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, 2022
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 **(State or other jurisdiction of incorporation or organization)**	**46-5696597** **(I.R.S. Employer Identification No.)**
3957 Point Eden Way **Hayward, CA** **(Address of principal executive offices)**	**94545** **(Zip Code)**

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 30, 2022, 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 $23,793,458. 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 March 27, 2023: 37,592,588

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant's definitive Proxy Statement relating to its 2023 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, 2022.

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

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

SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS

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

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

Part I

Item 1. Business

Overview

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

AF is a type of heart arrythmia, or irregular heartbeat, caused by faulty electrical signals in the heart. AF is a highly prevalent condition and is growing significantly with an ageing population. It is estimated that 43 million people worldwide are affected by AF. Treatment requires the precise and safe ablation of heart tissue to block or otherwise prevent these faulty electrical signals from causing the irregular heartbeat, and we believe nsPFA technology is uniquely suited to perform an integral role for this application and that it will prove to be highly differentiated from standard thermal energy modalities in use today. The Company has developed a cardiac ablation clamp for use in cardiac surgery and a cardiac ablation catheter for use in electrophysiology and we are currently testing both in preclinical models. While these devices serve different physicians, the application of the energy to safely and effectively ablate cardiac tissue and the treatment of AF are the same, and we believe there will be important synergies realized through their contemporaneous development. The Company's cardiac ablation clamp and cardiac ablation catheter both use the CellFX System to generate our proprietary pulses of electrical energy.

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

We believe our nsPFA technology can provide important advantages over today's thermal modalities in creating these ablation lines. For example, surgeons using the CellFX System should be able to deliver faster ablations through thicker tissue than thermal modalities because of the nonthermal mechanism of action that nsPFA employs, which is not affected by heatsinks such as the blood in the heart. Thermal modalities are also known to have problems with char formation on electrode surfaces which can cause gaps in the ablation lines leading to treatment failure and require the char to be scraped off by the surgeon during the procedure. Again, this should not be an issue with nsPFA ablation given its nonthermal nature. Because nsPFA ablation does not impact acellular tissue, such as collagen or cartilage, our technology has the potential to offer significant safety advantages over thermal modalities by allowing surgeons to ablate near and into vessels and valves without concern of permanent damage. And finally, nsPFA ablation has been shown to spare nerves of any permanent damage even when treated directly, which is another concern for thermal modalities. The Company believes these advantages will be profoundly important to cardiac surgeons treating AF, so it is working with leaders in the field to develop this technology quickly.

Over the last several years, we have been developing the cardiac ablation clamp from proof-of-concept to prototype, and we now have what we believe is our initial commercial design. The device was designed with the input of key physicians in cardiac surgery, and we believe it will offer a highly differentiated option relative to the standard of care thermal modalities. We plan to perform the necessary device testing in 2023 to prepare for human clinical use, including continued preclinical testing. In parallel with the continued testing of the device, we expect to meet with the U.S. Food and Drug Administration (the "FDA") to discuss the regulatory requirements for a potential FDA clearance or approval to market our cardiac clamp in the United States. This will be done as part of the FDA's standard Q-submission process, also known as a pre-submission meeting. We expect that our first meeting on this topic with the FDA will take place in the second quarter of 2023.

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

In recent years, Pulsed Field Ablation ("PFA") has gained attention in electrophysiology for the treatment of AF as a result of its safety profile and potential to improve efficacy. PFA differs from nsPFA in that the pulse widths are longer, typically in the 10's to 100's of microseconds. We believe nsPFA can offer similar safety advantages as PFA and may provide improved efficacy advantages based on the circumferential design of our catheter and the potential that nsPFA can create deeper ablations. Another potential advantage of nsPFA ablation is a much shorter pulse duration which appears to stimulate less muscle contraction than does millisecond or microsecond PFA.

Similar to the cardiac ablation clamp, our proprietary catheter has been in development for several years and we have been working with leaders in the electrophysiology field to test the catheter in preclinical studies. We believe the design we have now will be suitable to pursue a first-in-human clinical safety study. We are in the testing phase of the development process and expect to complete additional safety and performance preclinical studies throughout 2023. Once completed, we believe we will be in a position to begin a first-in-human feasibility study. In the United States, we believe the catheter will need to go through the FDA's Pre-Market Approval ("PMA") process for FDA approval to market and sell in the United States.

The CellFX System

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

While we are not investing R&D resources in applications outside of cardiology and the treatment of AF, we continue to believe nsPFA ablation and NPS technology more broadly has the potential to provide superior outcomes across additional medical disciplines and we may seek partnership opportunities to develop additional applications.

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.

Today, on a worldwide basis, we own 165 issued patents and pending patent applications, and we have an exclusive license to 72 additional issued patents and pending patent applications. The vast majority of our granted patents have an expiration date between 2035 and 2041. 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 and useful patent portfolio against competitors, such that an expiration of a single patent should not lessen our overall comprehensive coverage and competitive advantage. We believe our NPS platform and CellFX System are protected by several issued patents, as well as pending applications.

Employees and Human Capital

As of December 31, 2022, we had 61 employees, of which substantially all were located at our headquarters in Hayward, California. Of these employees, 39 were engaged in research and development activities and 22 were engaged in sales, marketing, business development, and general and administrative activities.

Talent Acquisition and Development. We are committed to providing a respectful work environment to our diverse workforce. We provide equal employment opportunities to all persons regardless of race, age, color, gender, sexual orientation, national origin, physical or mental disability, religion, or any other characteristic protected by federal, state, or local law.

We believe our employees are essential to our success and our ability to attract, develop, and retain key talent is a vital part of that. Our philosophy is to both develop talent from within and to strategically recruit key external talent. Our overall talent acquisition and retention strategy is designed to attract and retain diverse and qualified candidates to enable the success of the Company and achievement of our performance goals. The skills, experience and industry knowledge of key employees significantly benefit our operations and performance.

Compensation and Benefits Program. Our compensation program is designed to attract, motivate, and retain talented individuals who possess the skills necessary to support our business and contribute to our strategic goals, creating long-term value for our stockholders. We provide employees with competitive compensation packages that include base salary, annual incentive bonuses, 401(k), and equity awards tied to the value of our stock price. Our comprehensive benefits package also includes medical, dental, vision, life and disability plans, and an employee assistance program.

Wellness and Safety. The health and safety of our employees is of utmost importance to us. We currently operate under a hybrid model of onsite and remote work with our technical teams being mostly back onsite on a full-time basis. In response to the COVID-19 pandemic, we continue to require employees to be fully vaccinated for COVID-19 and have policies and guidelines which are designed to protect the safety of our employees.

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 cardiology, oncology, and dermatology, as well as in minimally invasive procedures. For example, Abbott Laboratories, AtriCure, Inc., Boston Scientific Corporation, Johnson & Johnson (Biosense Webster), Medtronic plc, and several other companies all sell ablation-based surgical and catheter-based medical devices for the treatment of heart arrhythmias, including AF, and additionally, many of these companies are also actively developing PFA products for the treatment of AF. All of these companies currently have greater financial, technical, research, and/or other resources than we do and have larger and more established manufacturing capabilities and marketing, sales, and support functions. 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 can influence many cellular functions depending on the energy applied. When it is used to stimulate primarily regulated cell death, such as through nsPFA ablation, we believe it would be less traumatic to treated tissue and would result in less scarring or collateral damage to surrounding tissues, which we feel will give us a competitive advantage over these more established companies despite formidable competition.

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 United States. The laws and regulations govern, among other things, product design and development, preclinical 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 United States.

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, *i.e.,* a predicate device. 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 preclinical, 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 efficacy 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

Even after a device is placed on the market with FDA clearance or approval, numerous 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 and FTC 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 efficacy data for the device.

The FDA has broad post-market and regulatory enforcement powers, and we must comply with the post-market surveillance regulations, including medical device reporting regulations. We are required to report to the FDA information if a device has, or may have, caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury, if the malfunction of the device or one of our similar devices were to recur. If we fail to report events required to be reported to the FDA within the required timeframes, or at all, the FDA could take enforcement action and impose sanctions against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require our time and capital, distract management from operating our business, and may harm our reputation and have a material adverse effect on our business, financial condition, and results of operations.

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 the 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 (the "EU") consists of 27-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 Union Medical Device Regulation (2017/745 or EU MDR) following its entry into application on May 26, 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: (i) the length of time the device is in contact with the body, (ii) the degree of invasiveness, and (iii) 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.

The EU MDR, which repealed and replaced the MDD, entered into force on May 25, 2017 with a transition period extending until May 26, 2021. The EU 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 EU 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 December 2028 at the latest. After the expiry of any applicable transitional period, only devices that have been CE marked under the EU MDR may be placed on the market in the EU.

U.S. Healthcare Reform

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

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

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 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.

In May 2022, the Company determined not to renew its annual director and officer liability insurance policy due to disproportionately high premiums quoted by insurance companies. Instead, on May 31, 2022, the Company and Robert W. Duggan, the Company's Executive Chairman, entered into a letter agreement (the “Letter Agreement”) pursuant to which Mr. Duggan has agreed with the Company to personally provide indemnity coverage for a one-year period, and he has agreed to deposit cash and/or marketable securities into a third-party escrow, as security for these obligations, if requested by the Company. The Company will pay a fee of $1.0 million to Mr. Duggan that shall be due on May 31, 2023, the last day of the one-year period, in consideration of the obligations set forth in the Letter Agreement. As of December 31, 2022, the amount owed to Mr. Duggan under the Letter Agreement was $0.6 million, recorded on the balance sheet under accrued expenses.

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 of 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 our website home page.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this 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. In addition, any worsening of the economic environment may exacerbate the risks described below, any of which could have a material impact on us.

Summary

Our business is subject to numerous risks and uncertainties that you should consider before investing in our common stock. These risks are described more fully below and include, but are not limited to, risks relating to the following:

- Our limited operating history and our limited revenue producing operations;
- Our inability to operate without additional fundraising;
- Our lack of experience developing and manufacturing medical products for cardiologists;
- Competition within our industry and in the markets and market segments we choose to pursue, including cardiology;
- Health epidemics, including the coronavirus pandemic;
- Our reliance on certain third parties, such as key suppliers;
- Potential loss of key management personnel and high employee attrition;
- Potential security breaches, loss of data, and other disruptions to us or to our third-party service providers that could compromise sensitive information;
- Potential product liability lawsuits and other litigation;
- The timing, unpredictability, and expense of our clinical and product development activities;
- The possibility of adverse clinical trial results and unfavorable long-term clinical trial data, especially given our limited pre-clinical experience using NPS technology in animal models of cardiac disease;
- Potential failure to obtain and maintain necessary regulatory clearances or approvals;
- Uncertainties concerning the long-term safety and effectiveness of our CellFX System and product candidates, and the potential for adverse side effects;
- The commercial uncertainties concerning whether there will be broad adoption of our CellFX System and NPS technology, especially in the cardiology market given our announced focus on cardiac care, and uncertainties about whether we will be able to secure a partner to promote further sales of the CellFX System in dermatology profitably;
- Possible challenges enrolling patients in our clinical trials;
- Uncertainties concerning our ability to obtain an adequate level of reimbursement by Medicare and other third-party payers;
- Protection of intellectual property, potential litigation related to intellectual property, and obligations under intellectual property agreements;
- Stringent domestic and foreign regulation in respect of any potential devices and products, including healthcare laws and regulations;

- Healthcare policy changes;
- Volatility of the price of our common stock;
- Concentration of ownership by our principal stockholder and Executive Chairman, Robert W. Duggan;
- Potential material weaknesses and uncertainties concerning our ability to maintain an effective system of internal control over financial reporting; and
- Unfavorable global economic or political conditions.

Risks Relating to Our Business, Industry and Financial Condition

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

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

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

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

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

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

We must have sufficient sources of liquidity to fund our working capital requirements and execute on our strategic initiatives. Future new product launches or investments in other growth initiatives may demand increased working capital before any long-term return is realized from increased revenue. Our ability to achieve our business and cash flow plans is based on a number of assumptions which involve significant judgments and estimates of future performance, borrowing capacity and credit availability, and financing opportunities which cannot at all times be assured. Additionally, in September 2022, to fund operations, we borrowed $65 million from our majority stockholder and Executive Chairman, Robert W. Duggan, and we will need to raise additional capital in order to repay this loan by no later than its maturity date in September 2024. Accordingly, there is no assurance that cash flows from operations and other internal and external sources of liquidity will at all times be sufficient for our cash requirements, including repayment of the loan and other indebtedness. If necessary, we may need to consider actions and steps to improve our cash position and mitigate any potential liquidity shortfall, such as modifying our business plans, pursuing additional financing to the extent available, reducing capital expenditures, suspending certain activities or programs, pursuing and evaluating other alternatives and opportunities to obtain additional sources of liquidity, and other potential actions to reduce costs. There can be no assurance that any of these actions would be successful, sufficient or available on favorable terms. Any inability to generate or obtain sufficient levels of liquidity to meet our cash requirements at the level and times needed could have a material adverse impact on our business and financial position.

