement actions, and civil and/or criminal penalties and could have a material adverse effect on our business.

If we or our operations are found to be in violation of HIPAA, HITECH or their implementing regulations, we may be subject to penalties, including civil and criminal penalties, fines, and exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. HITECH increased the civil and criminal penalties that may be imposed against Covered Entities, their Business Associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

Federal, State and Foreign Fraud and Abuse Laws

Because of the significant federal funding involved in Medicare and Medicaid, Congress and the states have enacted, and actively enforce, a number of laws to eliminate fraud and abuse in federal healthcare programs. Our business is subject to compliance with these laws. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Affordability Reconciliation Act, which we refer to collectively as the Affordable Care Act, was enacted in the U.S. The provisions of the Affordable Care Act are effective on various dates. The Affordable Care Act expands the government's investigative and enforcement authority and increases the penalties for fraud and abuse, including amendments to both the Anti-Kickback Statute and the False Claims Act, to make it easier to bring suit under these statutes. The Affordable Care Act also allocates additional resources and tools for the government to police healthcare fraud, with expanded subpoena power for HHS, additional funding to investigate fraud and abuse across the healthcare system and expanded use of recovery audit contractors for enforcement.

Anti-Kickback Statutes. The federal healthcare programs' Anti-Kickback Statute prohibits persons or entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as Medicare or Medicaid.

The definition of "remuneration" has been broadly interpreted to include anything of value, including, for example, gifts, certain discounts, the furnishing of free supplies, equipment or services, credit arrangements, payment of cash and waivers of payments. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration for inducing referrals of federal healthcare covered businesses, a violation of the statute can be found. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. In addition, a kickback violation can serve as a predicate for a violation under the Federal False Claims Act, discussed in more detail below.

The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are otherwise lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, Congress authorized the Office of Inspector General (OIG), of HHS to issue a series of regulations known as "safe harbors." These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is per se illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy an applicable safe harbor may result in increased scrutiny by government enforcement authorities such as OIG.

Many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to referral of recipients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

Government officials have focused their enforcement efforts on the marketing of healthcare services and products, among other activities, and recently have brought cases against companies, and certain individual sales, marketing and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

Federal *False Claims Act.* Another broad statute affecting the healthcare industry is the increased use of the federal False Claims Act, and in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has violated the False Claims Act and to share in any monetary recovery. In recent years, the number of suits brought against healthcare providers by private individuals has increased dramatically. In addition, various states have enacted false claims laws analogous to the False Claims Act, and many of these state laws apply where a claim is submitted to any third-party payor and not just a federal healthcare program.

When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between $11,463 and $22,927 for each separate instance of false claim, subject to adjustment for inflation. As part of any settlement, the government may ask the entity to enter into a corporate integrity agreement, which imposes certain compliance, certification and reporting obligations. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The federal government has used the False Claims Act to assert liability on the basis of inadequate care, non-compliance with medical necessity criteria, kickbacks and other improper

referrals, and improper use of Medicare numbers when detailing the provider of services, in addition to the more predictable allegations as to misrepresentations with respect to the services rendered. In addition, the federal government has prosecuted companies under the False Claims Act in connection with off-label promotion of products. Our future activities relating to the reporting of wholesale or estimated retail prices of our products, the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our products and the sale and marketing of our products may be subject to scrutiny under these laws.

While we are unaware of any current matters, we are unable to predict whether we will be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the costs of defending such claims, as well as any sanctions imposed, could significantly affect our financial performance.

The Sunshine Act. The Physician Payment Sunshine Act (the Sunshine Act), which was enacted as part of the Affordable Care Act, requires applicable manufacturers and certain distributors of prescription drugs, devices, biologics or other medical supplies available for coverage by Medicare, Medicaid or the Children's Health Insurance Program to report annually to the Secretary of HHS: (i) payments or other transfers of value made by that entity, or by a third-party as directed by that entity, to physicians and teaching hospitals or to third parties on behalf of physicians or teaching hospitals; and (ii) physician ownership (including immediate family ownership) and investment interests in the entity. The statute requires the federal government to make reported information available to the public starting September 2014, which it has. Failure to comply with the reporting requirements can result in significant civil monetary penalties ranging from $1,000 to $10,000 for each payment or other transfer of value that is not reported (up to a maximum per annual report of $150,000) and from $10,000 to $100,000 for each knowing failure to report (up to a maximum per annual report of $1.0 million). Additionally, there are criminal penalties if an entity intentionally makes false statements in such reports. Upon commercialization, we will be subject to the Sunshine Act and the information we disclose may lead to greater scrutiny, which may result in modifications to established practices and additional costs. Additionally, similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with healthcare professionals.

Foreign Corrupt Practices Act. The Foreign Corrupt Practices Act (FCPA) prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the U.S. to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, if any, and to devise and maintain an adequate system of internal accounting controls for international operations.

International Laws. In Europe, various countries have adopted anti-bribery laws providing for severe consequences, in the form of criminal penalties and/or significant fines, for individuals and/or companies committing a bribery offense. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation. For instance, in the United Kingdom, under the Bribery Act 2010, which went into effect in July 2011, a bribery occurs when a person offers, gives or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the Bribery Act 2010. Under the new regime, an individual found in violation of the Bribery Act of 2010, faces imprisonment of up to 10 years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

There are also international privacy laws that impose restrictions on the access, use, and disclosure of health information. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws restricting our ability to obtain required patient information could significantly impact our business and our future business plans.

U.S. Healthcare Reform

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

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

Environmental

We are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain hazardous and potentially hazardous substances used in connection with our operations. Although we believe that we have complied with these laws and regulations in all material respects and, to date, have not been required to take any action to correct any noncompliance, there can be no assurance that we will not be required to incur significant costs to comply with environmental regulations in the future.

Insurance

We maintain product and clinical trial liability insurance coverage which includes a maximum of per claim and an annual aggregate policy limits, subject to self-insured retentions. The policy covers, subject to policy conditions and exclusions, claims of bodily injury and property damage from any product manufactured by us or from trial-related adverse events.

There is no assurance that our level of coverage is adequate. We may not be able to sustain or maintain our current level of coverage and cannot assure you that adequate insurance coverage will continue to be available on commercially reasonable terms, or at all. A successful product liability claim may exceed our existing coverages and may make future coverages significantly more expensive, if available at all.

Employees

As of December 31, 2019, we had 82 full-time employees, of which 54 were in research and development and 28 were in general and administration. Substantially all of our employees are located at our headquarters in Hayward, California.

Available Information

Effective June 18, 2018, Pulse Biosciences reincorporated as a Delaware Corporation. We were originally incorporated in Nevada on May 19, 2014 under the name Electroblate, Inc. and changed our name to Pulse Biosciences, Inc. effective December 8, 2015. Our corporate offices are located at 3957 Point Eden Way, Hayward, California. Our telephone number is (510) 906-4600.

Our website is located at www.pulsebiosciences.com. The information that can be accessed through our website is not incorporated into this Annual Report on Form 10-K, and the inclusion of our website address is an inactive textual reference only. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through the “Investor Relations” section of our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (SEC).

Additionally, we use our website as a channel for distribution for important company information. Important information, including press releases, analyst presentations and financial information regarding us, as well as corporate governance information, is routinely posted and accessible on the “Investor Relations” section of the website, which is accessible by clicking “Investors” on the menu tab labeled “About Us” on our website home page.

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 Annual 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 and clinical studies of our technologies and implementation of the early parts of our business plan. We have incurred significant operating losses in each year since our inception and we 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 clearance or 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 cleared or 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, sales representatives and other operational personnel, and the continued development of relationships with potential partners as we continue to seek regulatory clearance or approval for our products. 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 cleared or 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.

There is substantial doubt about our ability to continue as a going concern.

Our independent registered public accounting firm has issued a “going concern” opinion, meaning that there is substantial doubt we can continue as an ongoing business for the next twelve months from the date that our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K were issued unless we obtain additional capital. To date, we have not generated any revenue. As a result, 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, in February 2020, we received a NSE letter from the FDA, indicating that based on the data provided, we had not demonstrated that the CellFX System is substantially equivalent to the predicate device, concluding the 510(k) review process without clearance.

We plan to raise additional capital to fund our operations, including via a proposed rights offering seeking to raise net proceeds of approximately $30 million, assuming such rights offering is fully subscribed. There is no assurance that the rights offering will be successful, or that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to us. Accordingly, management cannot conclude that such plans will be effectively implemented within the twelve months from the date that our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K were issued.

These factors, combined with our forecast of cash required to fund operations for a period of at least twelve months from the date that our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K were issued, raise substantial doubt about our ability to continue as a going concern.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should we be unable to continue as a going concern within twelve months after the date the financial statements are issued.

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.

We will need to raise additional capital in order to continue to execute our business plan in the future including by pursuing a rights offering, which has been approved by our board of directors, to raise net proceeds of approximately $30 million, assuming such rights offering is fully subscribed.

There is no assurance that the rights offering will be successful, or that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to us. If we are unable to raise sufficient additional funds, we will have to scale back our operations.

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 certain of 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 U.S. or internationally;
- the timing and status of enrollment for our clinical trials;
- coverage and reimbursement policies with respect to our product candidates, if approved or cleared, including the degree to which treatments using our products are covered and receive adequate reimbursement from third-party payors, 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.

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 cleared or approved, may compete with other dermatological products, including over-the-counter (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.

Our business may be adversely affected by health epidemics including the recent coronavirus outbreak.

In December 2019, an outbreak of a novel strain of coronavirus (COVID-19) originated in Wuhan, China and has since spread to a number of other countries, including the U.S. On March 11, 2020, the World Health Organization characterized COVID-19 as a pandemic. In addition, several states in the U.S., including California, where we are headquartered, have declared a state of emergency.

Potential impacts to our business include disruptions or restrictions on our employees' ability to work. In addition, our clinical trials may be affected by the COVID-19 outbreak. Site initiation and patient enrollment may be delayed, for example, due to prioritization of hospital resources toward the COVID-19 outbreak, travel restrictions imposed by governments, and the inability to access sites for initiation and monitoring. Also, some of our suppliers of certain materials used in the production of our product candidates are located in areas impacted by COVID-19 which could limit our ability to obtain sufficient materials for our product candidates. COVID-19 could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could affect demand for our product candidates, if approved, and impact our operating results. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which health epidemics such as COVID-19 could adversely impact our business. Although we are continuing to monitor and assess the effects of the COVID-19 pandemic on our business, the ultimate impact of the COVID-19 outbreak or a similar health epidemic is highly uncertain and subject to change.

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. These third parties may be adversely impacted by COVID-19 which could affect their ability to perform satisfactorily. 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 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 members of our finance, 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.

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 and NPS therapies and treatments, which could result in inefficiencies and unanticipated costs, reduced quality and disruptions to our operations. In addition, rapid and significant growth may strain our administrative and operational infrastructure, and the failure to continue to upgrade our technical, administrative, operating and financial control systems or the occurrence of unexpected expansion difficulties could have a material adverse effect on

our business, financial condition and results of operations and our ability to timely execute our business plan. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets including COVID-19. Furthermore, the market for aesthetic medical treatments may be particularly vulnerable to unfavorable economic conditions. 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.

We are subject to laws and regulations relating to personally identifiable information, and maintain other sensitive information. 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, data, 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, or those of our vendors, 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, we, and our vendors may be unable to anticipate attacks, to implement adequate preventative or mitigation measures, to identify any attacks or incidents on a timely basis, or to remediate or otherwise address any attacks or incidents in a timely manner. If any such attack or other incident were to occur, our systems and networks would be compromised and the information we store on those systems and networks could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in a loss of intellectual property protection, legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the federal HIPAA, as amended by the HITECH, and the California Consumer Privacy Act of 2018 (the CCPA), which was enacted in June 2018 and became operative on January 1, 2020, or regulatory penalties, and could require substantial efforts to remediate and otherwise respond to the incident. The CCPA requires covered companies to, among other things, make certain enhanced disclosures related to California residents regarding our use or disclosure of their personal information, allow California residents to opt-out of certain uses and disclosures of their personal information without penalty, provide Californians with other choices related to personal data in our possession, and obtain opt-in consent before engaging in certain uses of personal information relating to Californians under the age of 16. The California Attorney General may seek substantial monetary penalties and injunctive relief in the event of our non-compliance with the CCPA. The CCPA also allows for private lawsuits from Californians in the event of certain data breaches. Certain aspects of the CCPA and its interpretation remain uncertain, and we may need to modify our policies or practices in an effort to comply with it.

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. We cannot be certain that our insurance coverage will be adequate for data handling or data security liabilities actually incurred, that insurance will continue to be available to us on economically reasonable terms, or at all, or that any future claim will not be excluded or otherwise be denied coverage by any insurer. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, including our financial condition, operating results and reputation.

In addition, the interpretation and application of federal and state consumer, health-related and data protection laws in the U.S. are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is, or alleged to be, inconsistent with our practices. If so, this could result in regulatory investigations and enforcement actions, private litigation, claims for damages, and government-imposed fines or orders requiring that we change our practices, any of 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 net operating losses (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 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 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 (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 in our financial statements.

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

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 Generally Accepted Accounting Principles. 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 preparation 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 identification of one or more material weaknesses would preclude a conclusion that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

We are required to disclose changes made in our internal control and procedures on a quarterly basis. However, our independent registered public accounting firm will not be required to report on the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act until we are no longer an "emerging growth company" as defined in the Jumpstart Our Business Startups Act (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 unqualified opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected, and we could become subject to 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 Hayward, California are located near known earthquake fault zones and are vulnerable to damage from earthquakes. We are also vulnerable to damage from other types of disasters, including fire, floods, power loss, communications failures and similar events. If any disaster were to occur, our ability to operate our business at our facilities would be seriously, or potentially completely, impaired. In addition, the nature of our activities could 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. Pending regulatory clearance or approval of our CellFX System, we plan to commercially introduce our CellFX System in the U.S. However, 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 and indications that we have studied, 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 all clinical trials;
- the actual and perceived effectiveness and reliability of our products, especially relative to alternative products;
- the results of clinical trials relating to the use of our products;
- the availability, relative cost and perceived advantages and disadvantages of alternative technologies or uses thereof;
- the degree to which physicians adopt our products;
- our ability to obtain, maintain, protect and enforce our intellectual property rights with respect to our products;
- our ability to sustain a meaningful clinical benefit better than our competitors and alternative treatments or therapies;
- achieving and maintaining compliance with all regulatory requirements applicable to our products;
- the extent to which we are successful in educating medical professionals in general, and the benefits of our products;
- the strength of our marketing and distribution infrastructure;
- the effectiveness of our and our distributors' marketing and sales efforts in the U.S. and abroad, including our efforts to build out our sales team;
- the level of education and awareness among medical professionals concerning our products;
- our reputation among physicians and clinics;
- our ability to continue to develop, validate and maintain a commercially viable manufacturing process that is compliant with current Good Manufacturing Practices (cGMP) and Quality Systems Regulations (QSR); and
- whether we are required by the FDA or comparable non-U.S. regulatory authorities to conduct additional clinical trials for future or current indications.
- 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 U.S. 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 or approval;
- record keeping;
- device marketing, promotion and advertising, sales and distribution; and
- post-marketing surveillance, including reporting of deaths and serious injuries and recalls and correction and removals.

Before a new medical device or a new intended use for, an existing device can be marketed in the U.S., 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 reasonable 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. In February 2020, we received a NSE letter from the FDA, indicating that based on the data provided, we had not demonstrated that the CellFX System is substantially equivalent to the predicate device, concluding the 510(k) review process without clearance. This failure to obtain 510(k) clearance has added significant time and expense to our regulatory clearance process (including additional expense that we will incur in preparing a new 510(k) submission), has delayed our ability to generate revenue, and has had a negative impact on our stock price. We will continue to work with the FDA in pursuit of a clearance via a new 510(k) submission. However, we may not be able to obtain the necessary clearances or approvals necessary to market our CellFX System or such approvals or clearances may be unduly delayed, which could harm our business. If the FDA rejects our new 510(k) submission, we may be required to obtain FDA approval through the de novo pathway, which will require additional time and resources, including the need to conduct more clinical studies to demonstrate safety and effectiveness of our candidate device.