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

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

We will need to raise additional capital in order to continue to execute our business plan. If we are unable to raise sufficient additional funds, we may need to scale back our future operations. Also, the ongoing hostilities between Russia and Ukraine and the ongoing COVID-19 pandemic and resulting negative impact on the global macroeconomic environment and capital markets may make it more difficult for us to raise additional funds. Also, the existing debt obligations we owe to our Executive Chairman may make future equity financings difficult to structure, more costly to the Company, and harder to complete, and additionally we may be required to incur more debt in the future.

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

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

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

Our corporate restructuring and the associated headcount reduction announced in March and September 2022 and February 2023 may not result in anticipated savings, could result in total costs and expenses and attrition that are greater than expected and could disrupt our business.

On March 31, 2022, we announced an approximate 20% reduction in headcount as part of a corporate restructuring plan. On September 30, 2022, we announced an approximate 40% reduction in headcount as part of our decision to focus our activities on product development outside of dermatology. As a consequence of our announced corporate realignment, we have experienced employee turnover in 2022 higher than industry norms, and in February 2023 we continued to reduce headcount by eliminating another seven positions at the Company. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring plan, our operating results and financial condition would be adversely affected. We may have to undertake additional headcount reductions or restructuring activities in the future. Furthermore, our restructuring activities may be disruptive to our operations and could result in material delays in our new product development programs. For example, our headcount reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, or increase difficulties in our day-to-day operations, servicing of commercial accounts, and product development activities. Our headcount reductions could also harm our ability to attract and retain qualified management, scientific, clinical, regulatory, manufacturing, engineering, and other personnel critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing and commercializing our new product candidates in the future and could also harm our existing and planned commercial activities in dermatology.

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

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

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

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

Aesthetic and medical dermatologists have been slow to adopt our products and they have used our products in only a small percentage of their eligible patients for a variety of reasons. Even if we are able to develop a safe and effective treatment for atrial fibrillation using our proprietary NPS technology, we can give no assurance that cardiologists would adopt NPS technology into their medical practices faster than dermatologists have.

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

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

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

We may also face increased competition in the future as new companies enter our markets and as scientific developments surrounding electro-signaling therapeutics continue to accelerate. For example, the current standard of care in cardiac tissue ablation for the treatment of atrial fibrillation is the use of thermal ablation modalities, primarily the use of radiofrequency ablation. 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 dermatology, we commenced revenue-producing operations in 2021; however, we have been unsuccessful in earning significant revenues. We therefore intend to seek development and marketing partners and license our technology to others in order to avoid having to provide 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 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, Kevin Danahy, and our Chief Technology Officer, Darrin Uecker, and members of our finance, scientific and engineering teams. These persons have significant experience and knowledge with sub-microsecond pulsed electric fields and more broadly in life sciences and medical technologies. The loss of any team member could impair our ability to design, identify, and develop new intellectual property and new scientific or product ideas. The loss of a key employee, the failure of a key employee to perform in his or her current position, or our inability to attract and retain skilled employees could result in our inability to continue to grow our business or to implement our business strategy. We compete for qualified management and scientific personnel with other life science companies, academic institutions, and research institutions. Our employees could leave our Company with little or no prior notice. They are free to work for a competitor. If one or more of our senior executives or other key personnel were unable or unwilling to continue in their present positions, we may not be able to replace them easily or at all, and other senior management may be required to divert attention from other aspects of the business. In addition, we do not have "key person" life insurance policies covering any member of our management team or other key personnel. The loss of any of these individuals or any inability to attract or retain qualified personnel, including scientists, engineers, and others, could prevent us from pursuing collaborations and materially and adversely affect our product development and introductions, business growth prospects, results of operations, and financial condition.

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

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

We have very limited experience selling the CellFX System.

Successfully commercializing medical devices such as ours is a complex and uncertain process. We began marketing and selling the CellFX System in the United States, Canada, and certain limited European markets in late 2021 to dermatologists through a limited direct sales force. However, we have had limited experience marketing and selling the CellFX System in dermatology, no sales experience in cardiology, and our revenues and cash flows have been volatile and difficult to predict. As of March 1, 2023, following two reductions in force in 2022 and a third elimination of positions in February 2023, we no longer had any employees engaged in sales and marketing activities on a fulltime basis.

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

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

We are subject to laws and regulations relating to personally identifiable health information, and 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, both 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 using 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 to data, data corruption, unauthorized disclosure of data, and unauthorized access of data, as well as risks associated with our ability to identify and audit such events.

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Product Development

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

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

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

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

We might be unable to successfully commercialize our current products with domestic or international regulatory clearances or approvals or develop or obtain regulatory clearances or approvals to market new products, either with or without a corporate partner in cardiology, for example. Additionally, despite our best efforts and the best efforts of any corporate partners we may secure, these products and any future products might not be accepted by dermatologists, cardiologists, or other health care workers or the third-party payors who reimburse for the procedures performed with our products or may not be successfully commercialized due to other factors. The success of any new product offering or enhancement to an existing product will depend on numerous factors, including our ability to:

- properly identify and anticipate clinician and patient needs;
- develop and introduce new products or product enhancements in a timely manner;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;
- demonstrate the safety and efficacy of new products; and
- obtain the necessary regulatory clearances or approvals for new products or product enhancements.

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

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

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

From time to time, we may publish interim top-line or preliminary results from our clinical trials. Interim results from clinical trials that we may announce are subject to the risk that one or more of the clinical outcomes may materially change as 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 maintain necessary regulatory clearance for our product, or if clearances or approvals for future devices and indications are delayed or not issued, the commercial prospects for our CellFX System and other NPS technologies would be harmed.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We currently purchase components for our products under development under purchase orders and do not have long-term contracts with most of the suppliers of these materials. If suppliers were to delay or stop producing our components, or if the prices they charge us were to increase significantly, or if they elected not to sell to us, we would need to identify other suppliers and we may not be able to secure alternative suppliers on favorable terms, or at all. Also, any number of our suppliers may be adversely impacted by COVID-19 which could affect their ability to perform satisfactorily. Any failure of these suppliers to perform satisfactorily could adversely impact our business and results of operations and we may experience delays in manufacturing of our devices while finding another acceptable supplier.

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

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

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

Risks Related to Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Government Regulation

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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 governments, 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.

Risks Related to Owning Our Common Stock

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

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

- results of clinical trials of our planned products or those of our competitors;
- actions by regulatory bodies, such as the FDA, that affect our business or have the effect of delaying or rejecting approval or clearance of our planned products;
- actual or anticipated fluctuations in our financial condition and operating results;
- announcements by our customers, partners or suppliers relating directly or indirectly to our products, services or technologies;
- announcements of technological innovations by us or our competitors;
- changes in laws or regulations applicable to the CellFX System or to our planned 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 negative impact of COVID-19 on the global economy and markets; and
- general economic and market conditions.

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

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

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

Additionally, 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 $160 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 some or all 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 exist for our common stock and as a result it may be difficult for you to sell your common stock.

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

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

A majority percentage of our outstanding stock is held by Robert W. Duggan, Executive Chairman of our Board, who beneficially owns approximately 56% of our common stock outstanding as of the date of this Annual Report. As a result, Mr. Duggan has control over corporate actions requiring stockholder approval, including the following actions:

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

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

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

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

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

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

Robert W. Duggan is our Executive Chairman, and he beneficially owns approximately 56% 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 of equity securities in connection with any rights offerings or any alternative equity or equity-linked offering that we may conduct, could result in his acquisition of a majority of our common stock. As a result of Mr. Duggan's controlling ownership and position as Executive Chairman, others may be less inclined to pursue an acquisition of us and therefore we may not have the opportunity to be acquired in a transaction that stockholders might otherwise deem favorable, including transactions in which our stockholders might realize a substantial premium for their shares. In addition, public speculation regarding Mr. Duggan, as well as our relationship with Mr. Duggan, could cause our stock price to fluctuate.

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

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

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

Furthermore, these and future rules and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. For example, we determined not to renew our director and officer liability insurance this year due to disproportionately high premiums quoted by insurance companies. Instead, we and Robert W. Duggan, Executive Chairman of our board of directors, have entered into a letter agreement pursuant to which Mr. Duggan has agreed with us to personally provide "Side A" indemnity coverage on substantially the same terms as our prior coverage program for a one-year period. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our executive officers.

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

Through the end of 2021, we were an "emerging growth company," as defined in the JOBS Act, and we took 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. While we are no longer an emerging growth company, we still qualify as a "smaller reporting company," as defined in the Exchange Act, and so long as we remain a smaller reporting company, we benefit from and may take advantage of scaled disclosure requirements. We cannot know if investors find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our reporting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected.

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

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

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

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

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

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

- authorize our board of directors to issue, without further action by the stockholders, up to 50,000,000 shares of preferred stock and up to approximately 500,000,000 shares of authorized but unissued shares of common stock;

- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;

- specify that special meetings of our stockholders can be called only by our board of directors, the chairman of our board of directors, any of our officers, or any stockholder holding at least fifteen percent (15%) of the voting power of the capital stock issued and outstanding and entitled to vote;

- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;

- require the affirmative vote of holders of at least 66 2/3% of the voting power of all the then outstanding shares of our voting stock, voting together as a single class, to amend provisions of our certificate of incorporation or our bylaws;

- give our board of directors the ability to amend our bylaws by majority vote; and

- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum.

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

General Risk Factors

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including the negative impact of COVID-19 on the global economy and markets. A global financial crisis or a banking crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets, as has recently been the case due to COVID-19. The Company places its cash equivalents and investments with high credit quality financial institutions and, by policy, limits the amounts invested with any one financial institution or issuer and restricts the Company's investments to U.S. treasuries and money market instruments. The Company does not bank with Silicon Valley Bank, however in general the Company's deposits held with banks may exceed the amount of insurance provided on such deposits. Despite our low risk investment policies, a severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy, banking crisis or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our products. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

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

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

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

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

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

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We currently lease approximately 50,300 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. In May 2019, we entered into an amendment which enabled us to expand the lease by approximately 34,600 additional square feet, for a total of approximately 50,300 square feet. The amendment also included an option to extend the term of the lease. Approximately 13,300 square feet of the additional space was occupied in November 2019 as part of the first phase, and the remaining approximately 21,300 square feet was occupied in May 2020 as part of the second phase. The term of the total lease was extended through October 2029.

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, including the matter described below. The outcome of any legal proceedings is unpredictable but, regardless of outcome, they can have an adverse impact on us because of defense and settlement costs, diversion of management resources, negative publicity, reputational harm, and other factors. We maintain insurance that may provide coverage for such matters, including customary employment practices liability insurance.

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

Item 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 Nasdaq and has been traded under the symbol "PLSE" since May 18, 2016.

Holders of Record

As of March 27, 2023, 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.

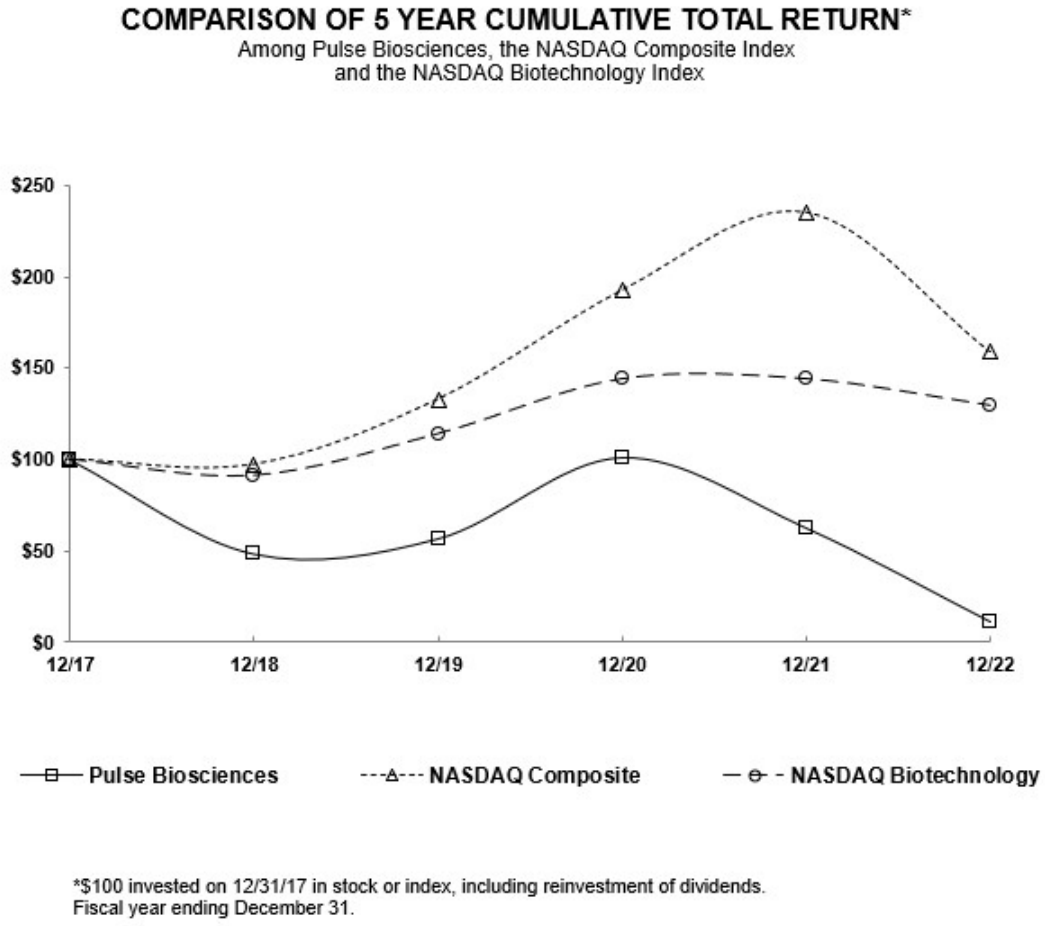
Sales of Unregistered Securities

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 ("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 matches our cumulative 5-year total shareholder return on common stock with the cumulative total returns of the Nasdaq Composite Index and the Nasdaq Biotechnology Index. The graph tracks the performance of a $100 investment in our common stock and in each index (with the reinvestment of all dividends) from December 31, 2017, to December 31, 2022. Such returns are based on historical results and are not intended to suggest future performance.



Item 6. Selected Financial Data

The Company is a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and is not required to provide the information required under this item.

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

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

AF is a type of heart arrythmia, or irregular heartbeat, caused by faulty electrical signals in the heart. AF is a highly prevalent condition and is growing significantly with an ageing population. It is estimated that 43 million people worldwide are affected by AF. Treatment requires the precise and safe ablation of heart tissue to block or otherwise prevent these faulty electrical signals from causing the irregular heartbeat, and we believe nsPFA technology is uniquely suited to perform an integral role for this application and that it will prove to be highly differentiated from standard thermal energy modalities in use today. We have developed a cardiac ablation clamp for use in cardiac surgery and a cardiac ablation catheter for use in electrophysiology and we are currently testing both in preclinical models. While these devices serve different physicians, the application of the energy to safely and effectively ablate cardiac tissue and the treatment of AF are the same, and we believe there will be important synergies realized through their contemporaneous development. Our cardiac ablation clamp and cardiac ablation catheter both use the CellFX System to generate our proprietary pulses of electrical energy.

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

We believe our nsPFA technology can provide important advantages over today's thermal modalities in creating these ablation lines. For example, surgeons using the CellFX System should be able to deliver faster ablations through thicker tissue than thermal modalities because of the nonthermal mechanism of action that nsPFA employs, which is not affected by heatsinks such as the blood in the heart. Thermal modalities are also known to have problems with char formation on electrode surfaces which can cause gaps in the ablation lines leading to treatment failure and require the char to be scraped off by the surgeon during the procedure. Again, this should not be an issue with nsPFA ablation given its nonthermal nature. Because nsPFA ablation does not impact acellular tissue, such as collagen or cartilage, our technology has the potential to offer significant safety advantages over thermal modalities by allowing surgeons to ablate near and into vessels and valves without concern of permanent damage. And finally, nsPFA ablation has been shown to spare nerves of any permanent damage even when treated directly, which is another concern for thermal modalities. We believe these advantages will be profoundly important to cardiac surgeons treating AF, so we are working with leaders in the field to develop this technology quickly.

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 have sufficient cash and cash equivalents on hand to support current operations for the twelve months following the filing of this Annual Report. We plan to seek to raise capital from time to time through public or private equity offerings, debt financings, our at-the-market equity offering program, or to enter into collaborations with third parties, to fund our future operations.

Over the past few years, Mr. Duggan has made significant investments in our Company to fund its operations. In June 2022, we completed a common stock rights offering to our existing stockholders of record, which raised $15 million in aggregate. Mr. Duggan purchased approximately 56% of the shares offered through this offering. Then, in September 2022, we entered into the 2022 Loan Agreement pursuant to which Mr. Duggan lent the Company $65 million to fund its product development operations. Mr. Duggan may or may not elect to participate in any number of our future fundraisings, as described above, and he may choose to invest more than his current pro rata share in any of these fundraisings, or alternatively he may offer to provide additional debt financing as may be needed in order to maintain the Company as a going concern.

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

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. We continually evaluate the accounting policies and estimates used in preparing our consolidated financial statements.

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 and various states. 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.

Results of Operations

Comparison of the Years ended December 31, 2022 and 2021

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

(in thousands)	Year Ended December 31, 2022	2021	$ Change
Revenues:			
Product revenues	$ 700	$ 1,418	$ (718)
Total revenues	700	1,418	(718)
Cost and expenses:			
Cost of revenues	11,944	1,968	9,976
Research and development	20,839	28,640	(7,801)
Sales and marketing	12,019	14,751	(2,732)
General and administrative	13,955	19,073	(5,118)
Total cost and expenses	58,757	64,432	(5,675)
Loss from operations	(58,057)	(63,014)	4,957
Other expense:			
Interest expense, net	(448)	(646)	198
Total other expense	(448)	(646)	198
Loss from operations, before income taxes	(58,505)	(63,660)	5,155
Income tax benefit	—	—	—
Net loss	$ (58,505)	$ (63,660)	$ 5,155

Revenues

Revenues decreased by $0.7 million to $0.7 million for the year ended December 31, 2022, from $1.4 million during the same period in 2021. The decrease in revenues was driven primarily by the September 2022 announcement to shift our strategic direction and advance our core NPS technology outside of dermatology, discontinuing further sales in the dermatology market.

Cost of Revenues

Cost of revenues increased by $10.0 million to $11.9 million for the year ended December 31, 2022, from $2.0 million during the same period in 2021 primarily driven by a $8.5 million inventory write-off recorded for excessive and obsolete inventory in accordance with our announced strategic shift to advance our core NPS technology outside of dermatology.

Research and Development

Research and development expenses consist of salaries and related expenses for research and development personnel, clinical trials and consulting costs related to the design, development and enhancement of our potential future products, prototype material and devices. Research and development expenses decreased by $7.8 million to $20.8 million in 2022 from $28.6 million in 2021 due to decreases of $3.6 million in stock-based compensation, $2.0 million in compensation and other employee related expenses and $2.0 million in clinical trial and other outside research costs. Compensation and other employee related expenses decreased primarily due to the decrease in headcount.

Sales and Marketing

Sales and marketing expenses consist of compensation and other related employee expenses for sales and marketing personnel, expenses associated with advertising and training, and marketing studies including our Controlled Launch program. Sales and marketing expenses decreased by $2.7 million to $12.0 million in 2022 from $14.7 million in 2021 due to decreases of $2.0 million in stock-based compensation and $1.9 million in paid services and promotional activities. These decreases were partially offset by an increase of $1.1 million in compensation and other employee related expenses. The reduction in paid services was related primarily to non-cash Controlled Launch expenses (see Footnote 8 for details of these non-cash expenses) and the reduction in stock-based compensation was related to the reduction in force. The increase in compensation and other employee related expenses was driven by timing, whereby the Company built up the sales force in the latter part of 2021 and early part of 2022, prior to the reduction in force in 2022.

General and Administrative

General and administrative expenses consist of compensation and other related employee expenses for executives, finance, legal, human resources, information technology and administrative personnel, professional fees, patent fees and costs, insurance costs, and other general corporate expenses. General and administrative expenses decreased by $5.1 million to $14.0 million in 2022 from $19.1 million in 2021 due to decreases of $3.8 million in stock-based compensation, $0.8 million in administrative costs driven by D&O insurance, $0.3 million in compensation and other employee related expenses, and $0.2 million in paid services. The reduction in stock-based compensation was related to the reduction in force and the decrease in compensation and other employee related expenses was driven by an overall reduction due to decrease in headcount, partially offset by an increase in severance costs in relation to the reduction in force.

Other Expense, net

Interest expense increased by $0.2 million to $0.9 million for the year ended December 31, 2022, from $0.7 million during the same period in 2021 driven by the 2022 Loan Agreement. Other expense increased by $0.2 million driven by a loss on disposal of assets. These were offset by an increase in interest income of $0.6 million primarily due to the higher cash and cash equivalents balance.

Comparison of the Years ended December 31, 2021, and 2020

Refer to Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations located in our Form 10-K for the fiscal year ended December 31, 2021, filed on March 31, 2022, for the discussion of the comparison of the fiscal year ended December 31, 2021, to the fiscal year ended December 31, 2020, the earliest of the three fiscal years presented in the consolidated financial statements.

Liquidity and Capital Resources

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

In June 2020, we completed a rights offering pursuant to which we sold an aggregate of 4,279,600 shares of our common stock, par value $0.001 per share, and 641,571 warrants, for net proceeds of $29.4 million. On December 31, 2020, the Company met the requirements for redemption of these warrants. Pursuant to the redemption, the Company redeemed 5,139 warrants at a redemption price of $0.01 per warrant. 636,432 warrants were exercised, generating approximately $4.5 million of additional net proceeds to the Company.

On February 4, 2021, we entered into a Sales Agreement with Stifel as sales agent, pursuant to which we may offer and sell, from time to time, through Stifel, up to $60.0 million in shares of our common stock, by any method permitted by law deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. We have no obligation to make any sales of our common stock pursuant to such Sales Agreement. During the year ended December 31, 2022, the Company did not issue or sell any shares of common stock under the Sales Agreement. During the year ended December 31, 2021, the Company issued and sold 288,490 shares of common stock under the Sales Agreement. The shares were sold at a weighted average price of $27.73 per share for aggregate net proceeds of approximately $7.4 million, after deducting sales commissions and offering costs payable by us.

In March 2021 we entered into a Loan Agreement with Robert W. Duggan, our Executive Chairman, in connection with Mr. Duggan lending the principal sum of $41.0 million to the Company. The Loan Agreement had a maturity date of June 11, 2022. Under the Loan Agreement, Mr. Duggan provided us, subject to certain conditions, an unsecured term loan facility in an original aggregate principal amount of $41.0 million. The Loan Agreement bore interest at a rate per annum equal to 5.0%, payable quarterly commencing on July 1, 2021. The Loan Agreement contained certain covenants and Events of Default.

On June 30, 2021, we entered into a Securities Purchase Agreement with Mr. Duggan, pursuant to which the Company issued and sold to Mr. Duggan 3,048,780 shares of the Company's common stock, par value $0.001 per share, in a private placement, at a price per share of $16.40. The shares were paid for through (i) the conversion of the $41 million aggregate principal amount, together with all accrued and unpaid interest outstanding, pursuant to the Loan Agreement by and between the Company and Mr. Duggan (Note 13), and (ii) additional cash in the amount of approximately $8.4 million. Upon closing of this Private Placement and satisfaction of the outstanding debt, the Loan Agreement was terminated, without early termination fees or penalties being owed by the Company, and no additional amounts were owed to Mr. Duggan under the Loan Agreement. The cash proceeds of approximately $8.4 million were received by the Company in July 2021.