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

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

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

- 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. Our 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 product candidates 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 pulses 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 product candidates 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 and/or narrow the indication 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 treatments over existing treatment modalities and to persuade them to prescribe CellFX treatments 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 (CMS) for the professional services they provide in administering CellFX treatments. 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 health care industry or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting trials and obtaining regulatory approval or clearance of planned products may be delayed. If there are delays in accumulating the required patients and patient data, there may be delays in completing the trial. Further, if any of our clinical trial sites fail to comply with required good clinical practices, we may be unable to use the data gathered at those sites. If our clinical investigators fail to carry out their contractual duties or regulatory obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be delayed, suspended, or terminated. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether, and delays in obtaining regulatory authorization for our products.

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

Observations and developments that may be achievable under laboratory circumstances may not be able to be replicated in broader research and development phases, in commercial settings, or in the use of any of the product candidates in the field. Furthermore, if commercialized, CellFX treatments 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 that may not be representative or predictive of real-world experience with our products.

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

The safety and effectiveness of CellFX treatments and therapies may depend, in part, on the function of firmware run by the microprocessors embedded in the device and associated software. This firmware and software is proprietary to us. While we have made efforts to test the firmware and software extensively, it is potentially subject to malfunction which in turn may harm a patient. Further, it may be vulnerable to physical break-ins, hackers, improper employee or contractor access, computer viruses, programming errors, data breaches, 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 applicable 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 with respect to complying with applicable regulatory requirements, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval or clearance 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 ability to obtain regulatory approval or clearance for our products and our business and 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 are not assured. It typically takes a period of use in the market place before coverage and reimbursement are granted, if it is granted at all. In the U.S. 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 reduce the fee or sales price than initially planned. 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 treatments 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 consistent with the approved intended uses of the device or product as approved or cleared by the FDA, but coverage can be narrower. A coverage determination may be so limited that relatively few patients will qualify for a covered use of a device or product.

Obtaining a coverage determination, whether local or national, is a time-consuming, expensive and highly uncertain proposition, especially for a new technology, and inconsistent local determinations are possible. On average, Medicare coverage determinations for medical devices and products lag behind FDA approval or clearance. The Medicare statutory framework is also subject to administrative rulings, interpretations and discretion that affect the amount and timing of reimbursement made under Medicare. Medicaid coverage determinations and reimbursement levels are determined on a state by state basis, because Medicaid, unlike Medicare, is administered by the states under a state plan filed with the Secretary of the 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 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 U.S., 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 U.S. Patent and Trademark Office (USPTO) 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 U.S.

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 U.S. 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 U.S. can be less extensive than those in the U.S. 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 U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. 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 U.S. 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 USPTO 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 (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 U.S. 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 U.S. 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 U.S. or in any foreign market. For example, during September 2017, we withdrew our application seeking clearance of our system for soft tissue ablation. In addition, in connection with the Pre-Market Notification 510(k) we submitted to the FDA seeking clearance to commercialize our CellFX System, in February 2020, we received a NSE letter from the FDA, indicating that based on the data provided, we had not demonstrated that the CellFX System is substantially equivalent to the predicate device, concluding the 510(k) review process without clearance. We will continue to work with the FDA in pursuit of a clearance via a new 510(k) submission. However, we may not be able to obtain the necessary clearances or approvals necessary to market our CellFX System or such approvals or clearances may be unduly delayed, which could harm our business. We may be required to seek FDA approval through the de novo pathway or file a PMA for our CellFX System, which will require additional clinical data, resources and time.

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, the receipt of the NSE letter from the FDA indicating failure to obtain 510(k) clearance on our February 2019 submission has added significant time and expense to our regulatory clearance process (including additional expense that we will incur in preparing a new 510(k) submission), has delayed our ability to generate revenue, and has had a negative impact on our stock price.

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 (OIG), the Department of Justice (DOJ,) state attorneys general, and other foreign and domestic government agencies. Our failure to comply with laws, rules and regulations governing our relationships with physicians, or an investigation into our compliance by the OIG, DOJ, state attorneys general and other government agencies, could significantly harm our business, including compromising the use or integrity of our clinical data in regulatory submissions to the FDA or similar regulatory authorities.

We 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 federal healthcare program, such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value, and the government can find a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the law or a specific intent to violate. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

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

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

- HIPAA, as amended by the 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. The CCPA went into effect in January 2020, 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 compliance program to help identify and deter healthcare violations by employees and other third parties that perform services for us. Notwithstanding our efforts, 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 violations of such laws, regulations and other obligations, or that fraud or other misconduct has taken place, even if none occurred. If any such actions are instituted against us, 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 if we are not successful in defending ourselves or asserting our rights. 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 U.S., 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 disagree with us regarding the design or conduct of our clinical trials, resulting in an increased risk of difficulties or delays in obtaining regulatory approval or clearance in the U.S. and increased costs. For example, in February 2020, we received a NSE letter from the FDA, indicating that based on the data provided, we had not demonstrated that the CellFX System is substantially equivalent to the predicate device, concluding the 510(k) review process without clearance. We will continue to work with the FDA in pursuit of a clearance via a new 510(k) submission, providing additional clinical data as required.

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 indication or labeling 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 U.S. through periodic inspections by state and federal agencies, including the FDA, and in international jurisdictions by comparable agencies. Failure to comply with regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure to obtain premarket clearance or premarket approval for devices, withdrawal of approvals or clearances previously obtained, and criminal prosecution. The restriction, suspension or revocation of regulatory approvals or clearances, or any other failure to comply with regulatory requirements 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 or employees, collaborators and other personnel, which could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the laws of the FDA and other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; or (iii) healthcare fraud and abuse laws in the U.S. and similar foreign fraudulent misconduct laws. These laws may impact, among other things, future sales, marketing and education programs. The promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud and abuse, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

We adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent 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. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business and financial condition.

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

Proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of healthcare and to reform the U.S. healthcare system may impact our business significantly. Certain proposals could limit the prices we are able to charge for our products or the coverage and reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of proposals to control costs could have a material adverse effect on our business and financial condition. We cannot predict the initiatives that may be adopted in the future or their full impact on our business. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may negatively impact our ability to set a price that we believe is fair for our products, our ability to generate revenue and achieve profitability, and the availability of capital.

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 U.S. 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. In December 2019, this excise tax was permanently repealed, effective after December 31, 2019.

On January 2, 2013, the American Taxpayer Relief Act of 2012, 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 U.S. 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 such as the CellFX System;
- 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;
- actual or alleged security breaches;
- announcements or expectations of additional financing efforts;
- sales of our common stock by us or our stockholders;
- stock price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- reports, guidance and ratings issued by securities or industry analysts;
- overall conditions in our industry and market including the impact of COVID-19; 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 certain of 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 (Nasdaq), the market for our shares has demonstrated varying levels of trading activity. As a result of these and other factors, you may not be able to sell your common stock quickly 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 stockholder 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 Robert W. Duggan, Chairman of our board of directors, who beneficially owns approximately 43% of our common stock outstanding as of the date of this Annual Report. As a result, Mr. Duggan has 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.

Mr. Duggan’s 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. In addition, Mr. Duggan is not subject to any contractual restrictions on his ability to acquire additional shares of common stock and any such purchases, including purchases in connection with the proposed rights offering or any alternative equity or equity-linked offering that we may conduct, could result in his acquisition of a majority of our common stock. If this were to occur, we would be considered a “controlled” company under the Nasdaq rules and would be exempt from the obligation to comply with certain Nasdaq corporate governance requirements.

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 impact our stock price and 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 of directors, and beneficially owns approximately 43% of our common stock outstanding as of the date of this Annual Report. In addition, Mr. Duggan is not subject to any contractual restrictions on his ability to acquire additional shares of common stock, and any such purchases, including purchases in connection with the proposed rights offering or any alternative equity or equity-linked offering that we may conduct, could result in his acquisition of a majority of our common stock. As a result of Robert W. Duggan's significant ownership and position as Chairman of the board of directors, 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. In addition, public speculation regarding Mr. Duggan, as well as our relationship with Mr. Duggan, could cause our stock price to fluctuate.

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

As a public company, listed in the U.S., 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, 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 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 from our IPO in 2016, 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 1B. Unresolved Staff Comments

None.

Item 2. Properties

We lease approximately 29,000 square feet of premises located in Hayward, California, which is used for our corporate headquarters and principal operating facility. The term of the original lease included approximately 15,700 square feet for 62 months and commenced on July 1, 2017. During May 2019, we entered into an amendment to the lease which amended the existing lease and provided for a total expansion of the premises to approximately 50,300 square feet and an option to extend the term of the lease. Approximately 13,300 square feet of the 34,600 square feet expansion was occupied in November 2019 during the first phase, the remaining approximately 21,300 square feet will be occupied in the second phase. The amended lease can be extended up to seven years.

We believe that our existing and expanded facilities will be sufficient to meet our needs for the foreseeable future.

Item 3. Legal Proceedings.

From time to time, we may be involved in a variety of claims, lawsuits, investigations and proceedings relating to securities laws, product liability, patent infringement, contract disputes and other matters relating to various claims that arise in the normal course of our business in addition 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 4. Mine Safety Disclosures

Not applicable.

Part II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is listed on Nadaq and has been traded under the symbol "PLSE" since May 18, 2016.

Holders of Record

As of February 28, 2020, there were approximately 11 stockholders of record of our common stock. We believe the actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in "street" name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividend on our common stock and have no present plans to do so. We intend to retain earnings for use in the operation and expansion of our business.

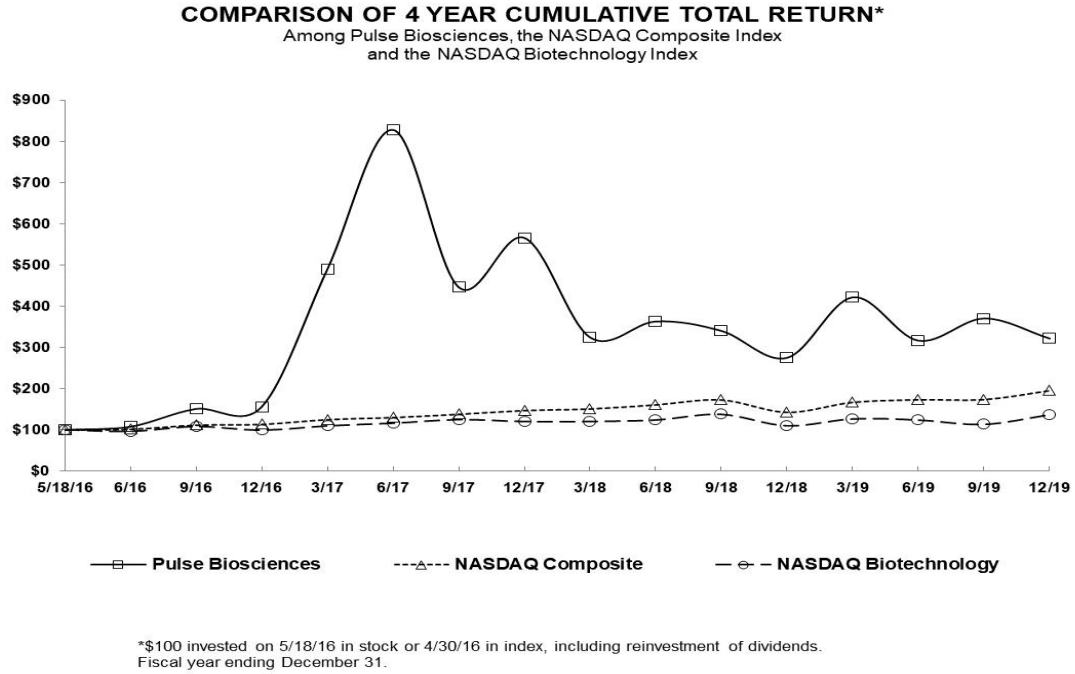
Sales of Unregistered Securities

None.

Performance Graph

The performance graph included in this Annual Report on Form 10-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference into any filing of Pulse Biosciences, Inc. under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

The following graph shows a comparison from May 18, 2016 (the date our common stock commenced trading on the Nasdaq through December 31, 2019 of the cumulative total return for our common stock, the Nasdaq Composite Index and the Nasdaq Biotechnology Index. Such returns are based on historical results and are not intended to suggest future performance. Data for the Nasdaq Composite Index and the Nasdaq Biotechnology Index assume reinvestment of dividends.



*$100 invested on 5/18/16 in stock or 4/30/16 in index, including reinvestment of dividends.
Fiscal year ending December 31.

Item 6. Selected Financial Data

The following tables set forth selected financial data as of and for the last five fiscal years. This selected financial data should be read in conjunction with our historical financial statements, including the notes thereto, and "Management's Discussion and Analysis of Financial Condition and Results of Operations," included elsewhere in this report.

	Year Ended December 31,				
(in thousands, except per share amounts)	2019	2018	2017	2016 (1)	2015 (1)
Revenue	$ —	$ —	$ —	$ —	$ —
Operating expenses:					
General and administrative	22,327	20,045	15,503	3,415	1,621
Research and development	24,961	17,253	9,646	5,506	2,181
Amortization of intangible assets	666	665	665	665	666
Total operating expenses	47,954	37,963	25,814	9,586	4,468
Other income (expense):					
Interest income	983	446	247	68	—
Other expense	—	(28)	—	—	—
Total other income	983	418	247	68	—
Loss from operations, before income taxes	(46,971)	(37,545)	(25,567)	(9,518)	(4,468)
Income tax benefit	—	—	—	—	(1,657)
Net loss	$ (46,971)	$ (37,545)	$ (25,567)	$ (9,518)	$ (2,811)
Net loss per share:					
Basic and diluted net loss per share	$ (2.26)	$ (2.20)	$ (1.73)	$ (0.86)	$ (0.37)
Weighted average shares used to compute net loss per common share — basic and diluted	20,746	17,078	14,754	11,009	7,565

(1) For the years ended December 31, 2016 and 2015, $0.5 million and $0.4 million, respectively, of patent legal costs were reclassified from research and development to general and administrative expenses.

	As of December 31,				
	2019	2018	2017	2016	2015
Cash, cash equivalents and investments	$ 25,398	$ 59,583	$ 38,069	$ 16,395	$ 3,606
Working capital	21,944	57,254	36,268	15,647	3,337
Total assets	41,915	70,640	49,821	26,314	14,325
Total liabilities	11,178	4,306	3,826	1,016	660
Total stockholders' equity	30,737	66,334	45,995	25,298	13,665

Item 7. 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 consolidated financial statements and the related notes thereto included in Item 8 under the heading "Financial Statements and Supplementary Data". Some of the information contained in this discussion and analysis or set forth elsewhere in this Form 10-K 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 Form 10-K 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 novel bioelectric medicine company committed to health innovation that improves and potentially extends the lives of patients. We are pursuing regulatory clearance from the FDA to market our first product, our proprietary CellFX™ System. The CellFX System utilizes its patented Nano-Pulse Stimulation™ (NPS™) technology to treat a variety of applications for which an optimal solution remains unfulfilled. NPS is a proprietary technology that delivers nanosecond duration pulses of high amplitude electrical energy to non-thermally clear targeted cells while sparing adjacent non-cellular tissue. The cell-specific effects of NPS technology have been validated in a series of completed and ongoing clinical studies.

We have incurred substantial operating losses and have used cash in our operating activities since inception. Based on our current operating plan, we believe we do not have sufficient cash and cash equivalents on hand to support current operations for at least twelve months from the date that our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K were issued. To finance our operations beyond that point, we will need to raise additional capital, which cannot be assured. We have concluded that this circumstance raises substantial doubt about our ability to continue as a going concern for at least twelve months from the date that our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K were issued. As such, we plan to seek to raise capital from time to time this year through future debt or equity financings to fund our future operations and remain as a going concern including by pursuing a proposed rights offering, seeking to raise net proceeds of approximately $30 million assuming such rights offering is fully subscribed. There is no assurance that the rights offering will be successful, or that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to us.

Plan of Operation

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

- Improve our technology by continuing our research and product development efforts. We expect to develop interchangeable tissue applicators to target different tissue types that will leverage the novel characteristics of our technology platform.
- Further explore and understand the benefits of NPS technology platform with the objectives of broadening the currently planned cosmetic and therapeutic applications and identifying new applications. We anticipate that results of our clinical studies will enable us to recognize certain unmet medical needs that may be addressed by our technology.
- Continue to protect and expand our intellectual property portfolio with respect to NPS technology, which we expect will increase our ability to deter competitors and position our company for favorable licensing and partnering opportunities.
- Partner with medical or biomedical device companies for certain applications which we anticipate may accelerate product development and acceptance into target market areas and allow us to gain the sales and marketing advantages of the distribution infrastructure.