On June 9, 2022, we completed the 2022 Rights Offering resulting in the sale of 7,317,072 Units, at a price of $2.05 per Unit, with each Unit consisting of one share of the Company's common stock, par value $0.001 per share, and one warrant to purchase one share of common stock. 7,317,072 shares of common stock and warrants to acquire up to an additional 7,317,072 shares of common stock were issued in the 2022 Rights Offering. The Company received aggregate gross proceeds from the 2022 Rights Offering of $15 million. If exercised, additional gross proceeds of up to $15 million may be received through the exercise of warrants issued in the 2022 Rights Offering. Each warrant is exercisable for one share of the Company's common stock at an exercise price equal to $2.05. Warrants are exercisable immediately and expire on the fifth anniversary of the closing of the 2022 Rights Offering.

In September 2022 we entered into the 2022 Loan Agreement with Robert W. Duggan, our Executive Chairman, in connection with Mr. Duggan lending the principal sum of $65.0 million to the Company. The 2022 Loan Agreement had a maturity date of March 20, 2024. Under the 2022 Loan Agreement, Mr. Duggan provided us, subject to certain conditions, an unsecured term loan facility in an original aggregate principal amount of $65.0 million. The 2022 Loan Agreement bears interest at a rate per annum equal to 5.0%, payable quarterly, commencing on January 1, 2023. On March 17, 2023, the Company and Mr. Duggan agreed to amend certain terms of the Loan Agreement. There were no changes to the interest rate, but the principal sum is now due and payable on September 30, 2024. The 2022 Loan Agreement contains certain covenants and Events of Default.

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

	Year Ended December 31,		
(in thousands)	**2022**	**2021**	**2020**
Net cash used in operating activities	$ (47,013)	$ (54,097)	$ (35,365)
Net cash provided by (used in) investing activities	$ (401)	$ 7,563	$ 10,044
Net cash provided by financing activities	$ 79,939	$ 62,685	$ 30,885
Net increase in cash and cash equivalents	$ 32,525	$ 16,151	$ 5,564

To date, we have generated limited revenue and used cash in our operating activities. As a result, we have incurred significant operating losses in each year since our inception and we may continue to incur additional losses for the next several years. As of December 31, 2022, the Company had cash and cash equivalents of $61.1 million. We believe that our existing cash and cash equivalents will be sufficient to fund our projected operating requirements for at least the next twelve months from the filing date of this Annual Report. However, we plan to raise additional capital in the future. We can give no assurance, at this time, that additional financing or a collaboration will be available when needed on terms acceptable to us, however.

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

Operating Activities

During 2022, we used cash of $47.0 million in operating activities. The difference between cash used in operating activities and net loss consisted primarily of stock-based compensation, reserve for excessive and obsolete inventory, depreciation and amortization, accounts payable and accrued expenses, and right-of-use assets, partially offset by increases in accrued interest and inventory.

During 2021, we used cash of $54.1 million in operating activities. The difference between cash used in operating activities and net loss consisted primarily of stock-based compensation, depreciation and amortization, accounts payable and accrued expenses, and right-of-use assets, partially offset by increases in prepaid expenses and inventory.

Investing Activities

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

During 2022, cash used in investing activities was $0.4 million, which was for the purchase of property and equipment.

During 2021, cash provided from investing activities was $7.6 million, of which $8.0 million was provided from the maturities of investments, partially offset by cash used for the purchase of property and equipment.

Financing Activities

During 2022, cash provided from financing activities was $79.9 million, primarily due to $65.0 million of proceeds from our 2022 Loan Agreement, $14.9 million of proceeds from the sale of common stock in our rights offering and $0.5 million from the sale of stock under our employee stock purchase plan, partially offset by payments made on the Insurance Loan Agreement.

During 2021, cash provided from financing activities was $62.7 million, primarily due to $49.3 million net cash received from our Loan Agreement and Private Placement, $7.4 million net cash received from our at-the-market equity offering, $5.0 million received from stock option and warrant exercises, $0.4 million received, net of payments made to date, from the Insurance Loan Agreement and $0.8 million received from the sale of stock under our employee stock purchase plan.

Comparison of the Years ended December 31, 2021 and 2020

Refer to Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations located in our Form 10-K for the fiscal year ended December 31, 2021, filed on March 31, 2022, for the discussion of the comparison of the fiscal year ended December 31, 2021, to the fiscal year ended December 31, 2020, 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 Old Dominion University Research Foundation ("ODURF") and Eastern Virginia Medical School ("EVMS"), effective on November 6, 2014, we sponsored certain approved research activities at ODURF's Frank Reidy Research Center under a sponsored research agreement ("SRA"). In September 2019, we agreed to sponsor a task order for research in the amount of $0.8 million each to be performed during the subsequent 12-month period. In March 2021, we agreed to sponsor a task order for research in the amount of $0.3 million and in May 2021 we sponsored an additional task order for $0.3 million each to be performed during their respective subsequent 12-month periods. These sponsored researches are 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 within 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, 2022, 2021 and 2020, we incurred costs relating to the SRA equal to $0.2 million, $0.3 million and $0.6 million, respectively. As of December 31, 2022, there are no unbilled SRAs left under the task orders.

Operating Lease

We currently lease approximately 50,300 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. In May 2019, we entered into an amendment which enabled us to expand the lease by approximately 34,600 additional square feet, for a total of approximately 50,300 square feet. The amendment also included an option to extend the term of the lease. Approximately 13,300 square feet of the additional space was occupied in November 2019 as part of the first phase, and the remaining approximately 21,300 square feet was occupied in May 2020 as part of the second phase. The term of the total lease was extended through October 2029.

The following table summarizes our contractual obligations as of December 31, 2022 (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	$ 13,969	$ 1,845	$ 3,887	$ 4,163	$ 4,074

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future material effect on our financial condition, results of operations, liquidity, or cash flows.

JOBS Act Accounting Election

Through the end of 2021, we were an emerging growth company as defined by the JOBS Act. Under the JOBS Act, we were given the option to 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 irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we were 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 the research and development of our technology, including, but not limited to, additional financing through follow-on stock offerings, debt financings, or co-development agreements and /or other alternatives.

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

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

Item 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 may 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. At December 31, 2022, we did not have any investments.

Foreign Exchange Risk

The majority of our expense and capital purchasing activities are transacted in U.S. dollars. In 2021, we expended operations and sales into Europe and Canada. While we currently have limited international operations, we may incur foreign exchange gains or losses in the future as we further commercialize and expand internationally.

Item 8. Financial Statements and Supplementary Data

PULSE BIOSCIENCES, INC.

Index to Consolidated Financial Statements

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 its wholly owned subsidiaries (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, stockholders' (deficit) equity, and cash flows, for each of the three years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

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.

Critical Audit Matter

Critical audit matters are matters arising from the current-period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Deloitte & Touche LLP

San Jose, California
March 31, 2023

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

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

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 61,139	$ 28,614
Accounts receivable	—	61
Inventory	—	5,824
Prepaid expenses and other current assets	1,008	2,131
Total current assets	62,147	36,630
Property and equipment, net	1,961	2,462
Intangible assets, net	2,551	3,216
Goodwill	2,791	2,791
Right-of-use assets	8,062	8,785
Other assets	365	365
Total assets	$ 77,877	$ 54,249
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,573	$ 2,904
Accrued expenses	2,595	4,389
Deferred revenue	—	16
Lease liability, current	896	774
Note payable, current	—	436
Related party note payable, current	917	—
Total current liabilities	5,981	8,519
Lease liability, less current portion	9,144	10,040
Related party note payable, less current	65,000	—
Total liabilities	80,125	18,559
Commitments and contingencies (Note 13)		
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 – 37,235 shares and 29,716 shares at December 31, 2022 and 2021, respectively	37	29
Additional paid-in capital	292,420	271,861
Accumulated other comprehensive income (loss)	—	—
Accumulated deficit	(294,705)	(236,200)
Total stockholders' (deficit) equity	(2,248)	35,690
Total liabilities and stockholders' equity	$ 77,877	$ 54,249

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,		
	2022	**2021**	**2020**
Revenues:			
Product revenues	$ 700	$ 1,418	$ —
Total revenues	700	1,418	—
Cost and expenses:			
Cost of revenues	11,944	1,968	—
Research and development	20,839	28,640	26,444
Sales and marketing	12,019	14,751	7,256
General and administrative	13,955	19,073	16,265
Total cost and expenses	58,757	64,432	49,965
Loss from operations	(58,057)	(63,014)	(49,965)
Other income (expense):			
Interest income (expense), net	(448)	(646)	114
Total other income (expense)	(448)	(646)	114
Loss from operations, before income taxes	(58,505)	(63,660)	(49,851)
Income tax benefit	—	—	—
Net loss	(58,505)	(63,660)	(49,851)
Other comprehensive gain (loss):			
Unrealized gain (loss) on available-for-sale securities	—	1	(5)
Comprehensive loss	$ (58,505)	$ (63,659)	$ (49,856)
Net loss per share:			
Basic and diluted net loss per share	$ (1.72)	$ (2.28)	$ (2.14)
Weighted average shares used to compute net loss per common share — basic and diluted	33,935	27,964	23,248

See accompanying notes to the consolidated financial statements.

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

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders' (Deficit)
	Shares	Amount	Capital	Loss	Deficit	Equity
Balance, December 31, 2019	20,825	$ 21	$ 153,401	$ 4	$ (122,689)	$ 30,737
Issuance of common stock upon exercise of stock options	175	—	887	—	—	887
Issuance of shares under employee stock purchase plan	83	—	490	—	—	490
Issuance of shares upon exercise of warrants	187	—	1,127	—	—	1,127
Issuance of common stock and warrants in connection with rights offering at $7.01 per unit, net of issuance cost of $565	4,280	4	29,430	—	—	29,434
Stock-based compensation expense	—	—	10,075	—	—	10,075
Unrealized loss on marketable investments, net of tax	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	(49,851)	(49,851)
Balance, December 31, 2020	25,550	25	195,410	(1)	(172,540)	22,894
Issuance of common stock as part of debt extinguishment and private investment, net of issuance cost of $106	3,049	3	49,891	—	—	49,894
Issuance of shares upon exercise of warrants	585	1	3,333	—	—	3,334
Issuance of common stock as part of ATM offering, net of issuance cost of $568	288	—	7,432	—	—	7,432
Issuance of common stock upon vesting of restricted stock units, net of shares withheld for employee taxes	99	—	(232)	—	—	(232)
Issuance of shares under employee stock purchase plan	91	—	810	—	—	810
Issuance of common stock upon exercise of stock options	54	—	616	—	—	616
Stock-based compensation expense	—	—	14,601	—	—	14,601
Unrealized gain on available-for-sale securities	—	—	—	1	—	1
Net loss	—	—	—	—	(63,660)	(63,660)
Balance, December 31, 2021	29,716	29	271,861	—	(236,200)	35,690
Issuance of shares in Rights Offering, net of issuance costs of $136	7,317	7	14,857	—	—	14,864
Issuance of shares under employee stock purchase plan	188	1	485	—	—	486
Issuance of shares upon exercise of warrants	14	—	26	—	—	26
Stock-based compensation expense	—	—	5,191	—	—	5,191
Net loss	—	—	—	—	(58,505)	(58,505)
Balance, December 31, 2022	37,235	$ 37	$ 292,420	$ —	$ (294,705)	$ (2,248)

See accompanying notes to the consolidated financial statements.