Critical Accounting Policies and Significant Judgments

The discussion and analysis of financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with the rules and regulations of the SEC. Certain accounting policies and estimates are particularly important to the understanding of our financial position and results of operations and require the application of significant judgment by management or can be materially affected by changes from period to period in economic factors or conditions that are outside of the company's control. As a result, these issues are subject to an inherent degree of uncertainty. In applying these policies, management uses its judgment to determine the appropriate assumptions to be used in the determination of certain estimates. Those estimates are based on our historical operations, future business plans and the projected financial results, the terms of existing contracts, trends in the industry and information available from other outside sources.

Long-Lived Assets

We review long-lived assets, consisting of property and equipment and 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. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the assets. Assets to be disposed of are separately presented in the consolidated balance sheet, reported at the lower of the carrying amount or fair value less costs to sell, and are no longer depreciated.

Goodwill

We record goodwill when the consideration paid in a business acquisition exceeds the fair value of the net tangible assets and the identified intangible assets acquired. 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 based on the fair value of the reporting units. If events or circumstances do not indicate that the fair value of a reporting unit is below its carrying amount, goodwill is not considered impaired and no further testing is required. If further testing is required, we perform a two step-process. The first step involves comparing the fair value of the reporting unit to its carrying value, including goodwill. If the carrying value of the reporting unit exceeds its fair value, the second step of the test is performed by comparing the carrying value of the goodwill in the reporting unit to its implied fair value. An impairment charge is recognized for the excess of the carrying value of goodwill over its implied fair value. For the purpose of impairment testing, we have determined that the Company has one reporting unit. To date, there has been no impairment of goodwill.

Stock-Based Compensation

We periodically issue stock options to officers, directors, employees and consultants for services rendered. Such issuances vest and expire according to terms established at the issuance date. Stock-based payments to officers, directors and employees, including grants of employee stock options, are recognized in the financial statements based on their fair values. Stock option grants, which are generally time vested, are measured at the grant date fair value and charged to operations on a straight-line basis over the vesting period. We estimate the grant date fair value of stock options, using the Black-Scholes option-pricing model.

The Black-Scholes option-pricing model requires the use of highly subjective assumptions which determine the fair value of stock-based awards. The assumptions used in our option-pricing model represent management's best estimates. These estimates are complex, involve a number of variables, uncertainties and assumptions and the application of management's judgment, so that they are inherently subjective. If factors change and different assumptions are used, our stock-based compensation expense could be materially different in the future.

Income Taxes

We account for income taxes using the asset and liability method, whereby deferred tax assets and liability account balances are determined based on differences between the financial reporting and tax bases of assets and liabilities, and are measured using the enacted rates and laws that will be in effect when the differences are expected to reverse.

We provide a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realized. If we determine that we would be able to realize deferred tax assets in the future in excess of the recorded amount, an adjustment

to the deferred tax assets would be credited to operations in the period such determination was made. Likewise, should we determine that we would not be able to realize all or part of its deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to operations in the period such determination was made.

We account for uncertainties in income tax law under a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns as prescribed by Financial Accounting Standards Board (FASB) issued Accounting Standards Codification (ASC) 740-10 - *Accounting for Uncertainty in Income Taxes*. The tax effects of a position are recognized only if it is "more-likely-than-not" to be sustained by the taxing authority as of the reporting date. If the tax position is not considered "more-likely-than-not" to be sustained, then no benefits of the position are recognized.

We are subject to U.S. federal income taxes and income taxes in California. As our net operating losses have yet to be utilized, previous tax years remain open to examination by federal authorities and other jurisdictions in which we currently operate or have operated in the past. We are not currently under examination by any tax authority.

Components of Results of Operations

Operating Expenses

We generally recognize operating expenses as general and administrative costs and research and development costs, as well as non-cash amortization of intangible assets. Our operating expenses also include non-cash components related to depreciation and amortization of property and equipment and stock-based compensation costs, which are allocated, as appropriate, to general and administrative costs and research and development costs.

- General and administrative expenses consist of salaries and related expenses for executive, finance, legal, human resources, information technology and administrative personnel, professional fees, patent filing fees and costs, insurance costs and other general corporate expenses. We expect general and administrative expenses to increase in the future as we hire personnel and incur additional costs to support the expansion of our research and development activities and our operation as a public company, including higher legal, accounting, insurance, compliance, compensation and other costs.

- Research and development expenses consist of salaries and related expenses and consulting costs related to the design, development and enhancement of our potential future products, prototypes material and devices, including rent. We expect research and development costs to increase in the future as we initiate additional clinical trials, continue development and enhancement of our CellFX System and pursue commercial applications of our NPS technology.

Results of Operations

Comparison of the Years ended December 31, 2019 and 2018

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

	Year Ended December 31,		
(in thousands)	2019	2018	$ Change
Revenue	$ —	$ —	$ —
Operating expenses:			
General and administrative	22,327	20,045	2,282
Research and development	24,961	17,253	7,708
Amortization of intangible assets	666	665	1
Total operating expenses	47,954	37,963	9,991
Other income (expense):			
Interest income	983	446	537
Other expense	—	(28)	28
Total other income	983	418	565
Loss from operations, before income taxes	(46,971)	(37,545)	(9,426)
Income tax benefit	—	—	—
Net loss	$ (46,971)	$ (37,545)	$ (9,426)

General and Administrative

General and administrative expenses consist of salaries and related expenses for executives, marketing, sales, finance, legal, human resources, information technology and administrative personnel. General and administrative expenses increased by $2.3 million to $22.3 million in 2019 from $20.0 million in 2018 due primarily to $1.2 million of increased headcount related expenses and $1.1 million of increased corporate insurance policy and Delaware franchise tax expense due to our expanded operational infrastructure. General and administrative expenses are expected to increase during 2020 with the buildout of additional operational infrastructure to support the anticipated commercialization of our CellFX System in the aesthetic dermatology market.

Research and Development

Research and development expenses consist of salaries and related expenses for research and development personnel, clinical trials professional fees and consulting costs related to the design, development and enhancement of our potential future products, engineering prototypes supplies and pre-commercial manufacturing supplies. Research and development expenses increased by $7.7 million to $25.0 million in 2019 from $17.3 million in 2018 due primarily to $3.7 million of increased headcount related expenses, $1.4 million of increased clinical trial and sponsored research related expense from the Company's expanded clinical studies of NPS technology including the treatment of sebaceous hyperplasia, seborrheic keratosis, warts, and other general benign lesions, $1.7 million of increased engineering and manufacturing supplies and consulting expenses in support of continued development of the CellFX System capabilities and pre-commercial supply chain, $0.5 million of increased CellFX ecommerce system development and facility expenses from the expansion of our Hayward facility, and $0.4 million of increased travel expenses.

Other Income (Expense)

Other income increased by approximately $0.6 million to $1.0 million in 2019 from $0.4 million due primarily to higher interest income earned as a result of higher average monthly investment balances.

Comparison of the Years ended December 31, 2018 and 2017

Refer to Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations located in our 10-K for the fiscal year ended December 31, 2018, filed on March 14, 2019, for the discussion of the comparison of the fiscal year ended December 31, 2018 to the fiscal year ended December 31, 2017, the earliest of the three fiscal years presented in the consolidated financial statements.

Liquidity and Capital Resources

To date, we have not generated any revenues from product sales. Since inception, we have funded our business plan through the issuance of equity securities and grants from governmental agencies. We intend to invest in research and development to develop commercially viable products and to assess the feasibility of potential future products. Additionally, we expect that our general and administrative expenses will increase as we continue to incur substantial incremental costs associated with being a public company.

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

	Year Ended December 31,		
(in thousands)	2019	2018	2017
Net cash used in operating activities	$ (34,174)	$ (23,896)	$ (11,087)
Net cash provided by (used in) investing activities	$ (10,112)	$ 26,117	$ (22,998)
Net cash provided by financing activities	$ 82	$ 45,496	$ 35,382
Net increase (decrease) in cash and cash equivalents	$ (44,204)	$ 47,717	$ 1,297

At December 31, 2019, we had cash, cash equivalents and investments of $25.4 million. Our independent registered public accounting firm has issued a "going concern" opinion, meaning that there is substantial doubt we can continue as an ongoing business for the next twelve months from the date that our audited consolidated financial statements included elsewhere

on this Annual Report on Form 10-K were issued unless we obtain additional capital. To date, we have not generated any revenue. As a result, 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.

We plan to raise additional capital in the future, including by pursuing a proposed rights offering, which was approved by our board of directors in February 2020, seeking to raise net proceeds of approximately $30 million assuming such rights offering is fully subscribed. There is no assurance that the rights offering will be successful, or that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to us.

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 certain 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

During 2019, we used cash of $34.2 million in operating activities. The difference between cash used in operating activities and net loss consisted primarily of stock-based compensation, depreciation and amortization, increased accounts payable and accrued expenses.

During 2018, we used cash of $23.9 million in operating activities. The difference between cash used in operating activities and net loss consisted primarily of stock-based compensation, depreciation and amortization, increased accounts payable and accrued expenses, partially offset by increased prepaid expenses and decreased deferred rent.

Investing Activities

During 2019, we used cash of $10.1 million for investing activities, of which $9.5 million was used for the net purchases of investments and $0.6 million for property and equipment.

During 2018, cash provided from investing activities of $26.1 million from the sale of investments of $24.9 million and $41.8 million of cash proceeds from the maturities of investments, partially offset by $40.3 million cash used for the purchase of investments and $0.3 million cash used for the purchase of property and equipment.

Financing Activities

During 2019, cash provided from financing activities was $0.1 million in connection with the proceeds from stock option exercises and employee stock purchases offset by tax payments withheld for the vesting of restricted stock units.

During 2018, cash provided from financing activities was $45.5 million due to net proceeds from our rights offering and the issuance of common stock in connection with the exercise of stock options and warrants and our employee stock purchase plan.

Comparison of the Years ended December 31, 2018 and 2017

Refer to Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations located in our 10-K for the fiscal year ended December 31, 2018, filed on March 14, 2019, for the discussion of the comparison of the fiscal year ended December 31, 2018 to the fiscal year ended December 31, 2017, the earliest of the three fiscal years presented in the consolidated financial statements.

Contractual Obligations

Frank Reidy Research Center Agreement

As provided for in the license agreement with ODURF and EVMS, effective on November 6, 2014, we sponsored certain approved research activities at ODURF's Frank Reidy Research Center under a sponsored research agreement. In June 2017,

we agreed to sponsor $0.7 million in research from July 1, 2017 to June 30, 2018. In August 2018, we agreed to sponsor $0.8 million in research from September 1, 2018 to August 1, 2019. In September 2019, we agreed to sponsor $0.8 million in research from October 1, 2019 to September 1, 2020. These sponsored researches were funded through monthly payments made upon ODURF certifying, to our 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 with our approval so long as the obligations of ODURF under the task order and statement of work remain unchanged and unimpaired. During the years ended December 31, 2019, 2018, and 2017, we incurred costs relating to the sponsored research agreement equal to $0.9 million, $0.7 million and $0.8 million, respectively. As of December 31, 2019, $0.6 million remained payable under this agreement.

In addition, during 2017, we agreed to provide $0.3 million in research funding to researchers affiliated with ODURF and EVMS matching funds made available to those researchers by the Virginia Biosciences Health Research Corporation. Our sponsorship affords access to certain intellectual property, if any, developed during the project. As of December 31, 2019, no amount remained available under this agreement.

Operating Lease

We lease approximately 29,000 square feet of premises located in Hayward, California, which is used for our corporate headquarters and principal operating facility. The term of the original lease included 15,700 square feet for 62 months and commenced on July 1, 2017. During May 2019, we entered into an amendment to the lease which amended the existing lease and provided for a total expansion of the premises to approximately 50,300 square feet and an option to extend the term of the lease. Approximately 13,300 square feet of the 34,600 square feet expansion was occupied in November 2019 during the first phase, the remaining approximately 21,300 square feet will be occupied in the second phase. The amended lease can be extended up to seven years.

Under the original lease agreement, the landlord provided $2.1 million allowance for tenant improvements, which was recorded as deferred rent at the inception of the lease term. Future minimum lease payment are net of amortization of tenant improvement allowance. The following table summarizes our contractual obligations as of December 31, 2019 (in thousands):

	Payments Due by Period				
(in thousands)	Total	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 Years
Operating leases	$ 10,988	$ 647	$ 2,057	$ 2,227	$ 6,057

Off-Balance Sheet Arrangements

At December 31, 2019, we did not have any transactions, obligations or relationships that could be considered 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 December 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, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Trends, Events and Uncertainties

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

We cannot assure investors that our technology will be adopted or that we will ever achieve sustainable revenues sufficient to support our operations. Even if we are able to generate revenues, there can be no assurances that we will be able to achieve profitability or positive operating cash flows. There can be no assurances that we will be able to secure additional financing in the future on acceptable terms or at all. If cash resources are insufficient to satisfy our ongoing cash needs, we would be required to scale back or discontinue our technology and product development programs, or obtain funds, if available, although there can be no assurances, through the sale, licensing or strategic alliances that could require us to relinquish rights to our technology and intellectual property, or to curtail, suspend or discontinue our operations entirely.

Other than as discussed above and elsewhere in this Annual Report on Form 10-K, 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 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates.

Interest Rate and Market Risk

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

Foreign Exchange Risk

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

Item 8. Financial Statements and Supplementary Data

PULSE BIOSCIENCES, INC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Pulse Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows of Pulse Biosciences, Inc. (as defined in Note 1 to the consolidated financial statements) (the "Company") for the year ended December 31, 2017, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the results of their operations and their cash flows for the year ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Gumbiner Savett Inc.

We had served as the Company's auditor since 2015 and our tenure ended on April 16, 2018.
Santa Monica, California
March 16, 2018

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Pulse Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Pulse Biosciences, Inc. and subsidiaries (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred recurring losses and negative cash flows from operations that raise substantial doubt about the Company’s ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, the Company has changed its method of accounting for leases in 2019 due to the adoption of Accounting Standards Update No. 2016-02, *Leases (Topic 842)*, using the optional transition method.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ *DELOITTE & TOUCHE LLP*

San Jose, California
March 16, 2020

We have served as the Company's auditor since 2018.

PULSE BIOSCIENCES, INC.
Consolidated Balance Sheets
(in thousands, except par value)

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,899	$ 51,103
Investments	18,499	8,480
Prepaid expenses and other current assets	1,005	779
Total current assets	26,403	60,362
Property and equipment, net	2,566	2,173
Intangible assets, net	4,547	5,213
Goodwill	2,791	2,791
Right-of-use assets	5,114	—
Other assets	494	101
Total assets	$ 41,915	$ 70,640
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,963	$ 1,272
Accrued expenses	2,496	1,421
Deferred rent, current	—	415
Total current liabilities	4,459	3,108
Deferred rent, net of current	—	1,198
Lease liability	6,719	—
Total liabilities	11,178	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 – 20,825 shares and 20,593 shares at December 31, 2019 and 2018, respectively	21	21
Additional paid-in capital	153,401	142,032
Accumulated other comprehensive loss	4	(1)
Accumulated deficit	(122,689)	(75,718)
Total stockholders' equity	30,737	66,334
Total liabilities and stockholders' equity	$ 41,915	$ 70,640

See accompanying notes to the consolidated financial statements.

PULSE BIOSCIENCES, INC.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except per share data)

	Year Ended December 31,		
	2019	2018	2017
Revenue	$ —	$ —	$ —
Operating expenses:			
General and administrative	22,327	20,045	15,503
Research and development	24,961	17,253	9,646
Amortization of intangible assets	666	665	665
Total operating expenses	47,954	37,963	25,814
Other income (expense):			
Interest income	983	446	247
Other expense	—	(28)	—
Total other income	983	418	247
Loss from operations, before income taxes	(46,971)	(37,545)	(25,567)
Income tax benefit	—	—	—
Net loss	(46,971)	(37,545)	(25,567)
Other comprehensive loss:			
Unrealized gain (loss) on available-for-sale securities, net of tax	5	50	(44)
Comprehensive loss	$ (46,966)	$ (37,495)	$ (25,611)
Net loss per share:			
Basic and diluted net loss per share	$ (2.26)	$ (2.20)	$ (1.73)
Weighted average shares used to compute net loss per common share — basic and diluted	20,746	17,078	14,754

See accompanying notes to the consolidated financial statements.

PULSE BIOSCIENCES, INC.
Consolidated Statements of Stockholders' Equity
(in thousands, except per share amount)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balance, December 31, 2016	13,315	$ 13	$ 37,898	$ (7)	$ (12,606)	$ 25,298
Shares issued upon closing of private placements, net of issuance costs of $199	2,820	3	34,840	—	—	34,843
Issuance of shares upon exercise of warrants	522	—	50	—	—	50
Issuance of shares upon exercise of stock options	162	1	488	—	—	489
Stock-based compensation expense	—	—	10,926	—	—	10,926
Unrealized loss on available-for-sale securities	—	—	—	(44)	—	(44)
Net loss	—	—	—	—	(25,567)	(25,567)
Balance, December 31, 2017	16,819	$ 17	$ 84,202	$ (51)	$ (38,173)	$ 45,995
Issuance of common stock in a rights offering at $12.57 per share for cash, net of issuance cost of $213	3,581	4	44,782	—	—	44,786
Issuance of shares upon exercise of warrants	24	—	—	—	—	—
Issuance of shares upon exercise of stock options	145	—	498	—	—	498
Issuance of shares under employee stock purchase plan	24	—	327	—	—	327
Stock-based compensation expense	—	—	12,338	—	—	12,338
Tax payments related to shares withheld for vested restricted stock units	—	—	(115)	—	—	(115)
Unrealized gain on available-for-sale securities	—	—	—	50	—	50
Net loss	—	—	—	—	(37,545)	(37,545)
Balance, December 31, 2018	20,593	$ 21	$ 142,032	$ (1)	$ (75,718)	$ 66,334
Issuance of shares upon exercise of warrants	37	—	—	—	—	—
Issuance of shares upon exercise of stock options	99	—	272	—	—	272
Issuance of shares under employee stock purchase plan	38	—	423	—	—	423
Issuance of shares on vesting of restricted stock units	58	—	—	—	—	-
Stock-based compensation expense	—	—	11,287	—	—	11,287
Tax payments related to shares withheld for vested restricted stock units	—	—	(613)	—	—	(613)
Unrealized gain on available-for-sale securities	—	—	—	5	—	5
Net loss	—	—	—	—	(46,971)	(46,971)
Balance, December 31, 2019	20,825	$ 21	$ 153,401	$ 4	$ (122,689)	$ 30,737

See accompanying notes to the consolidated financial statements.

PULSE BIOSCIENCES, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2019	2018	2017
Cash flows from operating activities:			
Net loss	$ (46,971)	$ (37,545)	$ (25,567)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	494	645	336
Loss on disposal of fixed assets	—	28	—
Amortization of intangible assets	666	665	665
Stock-based compensation	11,287	12,338	10,926
Net premium amortization and discount on available-for-sale securities	(521)	(140)	26
Landlord incentive for tenant improvements	—	—	2,119
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(226)	(367)	(144)
Accounts payable	646	490	517
Accrued expenses	841	387	245
Right-of-use assets	68	—	—
Other assets	(393)	—	(101)
Lease liabilities	(76)	—	—
Other current and non-current liabilities	—	(397)	(109)
Net cash used in operating activities	(34,185)	(23,896)	(11,087)
Cash flows from investing activities:			
Purchases of property and equipment	(608)	(276)	(2,551)
Purchases of investments	(77,993)	(40,297)	(43,595)
Maturities of investments	68,500	41,815	23,148
Sales of investments	—	24,875	—
Net cash provided by (used in) investing activities	(10,101)	26,117	(22,998)
Cash flows from financing activities:			
Proceeds from exercises of stock options and warrants	272	498	539
Proceeds from issuance of common stock from private placements, net of issuance costs of $199	—	—	34,843
Proceeds from issuance of common stock under employee stock purchase plan	423	327	—
Proceeds from issuance of common stock from rights offering, net of issuance costs of $213	—	44,786	—
Tax payments related to shares withheld for vested restricted stock units	(613)	(115)	—
Net cash provided by financing activities	82	45,496	35,382
Net increase (decrease) in cash and cash equivalents	(44,204)	47,717	1,297
Cash and cash equivalents at beginning of period	51,103	3,386	2,089
Cash and cash equivalents at end of period	$ 6,899	$ 51,103	$ 3,386
Supplemental disclosure of noncash investing and financing activities:			
Equipment purchases included in accounts payable and accrued expenses	$ 279	$ 33	$ 38

See accompanying notes to the consolidated financial statements.

PULSE BIOSCIENCES, INC.
Notes to Consolidated Financial Statements

1. Description of the Business

Pulse Biosciences, Inc. (the Company) is a novel bioelectric medicine company committed to health innovation that improves and potentially extends the lives of patients. The Company is pursuing regulatory clearance to market its first product, its proprietary CellFX System. The Company's CellFX System utilizes its patented Nano-Pulse Stimulation™ (NPS™) technology to treat a variety of applications for which an optimal solution remains unfulfilled. NPS is a proprietary technology that delivers nanosecond duration pulses of high amplitude electrical energy to non-thermally clear targeted cells while sparing adjacent non-cellular tissue. The cell-specific effects of NPS technology have been validated in a series of completed and ongoing clinical studies.

The Company was incorporated in Nevada on May 19, 2014, and was reincorporated in the State of Delaware on June 18, 2018. The Company's headquarters and research facility are located in Hayward, California.

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

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) and pursuant to the rules and regulations of the United States Securities Exchange Commission (the SEC). The consolidated financial statements include the financial statements of the Company and its wholly-owned subsidiaries and intercompany balances and transactions have been eliminated in consolidation.

Going concern

As of December 31, 2019, the Company had an accumulated deficit of $122.7 million, cash outflows from operations of $34.2 million, and cash, cash equivalents and investments of $25.4 million and anticipates that it will continue to incur significant operating losses for the next several years. Until such time as the Company can generate substantial product revenue and achieve profitability, the Company will need to raise additional capital. The Company plans to raise additional capital to fund its operations for at least the next twelve months from the date of issuance of the accompanying consolidated financial statements, including via a proposed rights offering that seeks to raise net proceeds of approximately $30 million, assuming such rights offering is fully subscribed. There is no assurance that the rights offering will be successful, or that additional financing will be available when needed or that management of the Company will be able to obtain financing on terms acceptable to the Company. Accordingly, the Company's management cannot conclude that such plans will be effectively implemented within twelve months from the date of issuance of the accompanying consolidated financial statements.

These factors, combined with the Company's forecast of cash required to fund operations for a period of at least twelve months from the date of issuance of the accompanying consolidated financial statements, raise substantial doubt about the Company's ability to continue as a going concern.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make estimates that affect the amounts reported in the financial statements and accompanying notes to the financial statements. Estimates include, but are not limited to, the valuation of investments, clinical trial accruals, the valuation and recognition of stock-based compensation and useful lives assigned to long-lived assets. Actual amounts could differ from these estimates.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents and investments. The Company places its cash equivalents and investments with high credit quality financial institutions and, by policy, limits the amounts invested with any one financial institution or issuer. Deposits held with banks may exceed the amount of insurance provided on such deposits. The Company has not experienced any losses since inception.

Fair Value of Financial Instruments

The Company believes the carrying amounts of its financial instruments, including cash equivalents, prepaid expenses and other current assets, accounts payable and accrued expenses, approximate fair value due to the short-term nature of such instruments.

Cash, Cash Equivalents and Investments

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. The Company has designated all investments as available-for-sale and therefore, such investments are reported at fair value, with unrealized gains and losses recognized in accumulated other comprehensive income (loss) (AOCI) in stockholders' equity. The cost of marketable securities is adjusted for the amortization of premiums and discounts to expected maturity. Premium and discount amortization is included in other income, net. Realized gains and losses, as well as interest income, on available-for-sale securities are also included in other income, net. The Company includes all of its available-for-sale securities in current assets.

All of the Company's investments are subject to annual impairment review. The Company recognizes an impairment loss when a decline in the fair value of its marketable investments below the cost basis is judged to be other-than-temporary. Factors considered in determining whether a loss is temporary include the length of time and extent to which the marketable investments fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, extent of the loss related to credit of the issuer, the expected cash flows from the security, the Company's intent to sell the security and whether or not the Company will be required to sell the security before the recovery of its amortized cost. No impairment losses were incurred during the periods presented.

Property and Equipment

Leasehold improvements are amortized using the straight-line method over the shorter of the lease term or estimated useful life. Equipment is recorded at cost and depreciated using the straight-line method over their estimated useful lives, ranging from three to five years.

Intangible Assets

The Company's intangible assets consist of acquired patents and licenses, which are amortized over their estimated useful lives of twelve years.

Long-Lived Assets

The Company reviews long-lived assets, consisting of property and equipment and intangible assets, for impairment during each fiscal year or when events or changes in circumstances indicate the carrying value of these assets may exceed their current fair values. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. No impairment losses were incurred during the periods presented.

Goodwill

The Company records goodwill when the consideration paid in a business acquisition exceeds the fair value of the net tangible assets and the identified intangible assets acquired. The Company reviews goodwill for impairment at the reporting unit level at least annually or whenever changes in circumstances indicate that the carrying value of the goodwill may not be recoverable. To date, there has been no impairment of goodwill.

Stock-Based Compensation

The Company recognizes the cost of stock-based compensation in the financial statements based upon fair value. The fair value of stock options is determined as of the grant date using the Black-Scholes option pricing model. The fair value of restricted stock and restricted stock unit (RSU) awards is determined based on the number of units granted and the closing price of the Company's common stock on the grant date. The fair value of each purchase under the employee stock purchase plan (ESPP) is estimated at the beginning of the offering period using the Black-Scholes option pricing model. The Company's determination of the fair value of equity-settled awards is impacted by the price of the Company's common stock as well as changes in assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, the expected term that awards will remain outstanding, expected common stock price volatility over the term of the awards, risk-free interest rates and expected dividends. The fair value of an award is recognized over the period during which service is required to be performed in exchange for the award, the requisite service period (usually the vesting period) on a straight-line basis.

Equity instruments issued to non-employees are recorded at their fair value on the grant date and are subject to periodic adjustments as the underlying equity instruments vest. The fair value of these equity instruments are expensed over the service period.

Estimates of the fair value of equity-settled awards as of the grant date using valuation models, such as the Black-Scholes option pricing model, are affected by assumptions regarding a number of complex variables. Changes in the assumptions can materially affect the fair value of the award and the stock-based compensation expense recognized. These inputs are subjective and generally require significant analysis and judgment to develop. The Company determines the volatility factor based on the historical volatilities of comparable public companies in similar industries. The risk-free interest rate is based on the yield available on U.S. Treasury zero-coupon issues similar in duration to the expected term of the equity-settled award. For all stock options granted to date, the Company used the simplified method to calculate the expected term, which is the average of the contractual term and vesting period. Prior to the Company's initial public offering, the fair value of common stock was determined by reference to either recent or anticipated cash transactions involving the sale of the Company's common stock.

The Company recognizes the fair value of stock-based compensation costs in general and administrative costs and in research and development costs, as appropriate, in the Company's consolidated statements of operations.

Research and Development Costs

Research and development costs consist primarily of compensation costs, fees paid to consultants and outside service providers and organizations (including university research institutes), costs associated with clinical trials, development prototypes and other expenses relating to the acquisition, design, development and testing of the Company's product candidates, and certain facilities related costs. Research and development costs incurred by the Company are expensed as incurred, unless the achievement of milestones, the completion of contracted work, or other information indicates that a different expensing schedule is more appropriate.

Patent Costs

The Company is the owner of numerous domestic and foreign patents. Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company's research efforts and any related patent applications, patent costs not related to acquired patents, including patent-related legal fees, filing fees and other costs, including internally generated costs, are expensed as incurred. During the years ended December 31, 2019, 2018 and 2017, patent costs totaled $0.6 million, $0.6 million and $0.8 million, respectively. Patent costs are included in general and administrative costs in the consolidated statements of operations and comprehensive loss.

Income Taxes

The Company accounts for income taxes under an asset and liability approach for financial accounting and reporting for income taxes. Accordingly, the Company recognizes deferred tax assets and liabilities for the expected impact of differences between the financial statements and the tax basis of assets and liabilities.

The Company records a valuation allowance to reduce its deferred tax assets to the amount that is more-likely-than-not to be realized. In the event the Company determines that it would be able to realize its deferred tax assets in the future in excess of its recorded amount, an adjustment to the deferred tax assets would be credited to operations in the period such determination

was made. Likewise, should the Company determine that it would not be able to realize all or part of its deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to operations in the period such determination was made.

The Company is subject to U.S. federal income taxes and income taxes in the State of California. As the Company's net operating losses have yet to be utilized, previous tax years remain open to examination by federal authorities and other jurisdictions in which the Company currently operates or has operated in the past. The Company is not currently under examination by any tax authority.

The Company accounts for uncertainties in income tax law under a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns as prescribed by U.S. GAAP. The tax effects of a position are recognized only if it is more-likely-than-not to be sustained by the taxing authority as of the reporting date. If the tax position is not considered more-likely-than-not to be sustained, then no benefits of the position are recognized. At December 31, 2019 and 2018, the Company had not recorded any liability for uncertain tax positions. The Company includes interest and penalties related to uncertain tax positions as a component of income tax expense.

Comprehensive Loss

Comprehensive loss consists of net loss and unrealized gains or losses on available-for-sale investments. The Company displays comprehensive loss and its components as part of the consolidated statements of operations and comprehensive loss.

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.

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

	Year Ended December 31,		
	2019	2018	2017
Common stock warrants	167,847	213,485	249,709
Common stock options	3,749,186	2,956,687	2,598,659
Restricted stock units	222,606	222,606	229,774
Total	4,139,639	3,392,778	3,078,142

Segment and Geographical Information

The Company operates and manages its business as one reportable and operating segment. The Company's 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 the Company's assets are based in the United States (U.S.).

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers*, requiring an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. This updated standard became effective for the Company in the first quarter of fiscal year 2018. Since the Company has not recognized or generated revenue to date, the adoption of this pronouncement did not have any impact to its financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*, amended Accounting Standard Codification (ASC) 842, *Leases*. The new standard requires lessees to record a right-of-use asset and a corresponding lease liability on the balance sheet (with the exception of short-term leases). The Company adopted ASC 842 on January 1, 2019, using the modified retrospective 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 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.

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Non-employee Share-Based Payment Accounting*, which expands the scope of Topic 718, Compensation—Stock Compensation to include share-based payments issued to non-employees for goods or services. Consequently, the accounting for share-based payments to non-employees and employees will be substantially aligned. The Company adopted ASU 2018-07 in the first quarter of 2019, and the adoption had no significant impact to its financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which eliminates certain exceptions related to the general principles in ASC 740 and makes amendments to other areas with the intention of simplifying various aspects related to accounting for income taxes. The new standard is effective for fiscal years beginning after December 15, 2020, including interim periods therein; with early adoption permitted. The Company is currently evaluating the impact that the standard will have on its financial statements and related disclosures; and does not expect the adoption to have a material impact on the Company's financial statements.