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

	Year Ended December 31,		
	2022	**2021**	**2020**
Cash flows from operating activities:			
Net loss	$ (58,505)	$ (63,660)	$ (49,851)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	690	480	430
Amortization of intangible assets	665	666	665
Stock-based compensation	5,191	14,601	10,075
Write-off of excessive and obsolete inventory	8,477	—	—
Net premium amortization and discount on available-for-sale securities	—	13	5
Loss on disposal of fixed assets	185	—	119
Gain on U.S. Treasury securities	—	—	(8)
Changes in operating assets and liabilities:			
Accounts receivable	61	(61)	—
Inventory	(2,653)	(5,824)	—
Prepaid expenses and other current assets	1,164	(1,374)	194
Other receivables	(41)	54	—
Right-of-use assets	723	653	509
Other long-term assets	—	—	129
Accounts payable	(1,304)	1,160	(266)
Accrued expenses	(1,794)	(937)	2,830
Deferred revenue	(16)	16	—
Lease liabilities	(774)	(542)	(196)
Accrued interest on related party note payable	917	—	—
Accrued interest on note payable	1	658	—
Net cash used in operating activities	(47,013)	(54,097)	(35,365)
Cash flows from investing activities:			
Purchases of property and equipment	(401)	(437)	(441)
Purchases of investments	—	—	(29,025)
Maturities of investments	—	8,000	35,000
Sales of investments	—	—	4,510
Net cash provided by (used in) investing activities	(401)	7,563	10,044
Cash flows from financing activities:			
Proceeds from issuance of common stock under employee stock purchase plan	486	810	490
Proceeds from exercises of warrants	26	4,217	244
Proceeds from exercises of stock options	—	786	717
Proceeds from issuance of common stock	14,864	56,697	29,434
Proceeds from issuance of related party note	65,000	—	—
Proceeds from insurance loan agreement	—	1,939	—
Payments made on insurance loan agreement	(437)	(1,532)	—
Tax payments related to shares withheld for vested restricted stock units	—	(232)	—
Net cash provided by financing activities	79,939	62,685	30,885
Net increase in cash and cash equivalents	32,525	16,151	5,564
Cash and cash equivalents at beginning of period	28,614	12,463	6,899
Cash and cash equivalents at end of period	$ 61,139	$ 28,614	$ 12,463
Supplemental disclosure of noncash investing and financing activities:			
Other receivable from exercise of warrants and stock options	$ —	$ —	$ 1,053
Change in unrealized gains on available-for-sale securities	$ —	$ 1	$ (5)
Equipment purchases included in accounts payable and accrued expenses	$ (27)	$ 27	$ 20
Accrued interest settled via issuance of common stock from private placement equity offering	$ —	$ 629	$ —

See accompanying notes to the consolidated financial statements.

PULSE BIOSCIENCES, INC.
Notes to Consolidated Financial Statements

1. Description of the Business

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

The Company was incorporated in Nevada on May 19, 2014. On June 18, 2018, the Company reincorporated from the State of Nevada to the State of Delaware. The Company is located in Hayward, California.

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

2. Summary of Significant Accounting Policies

Basis of Presentation

Certain prior period balances have been reclassified to conform to the current period presentation in the consolidated financial statements and the accompanying notes. Sales and marketing expenses are reclassified out of general and administrative expenses, both of which are presented as separate line items. Amortization of intangible assets are reclassified to general and administrative expenses.

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.

Use of Estimates

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

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 and Cash Equivalents

The Company invests its cash primarily in money market funds. The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents.

Property and Equipment

Property and Equipment is recorded at cost and depreciated using the straight-line method over their estimated useful lives, ranging from three to five years. Leasehold improvements are amortized using the straight-line method over the shorter of the lease term or estimated useful life. Upon the sale or retirement of property and equipment, the costs and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is reflected in operating expenses. Maintenance and repairs are charged to operations as incurred.

Valuation of Inventory

Inventory is stated at lower of cost or net realizable value. The Company establishes the inventory basis by determining the cost based on standard costs approximating the purchase costs on a first-in, first-out basis. Net realizable value is the estimated selling price in the ordinary course of the Company's business, less reasonably predictable costs of completion, disposal, and transportation. The cost basis of the Company's inventory will be reduced for any products that are considered excessive or obsolete based upon assumptions about future demand and market conditions. At December 31, 2022, the inventory balance has been fully written off due to excessive and obsolete inventory.

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.

Revenue from Contracts with Customers

The Company recognizes revenue at a point in time when it satisfies performance obligations by transferring control of promised goods to its customers. The amount of revenue recognized is equal to the consideration which the Company is entitled to in exchange for the promised goods, excluding any amounts assessed by government authorities for taxes which might be collected from a customer. Sales contracts often involve the sale and delivery of multiple products, each of which typically represent a separate performance obligation in the contract. While the Company sells these products on a stand-alone basis at their respective SSP, initial customer contracts will likely involve the bundling of products which will be delivered concurrently to the customer. In such instances, the full consideration of the contract will be recognized upon shipment of the products. The Company generally requires receipt of full payment prior to shipment, however, from time to time, payment terms may be extended to customers upon which the Company will perform a necessary credit evaluation to ensure future collectability of the outstanding balance. Refer to Note 9 for further details.

Product Warranty

The Company provides a standard warranty on eligible products which provides the customer assurances that the products comply with the agreed-upon specifications. The standard warranty does not provide any services in addition to those assurances. The Company accrues a warranty reserve for products sold based upon the best estimate of the nature, frequency, and costs of future claims. These estimates are inherently uncertain given the short history of sales, and changes to the historical or projected warranty experience may cause material changes to the warranty reserve in the future. The warranty reserve is included within Accrued expenses on the consolidated balance sheets. Warranty expense is recorded as a component of Cost of Revenues in the consolidated statements of operations and comprehensive loss.

Warranty accrual activity consisted of the following (in thousands):

	Year Ended December 31,	
	2022	2021
Beginning balance	$ 80	$ —
Add: Accruals for warranties issued during the period	42	80
Less: Adjustment for inventory at cost and excessive and obsolete inventory	(72)	—
Ending balance	$ 50	$ 80

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 Units ("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. The Company accounts for all equity instruments awarded to non-employees at the fair value of the award issued on the day of the grant. The fair value of these equity instruments are expensed over the requisite service period. Certain stock options awarded to the Company's executives and other key employees contain performance conditions related to certain financial measures and achievements of strategic/operational milestones ("performance options"). These performance options can contain both service and performance-based vesting conditions. The fair value of these performance options is recognized using the graded vesting method over the requisite service period beginning in the period in which the awards are deemed probable to vest, to the extent such awards are probable to vest.

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 its own historical volatility. 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.

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

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, 2022, 2021 and 2020, patent costs totaled $0.5 million, $0.6 million and $0.5 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 state income taxes in various states. 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, 2022 and 2021, 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,		
	2022	**2021**	**2020**
Common stock warrants	7,303,832	—	612,310
Common stock options	5,250,696	5,996,813	5,039,194
Restricted stock units	—	—	111,305
Total	12,554,528	5,996,813	5,762,809

Segment and Geographical Information

The Company operates in one segment and reports segment information in accordance with ASC 280, *Segment Reporting*. Management uses one measurement of profitability and does not segregate its business for internal reporting, however in making certain operating decisions and assessing performance, management will additionally review the disaggregated revenue results by product and geography. The Company's Chief Executive Officer acts as the chief operating decision makers ("CODM") of the Company. As of December 31, 2022 and 2021, 100% of long-lived assets were in the United States. Revenue is attributed to a geographic region based on the location of the end customer.

See Note 10 for details of revenue by product and geography.

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. The Company began to recognize revenue in 2021 using this updated standard. See Note 9 for additional details of the revenue recognition approach.

In November 2018, the FASB issued ASU No. 2018-18 *Collaborative Arrangements – Clarifying the Interaction between Topic 808 (Collaborative Arrangements) and Topic 606 (Revenue from Contracts with Customers)*, which clarifies the interaction between ASC 808, *Collaborative Arrangements* and ASC 606, *Revenue from Contracts with Customers* ("ASC 606"). The ASU clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer. In addition, the ASU precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue if the counterparty is not a customer for that transaction. The Company adopted the standard on January 1, 2020, however, did not record revenue until August 2021 and does not currently have any collaborative arrangements in place. The adoption of the new standard had no impact on the Company's consolidated 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 adopted the Topic 740 effective January 1, 2021. The adoption did not have a material impact on the Company's financial statements.

3. Fair Value of Financial Instruments

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, 2022			
Assets	**Classification**	**Level 1**	**Level 2**	**Level 3**	**Total**
Money market funds	Cash and cash equivalents	$ 57,973	$ —	$ —	$ 57,973
Total assets measured at fair value		$ 57,973	$ —	$ —	$ 57,973

		December 31, 2021			
Assets	**Classification**	**Level 1**	**Level 2**	**Level 3**	**Total**
Money market funds	Cash and cash equivalents	$ 23,675	$ —	$ —	$ 23,675
Total assets measured at fair value		$ 23,675	$ —	$ —	$ 23,675

During the years ended December 31, 2022 and 2021, the Company did not record impairment charges related to its marketable investments. During the years ended December 31, 2022 and 2021, 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, 2022 or 2021.

4. Balance Sheet Components

Inventory

Inventory consisted of the following (in thousands):

	Year Ended December 31,	
	2022	**2021**
Raw materials	$ —	$ 2,010
Work in process	—	1,371
Finished goods	—	2,443
Total inventory	$ —	$ 5,824

Property and Equipment, net

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

	December 31,	
	2022	**2021**
Leasehold improvements	$ 2,519	$ 2,519
Laboratory equipment	1,118	1,019
Furniture, fixtures and equipment	966	932
Software	289	202
Construction in progress	22	186
	4,914	4,858
Less: Accumulated depreciation and amortization	(2,953)	(2,396)
	$ 1,961	$ 2,462

Depreciation expense for the years ended December 31, 2022, 2021 and 2020 was $0.7 million, $0.5 million, and $0.4 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 ("SRA") 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,	
	2022	2021
Acquired patents and licenses	$ 7,985	$ 7,985
Less: Accumulated amortization	(5,434)	(4,769)
	$ 2,551	$ 3,216

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

Years ending December 31:	
2023	$ 665
2024	665
2025	665
2026	556
	$ 2,551

Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2022	2021
Compensation expense	$ 1,377	$ 2,932
Controlled launch (Note 8)	—	534
Director and officer liability insurance (Note 12)	571	—
Clinical trial fees and costs	64	245
Professional fees	318	85
Warranty	50	80
Other	215	513
	$ 2,595	$ 4,389

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, 2022, 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, 2022 and 2021. 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.

Rights Offering

On June 9, 2022, the Company completed a rights offering (the "2022 Rights Offering") resulting in the sale of 7,317,072 units (the "Units"), at a price of $2.05 per Unit, with each Unit consisting of one share of the Company's common stock, par value $0.001 per share, and one warrant (the "2022 Rights Offering Warrants") to purchase one share of common stock. The common stock and warrants comprising the Units separated upon the closing of the 2022 Rights Offering and were issued individually. 7,317,072 shares of common stock and warrants to acquire up to an additional 7,317,072 shares of common stock were issued in the 2022 Rights Offering. The Company received aggregate gross proceeds from the 2022 Rights Offering of $15 million. If exercised, additional gross proceeds of up to $15 million may be received through the exercise of the 2022 Rights Offering Warrants. Each 2022 Rights Offering Warrant is exercisable for one share of the Company's common stock at an exercise price equal to $2.05. The 2022 Rights Offering Warrants are exercisable immediately and expire on the fifth anniversary of the closing of the 2022 Rights Offering. The 2022 Rights Offering Warrants are subject to redemption by the Company for $0.01 per underlying share of common stock, on not less than 30 days written notice, if the volume weighted average price of the Company's common stock equals or exceeds 200% of the exercise price for the warrants, subject to adjustment, per share, for 20 consecutive trading days, provided that the Company may not redeem the warrants prior to the date that is three months after the issuance date. Robert W. Duggan, the Company's largest stockholder and Executive Chairman, purchased approximately 56% of the shares offered in the 2022 Rights Offering.

Private Placement Securities Purchase Agreement

On June 30, 2021, the Company entered into a Securities Purchase Agreement with Robert W. Duggan, the Company's largest stockholder and Executive Chairman, pursuant to which the Company issued and sold to Mr. Duggan 3,048,780 shares of the Company's common stock, par value $0.001 per share, in a private placement (the "Private Placement"), at a price per share of $16.40, which was the market closing price on the date of the transaction. These shares were paid for through (i) the conversion of $41.0 million aggregate principal amount, together with all accrued and unpaid interest outstanding, owed to Mr. Duggan under the Loan Agreement by and between the Company and Mr. Duggan (Note 13), and (ii) additional cash in the amount of approximately $8.4 million. Upon the closing of this Private Placement and satisfaction of the outstanding debt, the Loan Agreement terminated, without any early termination fees or penalties being owed by the Company, and no additional amounts were owed to Mr. Duggan under the Loan Agreement. The cash proceeds of approximately $8.4 million were received by the Company in July 2021.

At-the-Market Equity Offering

On February 4, 2021, the Company entered into a sales agreement (the "Sales Agreement") with Stifel, Nicolaus & Company, Inc. ("Stifel") as sales agent, pursuant to which the Company may offer and sell, from time to time, through Stifel, up to $60.0 million in shares of common stock, by any method permitted by law deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. The Company has no obligation to make any sales of its common stock pursuant to such Sales Agreement. During the year ended December 31, 2022, the Company did not issue or sell any shares of common stock under the Sales Agreement. During the year ended December 31, 2021 the Company issued and sold 288,490 shares of common stock under the Sales Agreement. The shares were sold at a weighted average price of $27.73 per share for aggregate net proceeds of approximately $7.4 million, after deducting sales commissions and offering costs payable by the Company.