3. Investments and Fair Value of Financial Instruments

Investments

The Company's investments have been classified and accounted for as available-for-sale. The Company's investments consisted of the following (in thousands):

	December 31, 2019			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities	$ 18,495	$ 4	$ —	$ 18,499
Total assets measured at fair value	$ 18,495	$ 4	$ —	$ 18,499

	December 31, 2018			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities	$ 8,481	$ —	$ (1)	$ 8,480
Total assets measured at fair value	$ 8,481	$ —	$ (1)	$ 8,480

The contractual maturities of the Company's investments were as follows (in thousands):

	December 31,	
Investments	2019	2018
Due in one year	$ 18,499	$ 8,480
Due in one to two years	—	—
Total	$ 18,499	$ 8,480

Fair Value of Financial Instruments

The Company determines the fair value of its financial instruments based on a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three levels:

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 in 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 (in thousands):

		December 31, 2019			
Assets	**Classification**	**Level 1**	**Level 2**	**Level 3**	**Total**
Money market funds	Cash and cash equivalents	$ 6,429	$ —	$ —	$ 6,429
U.S. Treasury securities	Investments	—	18,499	—	18,499
Total assets measured at fair value		$ 6,429	$ 18,499	$ —	$ 24,928

		December 31, 2018			
Assets	**Classification**	**Level 1**	**Level 2**	**Level 3**	**Total**
Money market funds	Cash and cash equivalents	$ 50,703	$ —	$ —	$ 50,703
U.S. Treasury securities	Investments	—	8,480	—	8,480
Total assets measured at fair value		$ 50,703	$ 8,480	$ —	$ 59,183

During year ended December 31, 2019 and 2018, the Company did not record impairment charges related to its marketable investments. During the years ended December 31, 2019 and 2018, the Company did not have any transfers between Level 1, Level 2 or Level 3 of the fair value hierarchy. Additionally, the Company did not have any financial assets and liabilities measured at fair value on a non-recurring basis as of December 31, 2019 or 2018.

4. Balance Sheet Components

Property and Equipment, net

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

	December 31,	
	2019	**2018**
Leasehold improvements	$ 2,248	$ 2,248
Laboratory equipment	677	518
Furniture, fixtures and equipment	466	248
Software	118	118
Construction in progress	543	33
	4,052	3,165
Less: Accumulated depreciation and amortization	(1,486)	(992)
	$ 2,566	$ 2,173

The lease for Company's current premises in Hayward, California began in July 2017, per terms of the lease, the landlord provided $2.1 million in tenant improvement allowance which was capitalized.

Depreciation and amortization expense for the years ended December 31, 2019, 2018, and 2017 was $0.5 million, $0.6 million, and $0.3 million, respectively.

Intangible Assets, net

Intangible assets primarily consist of a license 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 (EVMS), 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, a leading research organization in the field, 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):

	December 31, 2019	December 31, 2018
Acquired patents and licenses	$ 7,985	$ 7,985
Less: Accumulated amortization	(3,438)	(2,772)
	$ 4,547	$ 5,213

A schedule of the amortization of intangible assets is as follows (in thousands):

Years ending December 31:	
2020	$ 665
2021	665
2022	665
2023	665
2024	665
Thereafter	1,222
	$ 4,547

Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2019	December 31, 2018
Compensation expense	$ 1,699	$ 938
Accrued clinical	262	156
Professional fees	51	274
Property and equipment	234	—
Other	250	53
	$ 2,496	$ 1,421

The compensation expense includes approximately $0.3 million relating to the departure of an executive officer.

5. Goodwill

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

The Company reviews goodwill for impairment annually or whenever changes in circumstances indicate that the carrying amount of goodwill may not be recoverable. Based on the Company's annual review as of December 31, 2019, the Company determined that its goodwill was not impaired.

6. Stockholders' Equity and Stock-Based Compensation

Preferred Stock

The Company has authorized a total of 50,000,000 shares of preferred stock, par value $0.001 per share, none of which were outstanding at December 31, 2019 and 2018. The Company's Board of Directors (the Board) has the authority to issue preferred stock and to determine the rights, preferences, privileges, and restrictions, including voting rights, without any further vote or action by the Company's stockholders.

Common Stock

The Company has authorized a total of 500,000,000 shares of common stock, par value $0.001 per share.

Private Placements

During February 2017, the Company entered into a securities purchase agreement, pursuant to which the Company, in a

private placement, issued and sold an aggregate of 819,673 shares of the Company's common stock, par value $0.001 per share, at a price per share of $6.10, for net proceeds of approximately $5.0 million.

During September 2017, the Company entered into a securities purchase agreement with an existing investor, pursuant to which the Company, in a private placement, issued and sold an aggregate of 2,000,000 shares of the Company's common stock, par value $0.001 per share, at a price per share of $15.02, for net proceeds of approximately $29.9 million.

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 shares of 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 (Private Placement Warrants). The Private Placement Warrants are exercisable for a period of seven years. As of December 31, 2019, there were a total of 46,238 of 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, as representatives of the underwriters of its initial public offering to purchase a total of 574,985 shares of its common stock at a price of $5.00 per share (IPO Warrants). The IPO Warrants are exercisable for a period of five years. As of December 31, 2019, there were a total of 121,609 of the IPO Warrants outstanding.

A summary of total warrants activity for the year ended December 31, 2019 is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Warrants outstanding at December 31, 2018	213,485	$ 4.00	2.37
Issued	—		
Exercised	(45,638)	$ 2.67	
Expired/terminated	—		
Warrants outstanding and exercisable at December 31, 2019	167,847	$ 4.36	1.28

During the year ended December 31, 2019, warrants to purchase 45,638 shares of common stock were net exercised, resulting in the issuance of approximately 37,320 shares of common stock.

The intrinsic value of exercisable in-the-money stock warrants was approximately $1.5 million as of December 31, 2019.

Equity Plans

2017 Equity Incentive Plan and 2017 Inducement Equity Incentive Plan

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

(the 2017 Plan).

The 2017 Plan has a 10-year term, and provides for the grant of stock options, stock appreciation rights, restricted stock, RSUs, performance units, and performance shares to employees, directors and consultants of the Company and any parent or subsidiary of the Company, as the Compensation Committee of the Board may determine. The 2017 Plan is administered by the Board's Compensation Committee.

Subject to an annual evergreen increase and adjustment in the case of certain capitalization events, the Company initially reserved 1,500,000 shares of the Company's common stock for issuance pursuant to awards under the 2017 Plan. In addition, shares remaining available under the Company's 2015 Equity Incentive Plan, as amended (the "2015 Plan"), and shares reserved but not issued pursuant to outstanding equity awards that expire or terminate without being exercised or that are forfeited or repurchased by the Company will be added to the shares of common stock available for issuance under the 2017 Plan.

Effective January 1, 2019, the number of shares of common stock available under the 2017 Plan increased by 823,716 shares pursuant to the evergreen provision of the 2017 Plan. Under the evergreen provision of the 2017 Plan, the share increase is determined based on the least of (i) 1,200,000 shares, (ii) 4% of the Company's common stock outstanding at December 31 of the immediately preceding year, or (iii) such number of shares as determined by the Board. As of December 31, 2019, 998,288 shares of common stock remained available for issuance under the 2017 Plan.

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

The Inducement Plan has a 10-year term, and provides for the grant of equity-based awards, including non-statutory stock options, RSUs, restricted stock, stock appreciation rights, performance shares and performance units, and its terms are substantially similar to the 2017 Plan, including with respect to treatment of equity awards in the event of a "merger" or "change in control" as defined under the Inducement Plan. Options issued under the Inducement Plan may have a term up to ten years and have variable vesting provisions. New hire grants 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 December 31, 2019, 78,950 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. 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. 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. During the year ended December 31, 2019 and 2018, the Company issued 38,279 and 23,869 shares of common stock under the 2017 ESPP, respectively. As of December 31, 2019, 440,195 shares of common stock remained available for issuance under the 2017 ESPP.

A summary of stock option activity under the 2015 Plan, 2017 Plan and Inducement Plan for the year ended December 31, 2019 is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Balances - December 31, 2018	2,956,687	$ 17.04	7.6
Options granted	1,162,616	13.60	
Options exercised	(98,928)	2.75	
Options canceled	(99,669)	15.66	
Options expired	(171,520)	21.61	
Balances - December 31, 2019	3,749,186	$ 16.18	7.9
Stock options exercisable at December 31, 2019	2,110,219	$ 16.33	6.5

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

The intrinsic value of stock options exercised during the year ended December 31, 2019, 2018 and 2017 was $1.0 million, $1.8 million, and $3.8 million, respectively.

The fair value of employee stock options was estimated using the Black-Scholes option-pricing model utilizing the following assumptions:

	Year Ended December 31,		
	2019	2018	2017
Expected term in years	0.4 - 6.1	5.3 - 6.1	0.4 - 6.1
Expected volatility	70%	70%	70% - 90%
Risk-free interest rate	1.4 - 2.6%	2.6 - 3.0%	1.0% - 2.2%
Dividend yield	—	—	—

The fair value of the stock options granted to employees and directors during the years ended December 31, 2019, 2018 and 2017 was $8.4 million, $6.4 million, and $26.8 million, respectively.

The fair value of ESPP was estimated using the Black-Scholes option-pricing model utilizing the following assumptions:

	Year Ended December 31,		
	2019	2018	2017
Expected term in years	0.5 - 1.0	0.5 - 1.0	0.5 - 1.3
Expected volatility	70%	70%	95%
Risk-free interest rate	1.7% - 2.6%	1.9% - 2.5%	1.1% - 1.2%
Dividend yield	—	—	—

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

	Year Ended December 31,		
	2019	2018	2017
General and administrative	$ 7,466	$ 9,004	$ 9,136
Research and development	3,821	3,334	1,790
Total stock-based compensation expense	$ 11,287	$ 12,338	$ 10,926

The fair value of RSU awards is determined based on the number of units granted and the closing price of the Company's common stock as of the grant date. The estimated fair value of RSUs is recognized on a straight-line basis over the requisite service period. During 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 for tax payments related to shares withheld in connection with the vesting of the RSUs. The stock-based compensation expense related to these RSUs was approximately $2.1 million and $2.9 million during the years ended December 31, 2018 and 2017, respectively. As of December 31, 2019, there was no unrecognized compensation expense related to these RSUs.

During the year ended December 31, 2017, the Company granted 68,800 RSUs to certain employees, of which 50% vested 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 recorded in 2018 and 2017 related to these RSUs was approximately $0.4 million and $0.1 million, respectively. As of December 31, 2018, there was $0.9 million of unrecognized compensation expense related to these RSUs.

During November 2017, the resignations of certain Board members resulted in full vesting of their outstanding equity awards. Accordingly, the Company recorded an additional $1.2 million of stock-based compensation expense for the year ended December 31, 2017.

At December 31, 2019, there was $14.2 million of unrecognized compensation cost related to unvested stock-based compensation arrangements, which is expected to be recognized over a weighted average period of 2.8 years.

7. Research Grants and Agreements

Sponsored Research Agreement

The Company entered into a Sponsored Research Agreement (SRA) with ODURF during 2014 pursuant to which the Company sponsors research activities performed by ODURF's Frank Reidy Center. ODURF is compensated by the Company for its conduct of each study in accordance with the budget and payment terms set forth in the applicable task order. During the years ended December 31, 2019, 2018 and 2017, the Company agreed to sponsor $0.8 million, $0.8 million and $0.7 million, respectively, in research during the subsequent 12-month period to be funded through monthly payments made upon ODURF certifying, to the Company's reasonable satisfaction, that ODURF has met its obligations pursuant to the specified task order and statement of work. The principal investigator may transfer funds with the budget as needed without the Company's approval so long as the obligations of ODURF under the task order and statement of work remain unchanged and unimpaired. As of December 31, 2019, $0.6 million remained payable under this research agreement.

In addition, during the year ended December 31, 2017, the Company agreed to provide $0.3 million in research funding to researchers affiliated with ODURF and EVMS 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 December 31, 2019, no amount remained payable under this agreement.

During the years ended December 31, 2019, 2018 and 2017, the Company incurred costs relating to the SRA equal to $0.9 million, $0.7 million and $0.8 million, respectively.

8. Income Taxes

The pre-tax book loss for the Company was approximately $47 million, $37.5 million and $25.8 million for the years ended December 31, 2019, 2018 and 2017, respectively; these losses were incurred in the U.S., the Company has no foreign subsidiaries. The income tax provision was $0 for the years ended December 31, 2019, 2018 and 2017.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets at December 31, 2019 and 2018 are summarized below (in thousands):

	December 31,	
	2019	2018
Temporary differences	$ 119	$ 111
Credits	4,409	5,330
Stock compensation	5,473	2,630
Lease liability under ASC 842	1,411	—
Net operating loss carryforwards	20,755	15,365
Total deferred tax assets before valuation allowance	32,167	23,436
Valuation allowance	(30,369)	(22,696)
Total deferred tax assets after valuation allowance	1,798	740
Technology deferred tax liability	(434)	(740)
Right of use assets under ASC 842	(1,364)	—
Net deferred tax assets	$ —	$ —

In assessing the potential realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the Company attaining future taxable income during the periods in which those temporary differences become deductible. At December 31, 2019 and 2018, management was unable to determine that it was more likely than not that the Company's deferred tax assets will be realized, and has therefore recorded an appropriate valuation allowance against deferred tax assets at such dates.

The Company's effective tax rate is different from the federal statutory tax rate of 21% due primarily to net losses that receive no tax benefit as a result of a valuation allowance recorded for such losses.

Presented below is the reconciliation of the difference between the tax rate computed by applying the U.S. federal statutory tax rate and the effective tax rate for the years ended December 31, 2019, 2018 and 2017:

	Year Ended December 31,		
	2019	2018	2017
U.S. federal statutory tax rate	(21.0)%	(21.0)%	(35.0)%
Valuation allowance	18.0	28.0	23.0
Tax reform	—	(2.0)	18.0
Credits	(2.0)	2.0	1.0
State tax benefit and other	5.0	(7.0)	(7.0)
Effective tax rate	— %	— %	— %

At December 31, 2019, the Company had federal and California state net operating loss carryforwards of approximately $87.8 million and $25.8 million, respectively, these will begin to expire in 2034. Of the total federal net operating loss (NOL) carryforward of $87.8 million, approximately $62.2 million was generated after tax year 2017 and has an indefinite carryover period; the utilizations of theses NOLs will be limited to 80% of the taxable income in the years in which these NOLs are utilized. Utilization of some of the federal and California net operating loss carry-forwards are subject to annual limitations due to the 'change in ownership' provisions of the Internal Revenue Code of 1986 and similar provisions.

At December 31, 2019, the Company had approximately $2.4 million and $2.0 million of federal and California research and development (R&D) credits, respectively. The federal R&D credits begin to expire after 2035 and the California R&D credits have an indefinite carryforward period.

These net operating loss carryforward and R&D credits amounts have full valuation allowances against them due to the remoteness of their expected utilization.

The Company's activity related to unrecognized tax benefits are summarized below (in thousands):

	December 31,		
	2019	2018	2017
Balance at the beginning of the year	$ 877	$ 512	$ 213
Gross increases - tax positions in prior periods	—	—	37
Gross decreases - tax positions in prior periods	—	—	—
Gross increases - tax position in current period	593	365	262
Settlements	—	—	—
Lapses in statutes of limitations	—	—	—
Balance at the end of the year	$ 1,470	$ 877	$ 512

Although it is reasonably possible that certain unrecognized tax benefits may increase or decrease within the next twelve months due to tax examination changes, settlement activities, expirations of statute of limitations, or the impact on recognition and measurement considerations related to the results of published tax cases or other similar activities, the Company does not anticipate any significant changes to unrecognized tax benefits over the next 12 months. During the years ended December 31, 2019, 2018 and 2017, no interest or penalties were required to be recognized related to unrecognized tax benefits. Although the Company is not under examination, the tax years for 2014 and forward are subject to examination by U.S. tax authorities.

9. 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 is also serves as the outside corporate counsel to the Company. During the years ended December 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 $0.5 million and $1.2 million, respectively. During the year ended December 31, 2018, the Company capitalized approximately $0.1 million for legal expenses incurred in connection with the rights offering (Note 6).

During December 2018, the Company completed a rights offering pursuant to which it sold an aggregate of 3,581,148 shares of its common stock, par value $0.001 per share, at a price per share of $12.57, for net proceeds of approximately $44.8 million. At the time of transaction, Robert W. Duggan, the Company's Chairman of the Board of Directors and the beneficial owner of approximately 35% of the Company's then outstanding common stock prior to the rights offering. After giving effect to the rights offering, Mr. Duggan was the beneficial owner or approximately 43% of the Company's outstanding stock as of December 31, 2019.

10. Commitments and Contingencies

Operating Leases

During January 2017, the Company entered into a five year for approximately 15,700 square feet for its corporate headquarters located in Hayward, California. The lease commenced during July 2017.

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

The Company evaluated the lease amendment under the provisions of ASC 842 that it adopted on January 1, 2019, and concluded that the Amendment would be accounted for as a single contract with the Existing Lease because the additional lease payments due to the Amendment was not commensurate with ROU asset granted to the Company. Though the Amendment was accounted for as a single contract, the Existing Premises, Expansion Premises 1 (occupied in November 2019) and Expansion Premises 2 (not yet occupied) are each accounted for as separate lease components. Accordingly, the Company measured and allocated consideration to each lease component as of the modification date. Upon commencement of each lease component, the Company will reassess and calculate the lease liability and ROU asset for the respective component. As a result, at the modification date, the Company remeasured its existing lease liability and recorded an additional ROU asset and lease

liability of $2.0 million. The Company also recorded an additional ROU asset and lease liability of $3.0 million at the commencement of Expansion Premises 1 in November 2019. At December 31, 2019, total ROU assets and lease lability including the impact of ASC 842 adoption, was approximately $5.1 million and $6.7 million, respectively.

During the years ended December 31, 2019, 2018 and 2017, rent expense, including common area maintenance charges, was $0.5 million, $0.2 million and $0.3 million, respectively.

Information related to the Company's ROU assets and related lease liabilities were as follows (in thousands except for remaining lease term and discount rate):

Year ending December 31:		
2020	$	647
2021		986
2022		1,071
2023		1,094
Thereafter		7,190
Total lease payments		10,988
Less imputed interest		(4,269)
Total lease liabilities	$	6,719
Other supplemental non-cash information:		
Cash paid for operating lease liabilities	$	406
Operating lease liabilities arising from ROU assets including impact of ASC 842 adoption	$	5,114
Current operating lease liabilities		—
Non-current operating lease liabilities		6,719
Total lease liabilities	$	6,719
Weighted-average remaining lease term		9.83
Weighted-average discount rate		10%

Indemnification

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. Employee Benefit Plans

The Company sponsors a defined contribution plan under which it may make discretionary contributions. The Company did not make any employer matching contributions to this plan during the years ended December 31, 2019, 2018 and 2017.

12. Selected Quarterly Financial Data (Unaudited)

The following table provides the selected quarterly financial data for the years ended December 31, 2019 and 2018 (in thousands, except per share data):

	Quarter Ended							
	2019				2018			
	December 31,	September 30,	June 30,	March 31,	December 31,	September 30,	June 30,	March 31,
Revenue	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ —
Operating expenses:								
General and administrative	7,174	5,606	5,146	4,401	3,814	5,675	5,173	5,383
Research and development	6,590	6,192	6,337	5,842	5,080	5,038	3,960	3,175
Amortization of intangible assets	167	166	166	167	166	166	167	166
Total operating expenses	13,931	11,964	11,649	10,410	9,060	10,879	9,300	8,724
Other income (expense):								
Interest income	143	218	290	332	135	118	137	56
Other expense	—	—	—	—	(28)	—	—	—
Total other income	143	218	290	332	107	118	137	56
Loss from operations, before income taxes	(13,788)	(11,746)	(11,359)	(10,078)	(8,953)	(10,761)	(9,163)	(8,668)
Income tax benefit	—	—	—	—	—	—	—	—
Net loss	(13,788)	(11,746)	(11,359)	(10,078)	(8,953)	(10,761)	(9,163)	(8,668)
Other comprehensive loss:								
Unrealized gain (loss) on available-for-sale securities, net of tax:	(4)	(14)	20	3	2	(3)	3	48
Comprehensive loss	$ (13,792)	$ (11,760)	$ (11,339)	$ (10,075)	$ (8,951)	$ (10,764)	$ (9,160)	$ (8,620)
Net loss per share								
Basic and diluted net loss per share	$ (0.66)	$ (0.57)	$ (0.55)	$ (0.49)	$ (0.51)	$ (0.64)	$ (0.54)	$ (0.51)
Weighted average shares used to compute net loss per common share — basic and diluted	20,799	20,774	20,728	20,679	17,656	16,927	16,881	16,842

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. 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 Annual Report on Form 10-K. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that 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.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of senior management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our internal control over financial reporting based on the framework in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the evaluation under that framework and applicable SEC rules, our management concluded that our internal control over financial reporting was effective as of December 31, 2019.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal controls over financial reporting during the quarter ended December 31, 2019, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

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

Item 9B. Other Information

None.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 11. Executive Compensation

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2020 Annual Meeting of Stockholder to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 14. Principal Accounting Fees and Services

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2020 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Part IV

Item 15. Exhibits, Financial Statement Schedules

(a) The following documents are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K:

1. *Financial Statements*: See Item 8 of this Annual Report on Form 10-K.

2. *Financial Statement Schedules*: All schedules are omitted because they are not required, are not applicable or the information is included in the consolidated financial statements or notes thereto.

(b) The following exhibits are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K:

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	File No.	Exhibit(s)	Filing Date
2.1	Plan of Conversion of Pulse Biosciences, Inc.	8-K12B	001-37744	2.1	June 18, 2018
3.1	Articles of Conversion	8-K12B	001-37744	3.1	June 18, 2018
3.2	Certificate of Conversion	8-K12B	001-37744	3.2	June 18, 2018
3.3	Certificate of Incorporation of Pulse Biosciences, Inc.	8-K12B	001-37744	3.3	June 18, 2018
3.4	Bylaws of Pulse Biosciences, Inc.	8-K12B	001-37744	3.4	June 18, 2018
4.1	Specimen Common Stock Certificate	8-K12B	001-37744	4.1	June 18, 2018
4.2	Form of Warrant dated November 9, 2014 issued to MDB Capital Group, LLC	S-1	333-208694	4.2	December 22, 2015
4.3	Form of Underwriter Warrant	S-1	333-208694	4.3	March 28, 2016
4.4	Form of Registration Rights Agreement dated November 6, 2014, among the purchasers of common stock and the Registrant	S-1	333-208694	10.6	December 22, 2015
4.5	Form of Registration Rights Agreement dated November 6, 2014, among the holders of placement warrants and the Registrant	S-1	333-208694	10.7	December 22, 2015
4.6*	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934				
10.1	Lease for facilities at 3955 Point Eden Way, Hayward, California, dated January 26, 2017	10-K	001-34899	10.1	March 20, 2017
10.2#	License Agreement among Old Dominion University Research Foundation, Eastern Virginia Medical School and the Registrant	S-1	333-208694	10.12	May 3, 2016
10.3	Amendments No. 1 to License Agreement among Old Dominion University Research Foundation, Eastern Virginia Medical School and the Registrant	S-1	333-208694	10.13	March 7, 2016
10.4#	License Agreement among University of Southern California, The Alfred Mann Institute and the Registrant	S-1	333-208694	10.14	May 3, 2016
10.5#	Amendment No. 1 to the License Agreement among University of Southern California, The Alfred Mann Institute and the Registrant	S-1	333-208694	10.15	May 3, 2016
10.6	Securities Purchase Agreement, dated February 7, 2017, by and between Pulse Biosciences, Inc. and certain purchasers	8-K	001-37744	10.1	February 10, 2017
10.7	Securities Purchase Agreement, dated September 24, 2017, by and between Pulse Biosciences, Inc. and certain purchasers	8-K	001-37744	10.1	September 25, 2017
10.8+	2015 Stock Incentive Plan	S-1	333-208694	10.2	December 22, 2015
10.9+	2017 Inducement Equity Incentive Plan and forms of agreements thereunder	8-K	001-37744	10.1	November 28, 2017
10.10+	2017 Equity Incentive Plan and forms of agreements thereunder	8-K	001-37744	10.1	May 19, 2017
10.11+	2017 Employee Stock Purchase Plan and forms of agreements thereunder	8-K	001-37744	10.2	May 19, 2017
10.12+	Form of Director Option Agreement, not issued under the 2015 Stock Incentive Plan	S-1	333-208694	10.3	December 22, 2015
10.13+	Executive Employment Agreement between Darrin R. Uecker and the Registrant	S-1	333-208694	10.9	December 22, 2015
10.14+	Amendment to Employment Agreement between Darrin R. Uecker and Pulse Biosciences, Inc. dated October 5, 2016	8-K	001-37744	10.1	October 11, 2016
10.15+	Form of At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement for Employees	S-1	333-208694	10.10	December 22, 2015
10.16+	Form of Indemnification Agreement	8-K12B	001-37744	10.1	June 18, 2018
10.17	First Amendment to the lease for facilities at 3955 Point Eden Way, Hayward, California, dated May 28, 2019	8-K	001-37744	10.19	May 31, 2019
10.18+	Executive Employment Agreement between Ed Ebbers and the Registrant	10-K	0001-34899	10.17	March 14, 2019
10.19+	Employment Agreement between Sandra Gardiner and the Registrant	8-K	001-37744	10.1	November 7, 2019
10.20+*	Separation Agreement and Release between Brian B. Dow and the Registrant				
16.1	Letter from Gumbiner Savett Inc. to the Securities and Exchange Commission dated April 6, 2018	8-K	001-37744	16.1	April 11, 2018

21.1*	List of Subsidiaries
23.1*	Consent of Independent Registered Public Accounting Firm.
23.2*	Consent of Independent Registered Public Accounting Firm
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	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith

\+ Indicates a management contract or compensatory plan or arrangement.

\# Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a grant of confidential treatment.

Item 16. Form 10-K Summary

None.

Signatures

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PULSE BIOSCIENCES, INC.

Date: March 16, 2020

By: /s/ Sandra A. Gardiner
Sandra A. Gardiner
Chief Financial Officer, Executive Vice President of Finance and Administration, Secretary and Treasurer
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Darrin R. Uecker and Sandra A. Gardiner, jointly and severally, as his true and lawful attorney-in-fact and agent, with full power of substitution, each with power to act alone, to sign and execute on behalf of the undersigned any and all amendments to this Annual Report on Form 10-K, and to perform any acts necessary in order to file the same, with all exhibits thereto and other documents in connection therewith with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requested and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or their or his or her substitutes, shall do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Darrin R. Uecker Darrin R. Uecker	President, Chief Executive Officer and Director (*Principal Executive Officer)*	March 16, 2020
/s/ Robert W. Duggan Robert W. Duggan	Chairman of the Board of Directors	March 16, 2020
/s/ Sandra A. Gardiner Sandra A. Gardiner	Chief Financial Officer, Executive Vice President, Secretary and Treasurer (*Principal Financial and Accounting Officer)*	March 16, 2020
/s/ Mitchell E. Levinson Mitchell E. Levinson	Director	March 16, 2020
/s/ Kenneth A. Clark Kenneth A. Clark	Director	March 16, 2020
/s/ Manmeet S. Soni Manmeet S. Soni	Director	March 16, 2020
/s/ Mahkam Zanganeh Mahkam Zanganeh	Director	March 16, 2020

Exhibit 4.6

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description of the capital stock of Pulse Biosciences, Inc. ("us," "our," "we" or the "Company") is a summary of the rights of our capital stock and summarizes certain provisions of our certificate of incorporation and our bylaws. This summary does not purport to be complete and is qualified in its entirety by the provisions of our certificate of incorporation and bylaws, copies of which have been filed as exhibits to this Annual Report on Form 10-K, as well as to the applicable provisions of the Delaware General Corporation Law.

Our authorized capital stock consists of 550,000,000 shares, with a par value of $0.001 per share, of which:

- 500,000,000 shares are designated as common stock; and

- 50,000,000 shares are designated as preferred stock.

Common Stock

Holders of shares of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders generally and do not have cumulative voting rights. Subject to the preferences that may be applicable to any preferred stock outstanding at the time, the holders of outstanding shares of our common stock are entitled to receive such dividends as may be declared from time to time by the board of directors out of funds legally available therefor, and in the event of liquidation, dissolution or winding up of the company to share ratably in all assets remaining after payment of liabilities and the liquidation preference of any then outstanding shares of preferred stock. The holders of shares of common stock have no preemptive or conversion rights. There are no redemption or sinking fund provisions applicable to the common stock.

Our common stock is listed on the Nasdaq Stock Market under the symbol "PLSE." The transfer agent and registrar for our common stock is Broadridge Corporate Issuers Solutions, Inc.

Preferred Stock

The following description of preferred stock is not complete. These descriptions are qualified in their entirety by reference to our certificate of incorporation and the certificate of designation relating to any series of preferred stock. The rights, preferences, rights and restrictions of the preferred stock of each series will be fixed by the certificate of designation relating to that series. Under the terms of our certificate of incorporation, our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors may designate the powers, designations, preferences, and relative participation, optional or other rights, if any, and the qualifications, limitations or restrictions thereof, including dividend rights, conversion rights, voting rights, redemption rights, liquidation preference, sinking fund terms and the number of shares constituting any series or the designation or any series. There are no restrictions presently on the repurchase or redemption of any shares of our preferred stock.

The issuance of shares of preferred stock will affect, and may adversely affect, the rights of holders of common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of common stock until our board of directors determines the specific rights attached to that preferred stock. The effects of issuing additional preferred stock could include one or more of the following:

- restricting dividends on the common stock;
- diluting the voting power of the common stock;
- impairing the liquidation rights of the common stock; or
- delaying or preventing changes in control or management of our company.

Registration Rights

Warrant Holders' Rights Agreement

In connection with a private placement offering of shares of common stock and an Investment Banking Agreement dated September 30, 2014, we entered into a Registration Rights Agreement for Warrants, dated November 6, 2014, with MDB Capital Group, LLC ("MDB") pursuant to which we agreed, upon request, to file a registration statement to cover the resale of up to 299,625 shares of common stock issuable upon exercise of warrants, and to keep such registration statement effective for 12 months starting from the date of effectiveness of such registration statement.

Underwriters' Warrants

In connection with the Underwriting Agreement, dated May 17, 2016, between the Company and MDB, as representative of the underwriters, we issued warrants to purchase up to 575,000 shares of our common stock. Pursuant to such warrants, we agreed, upon request, to file a registration statement to cover the resale of shares issuable upon exercise of such warrants, and to keep such registration statement effective until the date on which all of the shares registered for sale or resale under such registration statement are either sold pursuant to such registration statement or can be sold publicly without restriction or limitation under Rule 144 under the Securities Act.

Purchase Agreements

On February 7, 2017, we entered into a Purchase Agreement (the "February Purchase Agreement") with certain investors pursuant to which we issued and sold in a private placement a total of 819,673 shares of common stock. Pursuant to the February Purchase Agreement, we agreed to file a registration statement to cover the resale of the shares issued to the investors, and to keep such registration statement effective until the date on which all of the shares registered for sale or resale under such registration statement are either sold pursuant to such registration statement or can be sold publicly without restriction or limitation under Rule 144 under the Securities Act.

On September 24, 2017, we entered into a Purchase Agreement (the "September Purchase Agreement") with an investor pursuant to which we issued and sold in a private placement a total of 2,000,000 shares of common stock. Pursuant to the September Purchase Agreement, we agreed to file a registration statement to cover the resale of the shares issued to the investor, and to keep such registration statement effective until the date on which all of the shares registered for sale or resale under such registration statement are either sold pursuant to such registration statement or can be sold publicly without restriction or limitation under Rule 144 under the Securities Act.

Effect of Certain Provisions of our Certificate of Incorporation and Bylaws and the Delaware Anti-Takeover Statute

Some provisions of Delaware law and our certificate of incorporation and bylaws contain provisions that could make the following transactions more difficult:

- acquisition of us by means of a tender offer;
- acquisition of us by means of a proxy contest or otherwise; or
- removal of our incumbent officers and directors.

Those provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids and to promote stability in our management. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors.

Certificate of Incorporation and Bylaws

Our certificate of incorporation and our bylaws provide for the following:

- *Undesignated Preferred Stock*. The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue one or more series of preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of our company. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.
- *Stockholder Meetings*. Our bylaws provide that in general a special meeting of stockholders may 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.
- *Requirements for Advance Notification of Stockholder Nominations and Proposals*. Our bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of our board of directors or a committee of the board of directors.
- *Limits on Ability of Stockholders to Act by Written Consent*. We have provided in our bylaws that our stockholders may not act by written consent. This limit on the ability of our stockholders to act by written consent may lengthen the amount of time required to take stockholder actions. As a result, a holder controlling a majority of our capital stock would not be able to amend our bylaws or remove directors without holding a meeting of our stockholders called in accordance with our bylaws.
- Amendment of Certificate of Incorporation and Bylaws. The amendment of the above provisions of our certificate of incorporation and bylaws requires approval by holders of at least two-thirds of our outstanding capital stock entitled to vote generally in the election of directors.