Common Stock Warrants

In connection with a private placement in November 2014 of the Company's common stock, par value $0.001 per share, the Company issued warrants as compensation to the placement agent to purchase a total of 299,625 shares of its common stock at an exercise price of $2.67 per share (the "Private Placement Warrants"). The Private Placement Warrants were exercisable for a period of seven years from issuance. In March 2021, warrants to purchase 45,638 shares of common stock were net exercised, resulting in the issuance of 40,563 shares of common stock. In November 2021, the last remaining 600 Private Placement Warrants expired unexercised, resulting in no further Private Placement Warrants outstanding.

In connection with the closing of the Company's initial public offering in May 2016, the Company issued warrants as compensation to its underwriters, to purchase a total of 574,985 shares of its common stock at an exercise price of $5.00 per share (the "IPO Warrants"). The IPO Warrants were exercisable for a period of five years from issuance. In March 2021, warrants to purchase 85,385 shares of common stock were net exercised, resulting in the issuance of 68,958 shares of common stock. All IPO Warrants were exercised prior to their expiration in May 2021, resulting in no further IPO Warrants outstanding.

In connection with a June 2020 rights offering, the Company issued warrants (the "2020 Rights Offering Warrants") to purchase a total of 641,571 shares of its common stock at an exercise price of $7.01. These 2020 Rights Offering Warrants were exercisable immediately and expired on the fifth anniversary of the completion of the Rights Offering, or June 16, 2025, subject to certain redemption rights by the Company. The 2020 Rights Offering Warrants were subject to redemption by the Company, on or after December 16, 2020, six months after the issuance date, for $0.01 per warrant, with not less than 30 days written notice, if the volume weighted average price of our common stock equaled or exceeded 200% of the exercise price for the 2020 Rights Offering Warrants for 10 consecutive trading days. On December 31, 2020, the Company met the requirements for redemption of these warrants and delivered a notice of redemption to redeem all of the outstanding warrants that remained unexercised at February 5, 2021, for the redemption price of $0.01 per warrant. Pursuant to the redemption, the Company redeemed 5,139 warrants. Prior to the February 5, 2021 redemption date, 636,432 warrants were exercised, generating approximately $4.5 million of total gross proceeds to the Company. As of December 31, 2022, there were no 2020 Rights Offering Warrants outstanding.

In connection with the 2022 Rights Offering, the Company issued 2022 Rights Offering Warrants to purchase a total of 7,317,072 shares of its common stock at an exercise price of $2.05. The 2022 Rights Offering Warrants are exercisable immediately and expire on the fifth anniversary of the closing of the 2022 Rights Offering. The 2022 Rights Offering Warrants are subject to redemption by the Company for $0.01 per underlying share of common stock, on not less than 30 days written notice, if the volume weighted average price of the Company's common stock equals or exceeds 200% of the exercise price for the warrants, subject to adjustment, per share, for 20 consecutive trading days, provided that the Company may not redeem the warrants prior to the date that is three months after the issuance date. In the year ended December 31, 2022, a total of 13,240 warrants were exercised. As of December 31, 2022, there were 7,303,832 2022 Rights Offering Warrants outstanding.

A summary of total warrants activity for the year ended December 31, 2022 is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Warrants outstanding at December 31, 2021	—	$ —	—
Issued	7,317,072	2.05	
Exercised	(13,240)	2.05	
Expired/Redeemed	—	—	
Warrants outstanding and exercisable at December 31, 2022	7,303,832	$ 2.05	4.43

Equity Plans

2017 Equity Incentive Plan and 2017 Inducement Equity Incentive Plan

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

The 2017 Plan has a 10-year term, and provides for the grant of stock options, stock appreciation rights, restricted stock, RSUs, performance units, and performance shares to employees, directors and consultants of the Company and any parent or subsidiary of the Company, as the Compensation Committee of the Board may determine. Subject to an annual evergreen increase and adjustment in the case of certain capitalization events, the Company initially reserved 1,500,000 shares of the Company's common stock for issuance pursuant to awards under the 2017 Plan. In addition, shares remaining available under the Company's 2015 Equity Incentive Plan, as amended (the "2015 Plan"), and shares reserved but not issued pursuant to outstanding equity awards that expire or terminate without being exercised or that are forfeited or repurchased by the Company will be added to the shares of common stock available for issuance under the 2017 Plan. The 2017 Plan is administered by the Board's Compensation Committee. Effective January 1, 2022 and 2021, the number of shares of common stock available under the 2017 Plan increased by 1,188,657 and 1,022,002 shares, respectively, pursuant to the evergreen provision of the 2017 Plan. Under the evergreen provision of the 2017 Plan, the share increase is determined based on the least of (i) 1,200,000 shares, (ii) 4% of the Company's common stock outstanding at December 31 of the immediately preceding year, or (iii) such number of shares as determined by the Board. As of December 31, 2022, 2,368,716 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% per year starting upon the first anniversary of the grant. 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. In May 2021, the Board approved an amendment to the Inducement Plan to reserve an additional 1,000,000 shares of the Company's common stock for issuance pursuant to the Inducement Plan. As of December 31, 2022, 1,053,767 shares of common stock were available for issuance under the Inducement Plan.

A summary of stock option activity under the 2015 Plan, 2017 Plan and Inducement Plan for the year ended December 31, 2022 is presented below:

	Stock Options Outstanding		
	Number of shares	Weighted average exercise price	Weighted average remaining life (in years)
Balances — December 31, 2021	5,996,813	$ 15.77	7.33
Options granted	1,440,100	2.97	
Options exercised	—	—	
Options canceled	(1,472,385)	14.88	
Options expired	(713,832)	14.62	
Balances — December 31, 2022	5,250,696	$ 12.67	6.24
Exercisable — December 31, 2022	3,479,531	$ 15.17	5.06

Time-based Options

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

A summary of the time-based stock option activity under the 2015 Plan, 2017 Plan and Inducement Plan for the year ended December 31, 2022 is presented below:

	Stock Options Outstanding		
	Number of shares	Weighted average exercise price	Weighted average remaining life (in years)
Balances — December 31, 2021	4,796,716	$ 16.44	7.05
Options granted	1,240,100	2.59	
Options exercised	—	—	
Options canceled	(674,465)	16.73	
Options expired	(631,957)	15.05	
Balances — December 31, 2022	4,730,394	$ 12.95	6.16
Exercisable — December 31, 2022	3,230,670	$ 15.39	5.07

The intrinsic value of time-based options exercised during the years ended December 31, 2022, 2021 and 2020 was zero, $0.8 million, and $1.6 million, respectively.

The fair value of the time-based options granted to employees and directors during the years ended December 31, 2022, 2021 and 2020 was $2.3 million, $15.1 million, and $6.7 million, respectively.

Performance Options

Certain stock options awarded to the Company's executives and other employees contain performance conditions related to certain financial measures and achievements of strategic/operational milestones. The options will vest and become exercisable once the specific performance condition is fulfilled.

A summary of the performance option activity under the 2017 Plan and Inducement Plan for the year ended December 31, 2022 is presented below:

	Stock Options Outstanding		
	Number of shares	Weighted average exercise price	Weighted average remaining life (in years)
Balances — December 31, 2021	1,200,097	$ 13.11	8.44
Options granted	200,000	5.32	
Options exercised	—	—	
Options canceled	(797,920)	13.32	
Options expired	(81,875)	11.28	
Balances — December 31, 2022	520,302	$ 10.08	7.02
Exercisable — December 31, 2022	248,861	$ 12.25	4.92

The fair value of the performance options granted to employees during the years ended December 31, 2022, 2021 and 2020 was $0.8 million, $2.5 million, and $5.5 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,		
	2022	2021	2020
Expected term in years	5.3 - 6.8	5.3 - 6.1	5.3 - 6.1
Expected volatility	83 - 88%	78%	70%
Risk-free interest rate	1.9 - 3.2%	0.9 - 1.4%	0.3 - 0.5%
Dividend yield	—	—	—

2017 Employee Stock Purchase Plan

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

The 2017 ESPP is a broad-based plan that provides employees of the Company and its designated affiliates with the opportunity to become stockholders through periodic payroll deductions that are applied towards the purchase of Company common shares at a discount from the then-current market price. Subject to adjustment in the case of certain capitalization events, a total of 250,000 common shares of the Company were available for purchase at adoption of the 2017 ESPP. Pursuant to the 2017 ESPP, the annual share increase pursuant to the evergreen provision is determined based on the least of (i) 450,000 shares, (ii) 1.5% of the Company's common stock outstanding at December 31 of the immediately preceding year, or (iii) such number of shares as determined by the Board. In 2020 the Board determined not to increase the number of shares of common stock available pursuant to the evergreen provision. Effective January 1, 2021, pursuant to the evergreen provision of the 2017 ESPP, the number of shares of common stock available under the 2017 ESPP was increased by 383,250 shares. During the years ended December 31, 2022 and 2021, the Company issued 188,097 and 91,378 shares of common stock under the 2017 ESPP, respectively. As of December 31, 2022, 460,999 shares of common stock remained available for issuance under the 2017 ESPP.

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

	Year Ended December 31,		
	2022	2021	2020
Expected term in years	0.5 - 1.0	0.5 - 1.0	0.5 - 1.0
Expected volatility	83%	78%	70 %
Risk-free interest rate	0.6% - 3.5%	0.06% - 0.1%	0.1% - 1.0%
Dividend yield	—	—	—

Restricted Stock Units

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 the year ended December 31, 2017, the Company granted 160,974 RSUs to the Chief Executive Officer, all of which vested in June 2018. These shares were partially released in 2019, resulting in a net issuance of shares. Additional paid in capital was reduced for tax payments related to shares withheld in connection with the release. The remaining shares under this grant were released in 2021, and at December 31, 2022 no shares were outstanding under this grant. There was no stock-based compensation expense related to these RSUs recorded in the years ended December 31, 2022, 2021 and 2020. As of December 31, 2022, 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 while the remaining 50% vested on June 1, 2021. The stock-based compensation expense recorded in the years ended December 31, 2022, 2021 and 2020 related to these RSUs was approximately zero million, $0.1 million, and $0.3 million, respectively. As of December 31, 2022, there was no unrecognized compensation expense related to these RSUs.

Stock-based Compensation

Total stock-based compensation expense recorded in the consolidated statements of operations and comprehensive loss was as follows (in thousands):

	Year Ended December 31,		
	2022	**2021**	**2020**
Cost of revenues	$ 217	$ 129	$ —
Research and development	1,563	5,211	4,013
Sales and marketing	733	2,749	1,187
General and administrative	2,678	6,512	4,875
Total stock-based compensation expense	$ 5,191	$ 14,601	$ 10,075

As of December 31, 2022, not all of the performance conditions of the performance options are probable to be achieved. Compensation expense has only been recognized for those conditions that are assumed to be probable.

In February 2021, the Compensation Committee approved of a modification to certain vesting conditions of outstanding Performance Options. The Company had not recognized any compensation expense in relation to these Performance Options as the performance condition was previously deemed to be improbable. However, upon modification those specific performance conditions were deemed probable and fully vested. As such, during the year ended December 31, 2021 the full expense in relation to the amended performance conditions was recognized resulting in $4.1 million of additional stock-compensation expense.

In October 2021, the Board amended the outstanding option awards of Kenneth A. Clark upon his resignation from the Board. The requirement that Mr. Clark exercise his vested options within ninety days of his resignation was waived. Mr. Clark will have the ability to exercise his outstanding vested option awards at any time during their ten-year term from the date of each grant, subject to earlier termination as may occur under the 2017 Plan. This amendment resulted in $1.4 million of additional stock-compensation expense during the year ended December 31, 2021.

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

	Year Ended December 31,		
	2022	**2021**	**2020**
Time-based options	$ 4,467	$ 9,235	$ 8,739
Performance options	233	4,840	133
RSU	—	—	86
ESPP	491	526	1,117
Total stock-based compensation expense	$ 5,191	$ 14,601	$ 10,075

At December 31, 2022, there was $5.6 million of unrecognized compensation cost related to unvested stock-based compensation arrangements, which is expected to be recognized over a weighted average period of 2.25 years.

7. Research Grants and Agreements

Sponsored Research Agreement

The Company entered into a 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. In August 2018, we agreed to sponsor a task order for research in the amount of $0.8 million and in September 2019, we agreed to sponsor an additional task order for research in the amount of $0.8 million each to be performed during their respective subsequent 12-month periods. In March 2021, we agreed to sponsor a task order for research in the amount of $0.3 million and in May 2021 we sponsored an additional task order for $0.3 million each to be performed during their respective subsequent 12-month periods. These sponsored researches are 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 within 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, 2022, 2021 and 2020, we incurred costs relating to the SRA equal to $0.2 million, $0.3 million and $0.6 million, respectively. As of December 31, 2022, there are no unbilled SRAs left under the task orders.

8. Controlled Launch

In February 2021, the Company received 510(k) clearance from the FDA for its proprietary CellFX System for dermatologic procedures requiring ablation and resurfacing of the skin. In January 2021, the Company received CE marking approval for the CellFX System, which allows for marketing of the system in the EU for treatment of general dermatologic conditions, including SH, SK, and cutaneous non-genital warts. Additionally, in June 2021 the Company received Health Canada approval for the CellFX System, which allows for marketing of the system in Canada for use in dermatological procedures requiring ablation and resurfacing of the skin for the reduction, removal, and/or clearance of cellular-based benign lesions. In February 2021, the Company commenced a controlled launch of the CellFX System in the United States and European Union via its CellFX Expectations Excelled Program (the "Controlled Launch"). Subsequent to receiving Health Canada approval in June 2021, the Company also commenced its Controlled Launch in Canada.

As part of the Controlled Launch, the Company selected 70 physicians and their practices to be the first physician consultants to launch the CellFX System and the associated CellFX commercial procedures into their respective markets and geographies. In the Controlled Launch program, the Company provided and set up a CellFX System at each physician site and provided the physician with the necessary related products and components, free of charge, to complete the requirements of the Controlled Launch program. Each CellFX System and any unused component products remained the property of the Company throughout the Controlled Launch program. Under the Controlled Launch program, each physician was to identify and recruit up to 40 or 50 patients, depending on the contract, for participation in the Controlled Launch, performing a CellFX procedure on each of the appropriately selected patients. The physician and their patients complete evaluation surveys about their experiences with the CellFX System and provided other information helpful to the Company. Upon completion of the procedures and the survey feedback, the physician earned credits to be used towards the future purchase of the CellFX System or, in some jurisdictions, fair payment for their time and effort completing the paperwork required under the Controlled Launch program. Credits earned and, if applicable, any other payments earned were limited to a maximum amount dependent on the number of surveys received by the Company. Upon completion of the Controlled Launch program requirements, each physician could choose to enter into a purchase agreement with the Company, under which the physician could use the credits earned (or other payments earned, as applicable) towards the purchase of the already-delivered CellFX System, or the physician could return the CellFX System to the Company.

As patient procedures and surveys were completed under the Controlled Launch program, the Company accrued the value of the credits earned, which were recorded in accrued expenses, with a corresponding charge to sales and marketing expense. During the years ended December 31, 2022 and 2021 the Company recorded $0.1 million and $1.8 million, respectively, of net sales and marketing expense in relation to the Controlled Launch.

During the year ended December 31, 2022, certain consultants completed the Controlled Launch and entered into purchase agreements with the Company, whereby they used their credits or other earned payments towards the purchase of a CellFX System. Accordingly, approximately $0.4 million of the accrued liability related to the Controlled Launch was relieved and recognized as revenue on a non-cash basis as a result of the purchase. See Note 9 for additional detail of revenue transactions.

In September 2022, the Company concluded the Controlled Launch program and notified all remaining program participants. In accordance with the Controlled Launch program, physicians having completed the program requirements could elect to purchase their already delivered CellFX System, applying credits earned, or return the CellFX System to the Company. The Company concluded these efforts in the fourth quarter of 2022 and has discontinued sales of the CellFX System, although the Company continues to offer its disposable treatment tips to dermatologists who have chosen to retain their existing CellFX consoles.

9. Revenue

The Company recognizes revenue at a point in time when it satisfies performance obligations by transferring control of promised goods to its customers. The amount of revenue recognized is equal to the consideration which the Company is entitled to in exchange for the promised goods, excluding any amounts assessed by government authorities for taxes which might be collected from a customer. This consideration may include non-cash services performed, as is the case with revenue recognized in connection with the Controlled Launch program. On September 20, 2022, the Company announced its shift in focus to advance its core NPS technology outside of dermatology and concluded its Controlled Launch program. Total revenue recognized for the years ended December 31, 2022 and 2021 was $0.7 million and $1.4 million, respectively, of which approximately $0.4 million and $1.1 million, respectively, was driven by the redemption of non-cash credits earned as part of the Controlled Launch, with the balances driven by cash purchases of cycle units ("CUs") and CellFX commercial consoles sold.

Sales contracts often involve the sale and delivery of multiple performance obligations in the contract.

Performance Obligations

Systems consist of the CellFX console and its embedded software, handpieces, and disposable tips. The console is a physical piece of hardware used by the customer to perform patient procedures. Individually the console and software are not distinct, therefore the Company combines the console and embedded software to form one distinct system performance obligation. Payment for systems is generally due prior to shipment, and the system performance obligation is satisfied upon shipment of the system to the customer.

Handpieces are attached to the console and used in conjunction with tips to perform patient procedures. Generally, upon initial sale of a system to a customer, the Company will include two handpieces. The handpiece has a shorter expected useful life than the console, and a customer can purchase additional handpieces when needed, as they are available for sale on a stand-alone basis. Payment for handpieces is generally due prior to shipment, and handpieces represent a distinct performance obligation which is satisfied either upon shipment, or upon delivery of the handpiece to the customer, depending on the specific contract.

Disposable treatment tips are single-patient multiple-use products that come in different sizes, each of which are to be used for specific procedures. Tips are attached to the handpiece for use in patient procedures and, upon detachment from the handpiece, a tip cannot be reused, and it must be disposed of. Tips represent a distinct performance obligation which is satisfied either upon shipment, or upon delivery of the tips to the customer, depending on the specific contract.

CUs are credits that authorize the customer to perform a procedure, or cycle. Each procedure requires a specific number of CUs, dependent upon type of tip used and procedure level selected. As the procedure is performed, the applicable number of CUs are decremented. When the customer's balance of CUs on a specific system is depleted, the system will no longer function until the customer purchases additional CUs. Customers can purchase additional CUs via the Company's CellFX Marketplace which is an online marketplace accessible directly from the CellFX System. Payment for CUs is due upon order placement and the CUs are immediately available for download to the console via CellFX CloudConnect. CUs represent a distinct performance obligation which is satisfied when CUs are made available for customers to download from the Company's CellFX CloudConnect, as customers can use purchased CUs at any time at their discretion, and the Company does not provide any ongoing service or other forms of involvement after the sale occurs.

Shipping and handling activities are not considered to be a separate performance obligation. The Company's standard commercial agreements generally include FOB shipping point terms. The Company has made an accounting policy election to account for shipping and handling costs as fulfillment costs because the shipping and handling activities occur after the customer obtains control of the product.

Transaction Price

The transaction price is the consideration to which the Company expects to be entitled to in exchange for providing the promised goods to customers. Customer orders placed for cash contemplate a fixed amount of consideration. Customer orders placed by physicians participating in the Controlled Launch when they elected to purchase the CellFX System were paid for via conversion of accumulated earned credits for prior services provided by the physicians under the terms of their participation in the Controlled Launch. For these transactions, the transaction price included noncash consideration. The services rendered by the physicians in the Controlled Launch were accounted for separately from the subsequent sales of the CellFX Systems because they were distinct from the system sales. They were distinct because they provided the Company with treatment data that could also be procured, and historically had been procured by the Company, without the corresponding system sales. This data was used by the Company to enhance marketing and promotion of its products.

The Company evaluates the possible impact of variable consideration in determining the transaction price, in particular the possibility of future returns or credits. Sales agreements allow for a right of return only if the product does not conform to the agreed upon quality standards or if the product was shipped due to Company error. The Company anticipates such returns will be minimal and has made no adjustments to the transaction price for any estimated returns. The transaction price is determined at the time of the initial revenue recognition and updated each quarter for any changes in circumstances (*e.g.*, changes in estimated return or credit rates).

The Company has made an accounting policy election to exclude from the measurement of the transaction price all taxes which are imposed on and concurrent with a specific revenue-producing transaction and collected by the entity from a customer.

When there are multiple performance obligations present, the total transaction price shall be allocated to each of the performance obligations based upon the relative SSPs of those performance obligations. The Company establishes SSPs based on multiple factors including, prices charged by the Company for similar offerings, product-specific business objectives, and the estimated cost to provide the performance obligation. However, upon the sale of a new CellFX System, all performance obligations are delivered concurrently and therefore there is no impact to revenue recognition timing, and the Company has determined allocations are not necessary. Should the customer purchase additional CUs, handpieces, or tips at a later time, those purchases will be made under separate purchase agreements, with all promised goods generally transferred at the same time, therefore no price allocation is necessary in that scenario either.

Controlled Launch Agreements

In August 2021 the Company began to recognize revenue in relation to the conversion of Controlled Launch Program participants into sales agreements (Note 8). These customers were already in possession of the system, handpiece, and tips. As such, upon execution of these purchase agreements, the Company recognized revenue on the agreements because control of all performance obligations were transferred at that time. These customers separately purchased CUs in order to operate the CellFX System and the revenue for these CUs was recognized upon delivery of the CUs to CellFX CloudConnect.

10. Segment Reporting

The Company operates and manages the business as one reportable and operating segment. The Company's Chief Executive Officer acts as the chief operating decision maker ("CODM") of the Company. The CODM reviews the results of the Company on a consolidated basis, however in making certain operating decisions and assessing performance, the CODM will additionally review the disaggregated revenue results by product and geography. All of the Company's long-lived assets are based in the United States.

Revenue by product consisted of the following (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Systems	$ 560	$ 1,189	$ —
Cycle units	140	229	—
Total consolidated revenue	$ 700	$ 1,418	$ —

Revenue by geography consisted of the following (in thousands):

	Year Ended December 31,		
	2022	2021	2020
North America	$ 517	$ 1,182	$ —
Rest of World	183	236	—
Total consolidated revenue	$ 700	$ 1,418	$ —

11. Income Taxes

Income (loss) before income taxes (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Domestic	$ (58,505)	$ (63,660)	$ (49,851)
Foreign	—	—	—
	$ (58,505)	$ (63,660)	$ (49,851)

The components of the provision for income taxes are as follows (in thousands):

	December 31,		
	2022	2021	2020
Current			
Federal	$ —	$ —	$ —
State	3	3	3
Foreign	—	—	—
Total current	3	3	3
Deferred			
Federal	—	—	—
State	—	—	—
Foreign	—	—	—
Total deferred	—	—	—
Total provision for income taxes	$ 3	$ 3	$ 3

State income taxes are immaterial in amount and therefore have not been recorded in the Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2022, 2021 and 2020.

The provision for income taxes differs from the amount estimated by applying the statutory federal income tax rate to income (loss) before taxes as follows:

	Year Ended December 31,		
	2022	2021	2020
Federal tax at statutory rate	21.0%	21.0%	21.0%
State tax at statutory rate	8.4	8.4	8.4
Research and development credits	0.9	1.9	2.1
Change in valuation allowance	(18.4)	(26.8)	(43.3)
Deferred adjustment	(5.3)	—	8.5
Change in tax rate	—	—	4.2
Uncertain Tax Position	(5.7)	(2.3)	—
Other	(0.9)	(2.2)	(0.8)
Provision for income taxes	—%	—%	—%

Deferred income taxes reflect the impact of carryforwards and temporary differences between the amounts of assets and liabilities for financial reporting purposes and such amounts as measured by tax laws. The carryforwards and temporary differences, which give rise to a significant portion of the Company's deferred tax asset (liability) as of December 31, 2022 and 2021, are as follows (in thousands):

	December 31,	
	2022	2021
Deferred tax assets		
Accruals	$ 3,404	$ 1,034
Net operating loss carryforwards	56,447	49,246
Tax credit carryforwards	7,111	6,611
Stock-based compensation	8,784	12,188
R&D Capitalization	3,810	—
Lease liability under ASC 842	2,948	3,182
Gross deferred tax assets	82,504	72,261
Valuation allowance	(79,779)	(69,006)
Total deferred tax assets	2,725	3,255
Deferred tax liabilities		
Intangibles	(117)	(365)
ROU asset under ASC 842	(2,593)	(2,862)
Fixed assets	(15)	(28)
Total deferred tax liabilities	(2,725)	(3,255)
Net deferred tax assets/(liabilities)	$ —	$ —

The Company's unrecognized tax benefits as of December 31, 2022, 2021 and 2020 were $8.9 million, $5.1 million, and $2.5 million, respectively. If recognized, none of the unrecognized tax benefits would impact income tax expense to the extent that the Company continues to maintain a full valuation allowance against its deferred tax assets.