Delaware Anti-Takeover Statute

We are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging, under certain circumstances, in a business combination with an interested stockholder for a period of three years following the date the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not for determining the outstanding voting stock owned by the interested stockholder, (i) shares owned by persons who are directors and also officers, and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns 15% or more of a corporation’s outstanding voting stock or is an affiliate or associate of a corporation and was the owner of 15% or more of the corporation’s outstanding voting stock within three years prior to the determination of interested stockholder status.

SEPARATION AGREEMENT AND RELEASE

This Separation Agreement and Release ("Agreement") is made by and between Brian Dow ("Executive") and Pulse Biosciences, Inc. (formerly known as Electroblate, Inc.) (together, Pulse Biosciences, Inc. and Electroblate, Inc. are the "Company") (collectively, Executive and the Company referred to as the "Parties" or individually referred to as a "Party").

RECITALS

WHEREAS, Executive was employed by the Company;

WHEREAS, Executive signed an Employment Agreement with the Company on November 20, 2015 (the "Employment Agreement");

WHEREAS, Executive signed an At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement with the Company on July 28, 2017 (the "Confidentiality Agreement");

WHEREAS, Company and Executive signed an Indemnification Agreement on January 29, 2018 (the "Indemnification Agreement");

WHEREAS, the Company and Executive have entered into certain Stock Option Agreements, dated November 30, 2015 and July 25, 2017, granting Executive the options to purchase 140,672 shares and 95,000 shares, respectively, of the Company's common stock (the "Options") subject to the terms and conditions of the Company's 2015 Stock Incentive Plan (the "2015 Plan"), the 2017 Stock Incentive Plan (the "2017 Plan") and the Stock Option Agreement (collectively, the "Stock Agreements"),

WHEREAS, Executive signed a Transition Agreement and Limited Release with the Company in connection with the transition of his services on November 18, 2019 (the "Limited Release");

WHEREAS, Executive separated from employment with the Company effective December 31, 2019 (the "Separation Date");

WHEREAS, as of November 18, 2019, Executive has resigned as the Chief Financial Officer ("CFO") and Senior Vice President of Finance and Administration ("SVP") of the Company, and has resigned from all of Executive's positions on the Company's Board of Directors (the "Board"), including, but not limited to, as Secretary and Treasurer; and

WHEREAS, the Parties wish to resolve any and all disputes, claims, complaints, grievances, charges, actions, petitions, and demands that the Executive may have against the Company and any of the Releasees as defined below, including, but not limited to, any and all claims arising out of or in any way related to Executive's employment with or separation from the Company.

NOW, THEREFORE, in consideration of the mutual promises made herein, the Company and Executive hereby agree as follows:

COVENANTS

1. Consideration. In accordance with Sections 7 and 8 of the Employment Agreement, in consideration of Executive's execution and non-revocation of this Agreement under the "Acknowledgment of Waiver of Claims under ADEA" provision below, and in consideration of Executive's fulfillment of all of the Agreement's terms and conditions, the Company agrees to the following:

a. *Severance Payment.* The Company agrees to pay Executive a total of one hundred sixty-eight thousand dollars ($168,000), less applicable withholdings, which amount represents the sum of six (6) months of Executive's annual base salary in effect immediately prior to the Separation Date (the "Severance Payment"). The Severance Payment will be paid to Executive in twelve (12) semi-monthly equal installments, commencing on the first regular payroll date following the Effective Date (as defined below) in accordance with the Company's regular payroll practices. Executive acknowledges that the Company will issue a Form W-2 in connection with the payments set forth in this Section.

b. *Additional Consideration.* The Company agrees to pay Executive an additional severance payment of one hundred thousand eight hundred dollars ($100,800), less applicable withholdings, which amount is calculated based on Executive's target Annual Bonus for 2019 for the calendar year of the Separation Date, or portion thereof, that the Company might and/or would have owed to Executive had such amounts been earned. This payment will be paid on the first regular payroll date following the Effective Date (as defined below). Executive acknowledges that the Company will issue a Form W-2 in connection with the payments set forth in this Section.

c. *COBRA.* Provided Executive timely elects for continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), within the time period prescribed pursuant to COBRA. COBRA payments shall be made by the Company for the benefit of the Executive for COBRA coverage (at the coverage levels in effect for Executive and the dependents covered immediately prior to Executive's termination) until either: 1) the date upon which Executive and/or Executive's eligible dependents becomes covered under similar plans, or 2) until the date upon which Executive ceases to be eligible for coverage under COBRA, whichever occurs first., Notwithstanding the preceding, if the Company determines in its sole discretion that it cannot provide COBRA reimbursement benefits without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company will instead provide the Executive a taxable payment in an amount that the Executive would be required pay for Executive to obtain coverage at the coverage levels in effect for Executive and the dependents covered immediately prior to Executive's termination until either: 1) the date upon which Executive and/or Executive's eligible dependents becomes covered under similar plans, or 2) until the date upon which Executive would otherwise cease to be eligible for coverage under COBRA, whichever occurs first., to pay to continue the Executive's group health coverage in effect on the date of termination of employment (which amount will be based on the premium for the first month of COBRA coverage), which payments will be made regardless of whether the Executive elects COBRA continuation coverage and will commence in the month following the month of the Separation Date and continue for the period of months indicated in this section.

d. *Acceleration.* The unvested portion of Executive's Option (and any Board-approved and issued and outstanding equity grants) that would normally vest over twelve (12) months from the Separation Date, will *immediately* vest prior to Executive's termination and become exercisable (the "Vesting Acceleration").

e. *Extended Exercise Period.* The period in which Executive must exercise his vested Options pursuant to the Stock Agreements will be extended from 90-days following the Separation Date, as

currently provided in the Stock Agreements, to a period of twelve (12) months following the Separation Date. The exercise of Executives Options shall in all other respects continue to be governed by the Stock Agreements.

f. *Resignation.* The Company shall process the separation of Executive's employment with the Company as a resignation and shall represent that Executive resigned from Executive's employment to any potential future employer who contacts the Company's human resources department and requests confirmation of this information. Executive agrees to execute any documentation deemed reasonably necessary by the Company to confirm Executive's resignation from employment and resignation from the Board. Executive acknowledges that while said resignation occurred in expectation of this Agreement, Executive's resignation itself shall not be considered a part of, or a term or condition of, this Agreement, and that if the Executive subsequently revokes this Agreement as provided for herein, said revocation does not affect or nullify in any way his resignation and termination of employment.

g. *No Further Severance and Acknowledgement.* Except as explicitly set forth in this section, Executive acknowledges and agrees that Executive is not entitled to receive any severance benefits or other post-employment benefits from the Company, including, but not limited to, under the Employment Agreement or the Stock Agreements. Executive further specifically acknowledges and agrees that the consideration provided to Executive hereunder fully satisfies any obligation that the Company had to pay Executive wages or any other compensation for any of the services that Executive rendered to the Company, that the amount paid is in excess of any disputed wage claim that Executive may have, that the consideration paid shall be deemed to be paid first in satisfaction of any disputed wage claim with the remainder sufficient to act as consideration for the release of claims set forth herein, and that Executive has not earned and is not entitled to receive any additional wages or other form of compensation from the Company. Executive acknowledges and agrees that no payment or other consideration provided herein constitutes a raise, a bonus, or continued employment and that this Agreement is not a condition of employment or continued employment. Executive hereby acknowledges that without this Agreement, Executive is not otherwise entitled to the consideration listed in this Section 1.

2. Equity. The Parties agree that for purposes of determining the number of shares of the Company's common stock that Executive is entitled to purchase from the Company, pursuant to the exercise of the Options, Executive will be considered to have vested only up to the Separation Date. Executive acknowledges that, without the Vesting Acceleration set forth in Section 1 of this Agreement, as of the Separation Date, Executive will have vested in 211,922 shares subject to the Options and no more. However, after accounting for the Vesting Acceleration set forth in Section 1, Employee will have vested instead in 231,713 shares subject to the Options and no more. The exercise of the vested portion of the Options and any shares acquired through such exercise shall continue to be governed by the terms and conditions of the applicable Stock Agreements.

3. Benefits. Executive's health insurance benefits shall cease on or before December 31, 2019, subject to Executive's right to continue Executive's health insurance under COBRA. Executive's participation in all benefits and incidents of employment, including, but not limited to, vesting in stock options, and the accrual of bonuses, vacation, and paid time off, ceased as of the Separation Date.

4. Payment of Salary and Receipt of All Benefits. Executive acknowledges and represents that, other than the consideration set forth in this Agreement, the Company has paid or provided all salary, wages, bonuses, accrued vacation/paid time off, premiums, leaves, housing allowances, relocation costs, interest, severance, outplacement costs, fees, reimbursable expenses, commissions, stock, stock options, vesting, and any and all other benefits and compensation due to Executive.

5. Release of Claims. Executive agrees that the foregoing consideration represents settlement in full of all outstanding obligations owed to Executive, other than the Company's continuing obligations pursuant to the Indemnification Agreement, by the Company and its current and former officers, directors, employees, agents, investors, attorneys, shareholders, administrators, affiliates, benefit plans, plan administrators, professional employer organization or co-employer, insurers, trustees, divisions, subsidiaries, predecessor and successor corporations, and assigns (collectively, the "Releasees"). Executive, on Executive's own behalf and on behalf of Executive's respective heirs, family members, executors, agents, and assigns, hereby and forever releases the Releasees from, and agrees not to sue concerning, or in any manner to institute, prosecute, or pursue, any claim, complaint, charge, duty, obligation, demand, or cause of action relating to any matters of any kind, whether presently known or unknown, suspected or unsuspected, that Executive may possess against any of the Releasees arising from any omissions, acts, facts, or damages that have occurred up until and including the date Executive signs this Agreement, including, without limitation:

a. any and all claims relating to or arising from Executive's employment relationship with the Company and the termination of that relationship;

b. any and all claims relating to, or arising from, Executive's right to purchase, or actual purchase of shares of stock of the Company, including, without limitation, any claims for fraud, misrepresentation, breach of fiduciary duty, breach of duty under applicable state corporate law, and securities fraud under any state or federal law;

c. any and all claims for wrongful discharge of employment, termination in violation of public policy, discrimination, harassment, retaliation, breach of contract (both express and implied), breach of covenant of good faith and fair dealing (both express and implied), promissory estoppel, negligent or intentional infliction of emotional distress, fraud, negligent or intentional misrepresentation, negligent or intentional interference with contract or prospective economic advantage, unfair business practices, defamation, libel, slander, negligence, personal injury, assault, battery, invasion of privacy, false imprisonment, conversion, and disability benefits;

d. any and all claims for violation of any federal, state, or municipal statute, including, but not limited to, Title VII of the Civil Rights Act of 1964, the Civil Rights Act of 1991, the Rehabilitation Act of 1973, the Americans with Disabilities Act of 1990, the Equal Pay Act, the Fair Labor Standards Act, the Fair Credit Reporting Act, the Age Discrimination in Employment Act of 1967, the Older Workers Benefit Protection Act, the Employee Retirement Income Security Act of 1974, the Worker Adjustment and Retraining Notification Act, the Family and Medical Leave Act, the Immigration Reform and Control Act, the National Labor Relations Act, the California Family Rights Act, the California Labor Code, the California Workers' Compensation Act, and the California Fair Employment and Housing Act (the "FEHA");

e. any and all claims for violation of the federal or any state constitution;

f. any and all claims arising out of any other laws and regulations relating to employment or employment discrimination;

g. any claim for any loss, cost, damage, or expense arising out of any dispute over the nonwithholding or other tax treatment of any of the proceeds received by Executive as a result of this Agreement; and

h. any and all claims for attorneys' fees and costs.

Executive agrees that the release set forth in this section shall be and remain in effect in all respects as a complete general release as to the matters released. This release does not extend to any obligations incurred under this Agreement or the Indemnification Agreement. This release does not release claims that cannot be released as a matter of law. Any and all disputed wage claims that are released herein shall be subject to binding arbitration in accordance with this Agreement, except as required by applicable law. This release does not extend to any right Executive may have to unemployment compensation benefits.

6. Acknowledgment of Waiver of Claims under ADEA. Executive acknowledges that Executive is waiving and releasing any rights Executive may have under the Age Discrimination in Employment Act of 1967 ("ADEA"), and that this waiver and release is knowing and voluntary. Executive agrees that this waiver and release does not apply to any rights or claims that may arise under the ADEA after the date Executive signs this Agreement. Executive acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Executive was already entitled. Executive further acknowledges that Executive has been advised by this writing that: (a) Executive should consult with an attorney prior to executing this Agreement; (b) Executive has twenty-one (21) days within which to consider this Agreement; (c) Executive has seven (7) days following Executive's execution of this Agreement to revoke this Agreement; (d) this Agreement shall not be effective until after the revocation period has expired; and (e) nothing in this Agreement prevents or precludes Executive from challenging or seeking a determination in good faith of the validity of this waiver under the ADEA, nor does it impose any condition precedent, penalties, or costs for doing so, unless specifically authorized by federal law. In the event Executive signs this Agreement and returns it to the Company in less than the 21-day period identified above, Executive hereby acknowledges that Executive has freely and voluntarily chosen to waive the time period allotted for considering this Agreement. Executive acknowledges and understands that revocation must be accomplished by a written notification to the person executing this Agreement on the Company's behalf that is received prior to the Effective Date. The Parties agree that changes, whether material or immaterial, do not restart the running of the 21-day period.

7. California Civil Code Section 1542. Executive acknowledges that Executive has been advised to consult with legal counsel and is familiar with the provisions of California Civil Code Section 1542, a statute that otherwise prohibits the release of unknown claims, which provides as follows:

> A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULDHAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.

Executive, being aware of said code section, agrees to expressly waive any rights Executive may have thereunder, as well as under any other statute or common law principles of similar effect.

8. No Pending or Future Lawsuits. Executive represents that, with respect to the claims released herein, Executive has no lawsuits, claims, or actions pending in Executive's name, or on behalf of any other person or entity, against the Company or any of the other Releasees. Executive also represents that Executive does not intend to bring any claims on Executive's own behalf or on behalf of any other person or entity against the Company or any of the other Releasees.

9. Application for Employment. Executive understands and agrees that, as a condition of this Agreement, Executive shall not be entitled to any employment with the Company, and Executive hereby waives any right, or alleged right, of employment or re-employment with the Company.

10. Confidentiality. Subject to the Protected Activity provision, Executive agrees to maintain in complete confidence the existence of this Agreement, the contents and terms of this Agreement, and the consideration for this Agreement (hereinafter collectively referred to as "Separation Information"). Except as required by law, Executive may disclose Separation Information only to Executive's immediate family members, the Court in any proceedings to enforce the terms of this Agreement, Executive's attorney(s), and Executive's accountant(s) and any professional tax advisor(s) to the extent that they need to know the Separation Information in order to provide advice on tax treatment or to prepare tax returns, and must prevent disclosure of any Separation Information to all other third parties. Executive agrees that Executive will not publicize, directly or indirectly, any Separation Information.

11. Trade Secrets and Confidential Information/Company Property. Subject to the Protected Activity provision, Employee reaffirms and agrees to observe and abide by the terms of the Confidentiality Agreement, specifically including the provisions therein regarding nondisclosure of the Company's trade secrets and confidential and proprietary information. Notwithstanding the foregoing, the Company agrees that it will not seek to enforce Section 15 (Non-Compete) of the Confidentiality Agreement, but does reserve all rights should it contend Executive has breached his obligations to maintain the Company's trade secrets. Employee's signature below constitutes Employee's certification under penalty of perjury that Employee has returned all documents and other items provided to Employee by the Company (with the exception of a copy of the Employee Handbook and personnel documents specifically relating to Employee), developed or obtained by Employee in connection with Employee's employment with the Company, or otherwise belonging to the Company.

12. No Cooperation. Subject to the Protected Activity provision, Executive agrees that Executive will not knowingly encourage, counsel, or assist any attorneys or their clients in the presentation or prosecution of any disputes, differences, grievances, claims, charges, or complaints by any third party against any of the Releasees, unless under a subpoena or other court order to do so or upon written request from an administrative agency or the legislature or as related directly to the ADEA waiver in this Agreement. Executive agrees both to immediately notify the Company upon receipt of any such subpoena or court order or written request from an administrative agency or the legislature, and to furnish, within three (3) business days of its receipt, a copy of such subpoena or other court order or written request from an administrative agency or the legislature. If approached by anyone for counsel or assistance in the presentation or prosecution of any disputes, differences, grievances, claims, charges, or complaints against any of the Releasees, Executive shall state no more than that Executive cannot provide counsel or assistance.

13. Protected Activity Not Prohibited. Executive understands that nothing in this Agreement shall in any way limit or prohibit Executive from engaging in any Protected Activity. Protected Activity includes: (i) filing and/or pursuing a charge, complaint, or report with, or otherwise communicating, cooperating, or participating in any investigation or proceeding that may be conducted by any federal, state or local government agency or commission, including the Securities and Exchange Commission, the Equal Employment Opportunity Commission, the Occupational Safety and Health Administration, and the National Labor Relations Board ("Government Agencies"); and/or (ii) disclosing information pertaining to sexual harassment or any other unlawful or potentially unlawful conduct in the workplace, to the extent protected by applicable law. Executive understands that in connection with such Protected Activity under prong (i) of this section, Executive is permitted to disclose documents or other information

as permitted by law, without giving notice to, or receiving authorization from, the Company. Notwithstanding the foregoing, Executive agrees to take all reasonable precautions to prevent any unauthorized use or disclosure of any information that may constitute the Company's confidential information under the Confidentiality Agreement, to any parties other than the Government Agencies. Executive further understands that "Protected Activity" does not include the disclosure of any Company attorney-client privileged communications or attorney work product. Any language in the Confidentiality Agreement or the Employment Agreement regarding Executive's right to engage in Protected Activity that conflicts with, or is contrary to, this section is superseded by this Agreement. In addition, pursuant to the Defend Trade Secrets Act of 2016, Executive is notified that an individual will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (i) is made in confidence to a federal, state, or local government official (directly or indirectly) or to an attorney *solely* for the purpose of reporting or investigating a suspected violation of law, or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding, if (and only if) such filing is made under seal. In addition, an individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the individual's attorney and use the trade secret information in the court proceeding, if the individual files any document containing the trade secret under seal and does not disclose the trade secret, except pursuant to court order.

14. Mutual Nondisparagement. Subject to the Protected Activity provision above, the Company and Executive mutually agree to refrain from any disparagement, defamation, libel, or slander of any of the Releasees (including the Chief Financial Officer hired/to be hired to replace Executive) or Executive. Executive shall direct any inquiries by potential future employers to the Company's human resources department. The Company's obligations under this provision apply only to its current executive officers, the Chief Financial Officer hired/to be hired to replace Executive and members of its Board of Directors, and only for so long as such individuals are directors or employees of the Company. Company agrees to instruct its current executive officers, the Chief Financial Officer and its Board of Directors of their obligation not to disparage or defame Executive.

15. Breach. In addition to the rights provided in the "Attorneys' Fees" section below, Executive acknowledges and agrees that any material breach of this Agreement, unless such breach constitutes a legal action by Executive challenging or seeking a determination in good faith of the validity of the waiver herein under the ADEA, shall entitle the Company immediately to cease providing the consideration provided to Executive under this Agreement and to obtain damages, except as provided by law.

16. No Admission of Liability. Executive understands and acknowledges that with respect to all claims released herein, this Agreement constitutes a compromise and settlement of any and all actual or potential disputed claims by Executive unless such claims were explicitly not released by the release in this Agreement. No action taken by the Company hereto, either previously or in connection with this Agreement, shall be deemed or construed to be (a) an admission of the truth or falsity of any actual or potential claims or (b) an acknowledgment or admission by the Company of any fault or liability whatsoever to Executive or to any third party.

17. Cooperation and Assistance. Executive agrees to voluntarily cooperate with the Company if Executive has knowledge of facts relevant to any threatened or pending litigation against the Company by making Executive reasonably available without further compensation for interviews with the Company or its legal counsel, for up to five (5) hours for preparing for and providing deposition testimony, and for preparing for and providing trial testimony. Additional cooperation and assistance provided will be subject to compensation to be determined by Executive in good faith at the time such cooperation and assistance is requested.

18. Costs. The Parties shall each bear their own costs, attorneys' fees, and other fees incurred in connection with the preparation of this Agreement.

19. ARBITRATION. EXCEPT AS PROHIBITED BY LAW, THE PARTIES AGREE THAT ANY AND ALL DISPUTES ARISING OUT OF THE TERMS OF THIS AGREEMENT, THEIR INTERPRETATION, EXECUTIVE'S EMPLOYMENT WITH THE COMPANY OR THE TERMS THEREOF, OR ANY OF THE MATTERS HEREIN RELEASED, SHALL BE SUBJECT TO ARBITRATION UNDER THE FEDERAL ARBITRATION ACT (THE "FAA") AND THAT THE FAA SHALL GOVERN AND APPLY TO THIS ARBITRATION AGREEMENT WITH FULL FORCE AND EFFECT; HOWEVER, WITHOUT LIMITING ANY PROVISIONS OF THE FAA, A MOTION OR PETITION OR ACTION TO COMPEL ARBITRATION MAY ALSO BE BROUGHT IN STATE COURT UNDER THE PROCEDURAL PROVISIONS OF SUCH STATE'S LAWS RELATING TO MOTIONS OR PETITIONS OR ACTIONS TO COMPEL ARBITRATION. EXECUTIVE AGREES THAT, TO THE FULLEST EXTENT PERMITTED BY LAW, EXECUTIVE MAY BRING ANY SUCH ARBITRATION PROCEEDING ONLY IN EXECUTIVE'S INDIVIDUAL CAPACITY. ANY ARBITRATION WILL OCCUR IN SAN MATEO COUNTY, BEFORE JAMS, PURSUANT TO ITS EMPLOYMENT ARBITRATION RULES & PROCEDURES ("JAMS RULES"), EXCEPT AS EXPRESSLY PROVIDED IN THIS SECTION. THE PARTIES AGREE THAT THE ARBITRATOR SHALL HAVE THE POWER TO DECIDE ANY MOTIONS BROUGHT BY ANY PARTY TO THE ARBITRATION, INCLUDING MOTIONS FOR SUMMARY JUDGMENT AND/OR ADJUDICATION, AND MOTIONS TO DISMISS AND DEMURRERS, APPLYING THE STANDARDS SET FORTH UNDER THE CALIFORNIA CODE OF CIVIL PROCEDURE. THE PARTIES AGREE THAT THE ARBITRATOR SHALL ISSUE A WRITTEN DECISION ON THE MERITS. THE PARTIES ALSO AGREE THAT THE ARBITRATOR SHALL HAVE THE POWER TO AWARD ANY REMEDIES AVAILABLE UNDER APPLICABLE LAW, AND THAT THE ARBITRATOR MAY AWARD ATTORNEYS' FEES AND COSTS TO THE PREVAILING PARTY, WHERE PERMITTED BY APPLICABLE LAW. THE ARBITRATOR MAY GRANT INJUNCTIONS AND OTHER RELIEF IN SUCH DISPUTES. THE DECISION OF THE ARBITRATOR SHALL BE FINAL, CONCLUSIVE, AND BINDING ON THE PARTIES TO THE ARBITRATION. THE PARTIES AGREE THAT THE PREVAILING PARTY IN ANY ARBITRATION SHALL BE ENTITLED TO INJUNCTIVE RELIEF IN ANY COURT OF COMPETENT JURISDICTION TO ENFORCE THE ARBITRATION AWARD. THE PARTIES AGREE THAT THE COMPANY SHALL PAY THE ARBITRATOR'S FEES FOR ANY SUCH ARBITRATION, AND EACH PARTY SHALL SEPARATELY PAY FOR ITS RESPECTIVE COUNSEL FEES AND EXPENSES; PROVIDED, HOWEVER, THAT THE ARBITRATOR MAY AWARD ATTORNEYS' FEES AND COSTS TO THE PREVAILING PARTY, EXCEPT AS PROHIBITED BY LAW. THE PARTIES HEREBY AGREE TO WAIVE THEIR RIGHT TO HAVE ANY DISPUTE BETWEEN THEM RESOLVED IN A COURT OF LAW BY A JUDGE OR JURY. NOTWITHSTANDING THE FOREGOING, THIS SECTION WILL NOT PREVENT EITHER PARTY FROM SEEKING INJUNCTIVE RELIEF (OR ANY OTHER PROVISIONAL REMEDY) FROM ANY COURT HAVING JURISDICTION OVER THE PARTIES AND THE SUBJECT MATTER OF THEIR DISPUTE RELATING TO THIS AGREEMENT AND THE AGREEMENTS INCORPORATED HEREIN BY REFERENCE. SHOULD ANY PART OF THE ARBITRATION AGREEMENT CONTAINED IN THIS SECTION CONFLICT WITH ANY OTHER ARBITRATION AGREEMENT BETWEEN THE PARTIES, THE PARTIES AGREE THAT THIS ARBITRATION AGREEMENT IN THIS SECTION SHALL GOVERN.

20. Tax Consequences. The Company makes no representations or warranties with respect to the tax consequences of the payments and any other consideration provided to Executive or made on Executive's behalf under the terms of this Agreement. Executive agrees and understands that Executive is responsible for payment, if any, of local, state, and/or federal taxes on the payments and any other consideration provided hereunder by the Company and any penalties or assessments thereon. Executive further agrees to indemnify and hold the Releasees harmless from any claims, demands, deficiencies, penalties, interest, assessments, executions, judgments, or recoveries by any government agency against the Company for any amounts claimed due on account of (a) Executive's failure to pay or delayed payment of federal or state taxes, or (b) damages sustained by the Company by reason of any such claims, including attorneys' fees and costs. The Parties agree and acknowledge that the payments made pursuant to section 1 of this Agreement are not related to sexual harassment or sexual abuse and not intended to fall within the scope of 26 U.S.C. Section 162(q).

21. Section 409A. It is intended that this Agreement comply with, or be exempt from, Code Section 409A and the final regulations and official guidance thereunder ("Section 409A") and any ambiguities herein will be interpreted to so comply and/or be exempt from Section 409A. Each payment and benefit to be paid or provided under this Agreement is intended to constitute a series of separate payments for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations. The Company and Executive will work together in good faith to consider either (i) amendments to this Agreement; or (ii) revisions to this Agreement with respect to the payment of any awards, which are necessary or appropriate to avoid imposition of any additional tax or income recognition prior to the actual payment to Executive under Section 409A. In no event will the Releasees reimburse Executive for any taxes that may be imposed on Executive as a result of Section 409A.

22. Authority. The Company represents and warrants that the undersigned has the authority to act on behalf of the Company and to bind the Company and all who may claim through it to the terms and conditions of this Agreement. Executive represents and warrants that Executive has the capacity to act on Executive's own behalf and on behalf of all who might claim through Executive to bind them to the terms and conditions of this Agreement. Each Party warrants and represents that there are no liens or claims of lien or assignments in law or equity or otherwise of or against any of the claims or causes of action released herein.

23. Severability. In the event that any provision or any portion of any provision hereof or any surviving agreement made a part hereof becomes or is declared by a court of competent jurisdiction or arbitrator to be illegal, unenforceable, or void, this Agreement shall continue in full force and effect without said provision or portion of provision.

24. Attorneys' Fees. Except with regard to a legal action challenging or seeking a determination in good faith of the validity of the waiver herein under the ADEA, in the event that either Party brings an action to enforce or effect its rights under this Agreement, the prevailing Party shall be entitled to recover its costs and expenses, including the costs of mediation, arbitration, litigation, court fees, and reasonable attorneys' fees incurred in connection with such an action.

25. Entire Agreement. This Agreement represents the entire agreement and understanding between the Company and Executive concerning the subject matter of this Agreement and Executive's employment with and separation from the Company and the events leading thereto and associated therewith, and supersedes and replaces any and all prior agreements, including, but not limited to, the Limited Release, and understandings concerning the subject matter of this Agreement and Executive's relationship with the Company, with the exception of the Confidentiality Agreement, any surviving obligations under the Employment Agreement, and the Stock Agreements, except as otherwise modified or superseded herein.

26. No Oral Modification. This Agreement may only be amended in a writing signed by Executive and the Company's Chief Executive Officer.

27. Governing Law. This Agreement shall be governed by the laws of the State of California, without regard for choice-of-law provisions, except that any dispute regarding the enforceability of the arbitration section of this Agreement shall be governed by the FAA. Executive consents to personal and exclusive jurisdiction and venue in the State of California.

28. Effective Date. Executive understands that this Agreement shall be null and void if not executed by Executive within twenty-one (21) days. Each Party has seven (7) days after that Party signs this Agreement to revoke it. This Agreement will become effective on the eighth (8th) day after Executive signed this Agreement, so long as it has been signed by the Parties and has not been revoked by either Party before that date (the "Effective Date").

29. Counterparts. This Agreement may be executed in counterparts and each counterpart shall be deemed an original and all of which counterparts taken together shall have the same force and effect as an original and shall constitute an effective, binding agreement on the part of each of the undersigned. The counterparts of this Agreement may be executed and delivered by facsimile, photo, email PDF, or other electronic transmission or signature.

[THE REMAINDER OF THIS PAGE IS INTENTIONALLY LEFT BLANK;
SIGNATURE PAGE FOLLOWS]

30. Voluntary Execution of Agreement. Executive understands and agrees that Executive executed this Agreement voluntarily and without any duress or undue influence on the part or behalf of the Company or any third party, with the full intent of releasing all of Executive's claims against the Company and any of the other Releasees. Executive acknowledges that:

(a) Executive has read this Agreement;

(b) Executive has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of Executive's own choice or has elected not to retain legal counsel;

(c) Executive understands the terms and consequences of this Agreement and of the releases it contains;

(d) Executive is fully aware of the legal and binding effect of this Agreement; and

(e) Executive has not relied upon any representations or statements made by the Company that are not specifically set forth in this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement on the respective dates set forth below.

BRIAN DOW, an individual

Dated: December 31, 2019

/s/ Brian Dow
Brian Dow

PULSE BIOSCIENCES, INC.

Dated: December 31, 2019

By: /s/ Darrin Uecker
Darrin Uecker
Chief Executive Officer

List of Subsidiaries

Subsidiary	Jurisdiction of Incorporation	Ownership Position
Nanoblate Corp., a Delaware Corporation	Delaware	100%
BioElectroMed Corp., a California Corporation	California	100%

Exhibit 23.1

GUMBINER SAVETT INC.
CERTIFIED PUBLIC ACCOUNTANTS
& BUSINESS ADVISORS
Santa Monica, California

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors
Pulse Biosciences, Inc.

We hereby consent to the use in the Form 10-K for the year ended December 31, 2019 of our report dated March 16, 2018, relating to Pulse Biosciences, Inc.'s consolidated statements of operations and comprehensive loss, stockholders" equity and cash flows for the year ended December 31, 2017, and the related notes, which is included in the Form 10-K for the year ended December 31, 2019.

/s/ Gumbiner Savett Inc.
March 16, 2020
Santa Monica, California

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement Nos. 333-227974, 333-224800, 333-219104 and 333-219096 on Form S-3 and Nos. 333-229320, 333-222582, 333-221788, 333-218164, and 333-216897 on Form S-8 of our report dated March 16, 2020, relating to the financial statements of Pulse Biosciences, Inc. and its subsidiaries appearing in this Annual Report on Form 10-K of Pulse Biosciences, Inc. for the year ended December 31, 2019.

/s/ *DELOITTE & TOUCHE LLP*

San Jose, California
March 16, 2020

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, certify that:

1. I have reviewed this Annual Report on Form 10-K 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) 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

    d) 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

    a) 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: March 16, 2020

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, Sandra Gardiner, certify that:

1. I have reviewed this Annual Report on Form 10-K 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) 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

   d) 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: March 16, 2020

By: /s/ Sandra Gardiner
Sandra Gardiner
Chief Financial Officer, Executive Vice President of Finance and Administration, Secretary and Treasurer
(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 Annual Report of Pulse Biosciences, Inc. (the "Company") on Form 10-K for the fiscal year ended December 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: March 16, 2020

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

/s/ Sandra Gardiner
Sandra Gardiner
Chief Financial Officer, Executive Vice President of Finance and Administration, Secretary and Treasurer
(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.