A reconciliation of the beginning and ending amounts of unrecognized tax benefit is as follows (in thousands):

	December 31,		
	2022	2021	2020
Unrecognized tax benefits at beginning of year	$ 5,140	$ 2,491	$ 1,470
Increases related to current year tax positions	2,055	2,649	1,021
Increases related to prior year tax positions	1,730	—	—
Unrecognized tax benefits at end of year	$ 8,925	$ 5,140	$ 2,491

The Company's policy is to recognize interest and penalties related to income taxes as components of interest expense and other expense, respectively. The Company did not accrue interest and penalties related to unrecognized tax benefits as of December 31, 2022 and does not anticipate any significant change within twelve months of this reporting date.

The Company's valuation allowance increased by $10.8 million in the year ended December 31, 2022 and increased by $17.0 million in the year ended December 31, 2021.

As of December 31, 2022, the Company had federal and state net operating loss ("NOL") carryforwards of $199.9 million and $204.6 million, respectively, which begin to expire in 2034. Of the total federal NOL carryforward of $199.9 million, approximately $174.3 million is carried forward indefinitely but is limited to 80% of the taxable income.

As of December 31, 2022, the Company had approximately $5.8 million and $5.5 million of U.S. federal and California research and development ("R&D") credits, respectively. The federal R&D credits begin to expire in 2035 and the California R&D credits have an indefinite carryforward period.

The Company is subject to taxation in the United States for Federal and for State, within various states in which the Company operates. All jurisdictions and tax years currently remain open for IRS and state taxing authorities' examination. As of December 31, 2022, the Company was not under examination by the Internal Revenue Service or any state tax jurisdiction.

Internal Revenue Code Section 382 ownership change generally occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. The Company is not aware of any ownership changes in this financial period ending on December 31, 2022.

12. Related Party Transactions

On March 11, 2021, the Company and Robert W. Duggan, majority stockholder and Executive Chairman, entered into the 2021 Loan Agreement in connection with Mr. Duggan lending the principal sum of $41.0 million to the Company (Note 13).

On June 30, 2021, the Company and Mr. Duggan entered into a Securities Purchase Agreement (Note 6), pursuant to which the Company issued and sold to Mr. Duggan 3,048,780 shares of the Company's common stock, par value $0.001 per share, in a Private Placement, at a price per share of $16.40, for an aggregate investment in the amount of $50.0 million. The shares were paid for through (i) the conversion of the $41 million aggregate principal amount under the Loan Agreement, together with all accrued and unpaid interest outstanding, owed to Mr. Duggan under the Loan Agreement by and between the Company and Mr. Duggan (Note 13), and (ii) additional cash in the amount of approximately $8.4 million. Upon the closing of this Private Placement and satisfaction of the outstanding debt, the Loan Agreement terminated, without any early termination fees or penalties being owed by the Company, and no additional amounts were owed to Mr. Duggan under the Loan Agreement.

In May 2022, the Company determined not to renew its annual director and officer liability insurance policy due to disproportionately high premiums quoted by insurance companies. Instead, on May 31, 2022, the Company and Robert W. Duggan, the Executive Chairman, entered into a letter agreement (the "Letter Agreement") pursuant to which Mr. Duggan has agreed with the Company to personally provide indemnity coverage for a one-year period, and he has agreed to deposit cash and/or marketable securities into a third-party escrow, as security for these obligations, if requested by the Company. The Company will pay a fee of $1.0 million to Mr. Duggan that shall be due on May 31, 2023, the last day of the one-year period, in consideration of the obligations set forth in the Letter Agreement. As of December 31, 2022, the amount owed to Mr. Duggan under the Letter Agreement was $0.6 million, recorded on the balance sheet under accrued expenses.

On September 20, 2022, the Company and Robert W. Duggan, majority stockholder and Executive Chairman, entered into the 2022 Loan Agreement in connection with Mr. Duggan lending the principal sum of $65.0 million to the Company (Note 13).

13. Commitments and Contingencies

2021 Loan Agreement

On March 11, 2021, the Company and Robert W. Duggan, the Executive Chairman, entered into a Loan Agreement in connection with Mr. Duggan lending the principal sum of $41.0 million to the Company. The Loan Agreement bore interest at a rate per annum equal to 5.0%, payable quarterly commencing on July 1, 2021. During the year ended December 31, 2021, the Company recorded $0.6 million of interest expense in relation to this Loan Agreement. In June 2021, the Loan Agreement was terminated and $41.0 million principal, together with approximately $0.6 million of accrued and unpaid interest, was fully settled via issuance of the Company's common stock at a price per share of $16.40. Refer to Note 6 for additional details of the private placement sale.

2022 Loan Agreement

On September 20, 2022, the Company and Robert W. Duggan, the Executive Chairman, entered into a Loan Agreement ("2022 Loan Agreement") in connection with Mr. Duggan lending the principal sum of $65.0 million to the Company. The Loan Agreement bears interest at a rate per annum equal to 5.0%, payable quarterly commencing on January 1, 2023, with the principal sum payable on March 20, 2024. On March 17, 2023, the Company and Mr. Duggan agreed to amend certain terms of the Loan Agreement. There were no changes to the interest rate, but the principal sum is now due and payable on September 30, 2024. During the year ended December 31, 2022, the Company recorded $0.9 million of interest expense in relation to the 2022 Loan Agreement.

Insurance Loan Agreement

On May 13, 2021, the Company secured its annual director and officer liability insurance policy. The total premiums for the policy were approximately $2.6 million, of which the Company made a down payment of $0.7 million and financed the balance of $1.9 million via an Insurance Loan Agreement. The Insurance Loan Agreement had an annual interest rate of 3.69% and required monthly payments through February 2022, upon which the Insurance Loan Agreement was paid in full. During the year ended December 31, 2022, the Company recorded $1.0 thousand of interest expense in relation to the Insurance Loan Agreement.

Operating Leases

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

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

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

Upon commencement of each lease component, the Company reassessed and calculated the lease liability and right-of-use asset for the respective component. As a result, at the modification date, the Company remeasured its existing lease liability and recorded an additional right-of-use asset and lease liability of $2.0 million. The Company also recorded an additional right-of-use asset and lease liability of $3.0 million and $4.8 million at the commencement of Expansion Premises 1 in November 2019 and Expansion Premises 2 in May 2020, respectively. At December 31, 2022, total right-of-use assets and lease lability was approximately $8.1 million and $10.0 million, respectively.

During the years ended December 31, 2022, 2021 and 2020, rent expense, including common area maintenance charges, was $2.1 million, $1.9 million and $1.7 million, respectively.

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

	Year Ended December 31,	
Assets:	**2022**	**2021**
Right-of-use assets	$ 8,062	$ 8,785

	Year Ended December 31,	
Liabilities:	**2022**	**2021**
Current operating lease liabilities	$ 896	$ 774
Non-current operating lease liabilities	9,144	10,040
Total lease liabilities	$ 10,040	$ 10,814

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

	Year Ended December 31,		
	2022	**2021**	**2020**
Cash paid for operating lease liabilities	$ 1,806	$ 1,643	$ 1,045

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

Year ending December 31:		
2023	$	1,845
2024		1,910
2025		1,977
2026		2,046
2027		2,117
Thereafter		4,074
Total lease payments		13,969
Less imputed interest		(3,929)
Total lease liabilities	$	10,040

Weighted-average remaining lease term and discount rate, as of December 31, 2022, were as follows:

Weighted-average remaining lease term	6.83
Weighted-average discount rate	10%

Legal Proceedings

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

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

14. Restructuring Charges

On March 31, 2022, the Company initiated a plan to reduce its operating expenses, preserve financial resources, and focus its sales and marketing efforts on increasing utilization of CellFX Systems. The Company's Board of Directors approved changes to the Company's commercial leadership, restructuring of its commercial field organization and reductions in other personnel and expenses across the Company. The Company announced a reduction in force effective as of March 31, 2022. The affected employees were offered separation benefits, including severance payments along with temporary healthcare coverage assistance. The Company incurred a discrete restructuring related charge of $0.7 million which was fully recorded in March 2022 and the related expenses are included within total cost and expenses on the consolidated statement of operations for the year ended December 31, 2022. This charge represents the total amount to be incurred in connection with the activity. During the year ended December 31, 2022, the Company paid the entire $0.7 million.

On September 20, 2022, the Company initiated an additional reduction in force to align its workforce with its shift in strategic direction to advance its core NPS technology outside of dermatology. The reduction primarily impacted dermatological sales, marketing and other related support personnel. The affected employees were offered separation benefits, including severance payments along with temporary healthcare coverage assistance. The Company incurred a discrete restructuring related charge of $0.2 million which was fully recorded in September 2022 and the related expenses are included within total cost and expenses on the consolidated statement of operations for the year ended December 31, 2022. During the year ended December 31, 2022, the Company paid the entire $0.2 million.

15. 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, 2022, 2021 and 2020.

16. Supplementary Financial Information

There are no retrospective changes to the statements of comprehensive income for any of the quarters within the two most recent fiscal years that individually or in the aggregate are material.

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, our principal executive and principal financial officer conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934, as amended, as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our Chief Executive Officer has 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 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 Corporate Controller, 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, 2022.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal controls over financial reporting during the year ended December 31, 2022, 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.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not Applicable.

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 2023 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 2023 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 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 2023 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 2023 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 2023 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	S-3/A	333-237577	4.3	May 1, 2020
4.3	Form of Warrant Agent Agreement	S-3/A	333-237577	4.4	May 1, 2020
10.1	Lease for facilities at 3955 Point Eden Way, Hayward, California, dated January 26, 2017	10-K	001-37744	10.1	March 20, 2017
10.2#	License Agreement among Old Dominion University Research Foundation, Eastern Virginia Medical School and the Registrant	S-1/A	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/A	333-208694	10.13	March 7, 2016
10.4+	Employment Agreement between Mitchell E. Levinson and the Registrant	10-K	001-37744	10.4	March 31, 2022
10.5+	Employment Agreement between Kevin Danahy and the Registrant	10-K	001-37744	10.5	March 31, 2022
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	10-K	001-37744	10.10	March 12, 2021
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	At-the-Market Equity Offering Sales Agreement	8-K	001-37744	1.1	February 4, 2021
10.19	Securities Purchase Agreement, dated June 30, 2021, by and between Pulse Biosciences, Inc. and Robert W. Duggan	8-K	001-37744	10.1	July 1, 2021
10.20	Indemnification Letter, dated May 27, 2022, by and between Pulse Biosciences, Inc. and Robert W. Duggan	10-Q	001-37744	10.1	August 10, 2022
10.21	Loan Agreement, dated as of September 20, 2022, by and between Pulse Biosciences, Inc. and Robert W. Duggan	8-K	001-37744	10.1	September 23, 2022
10.22+	Amendment to Employment Agreement, between Darrin Uecker and Pulse Biosciences, Inc., dated September 20, 2022	8-K	001-37744	10.2	September 23, 2022
10.23+	Amendment to Employment Agreement, between Kevin Danahy and Pulse Biosciences, Inc., dated September 23, 2022	8-K	001-37744	10.1	September 28, 2022

21.1*	List of Subsidiaries
23.1*	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.
32.1*	Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* 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 31, 2023

By: /s/ Kevin P. Danahy
Kevin P. Danahy
Chief Executive Officer
(Principal Executive and Principal Financial Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Kevin Danahy and Timothy Mitsuoka, 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/ Kevin P. Danahy Kevin P. Danahy	Chief Executive Officer (*Principal Executive and Principal Financial Officer)*	March 31, 2023
/s/ Robert W. Duggan Robert W. Duggan	Executive Chairman of the Board of Directors	March 31, 2023
/s/ Darrin R. Uecker Darrin R. Uecker	Chief Technology Officer and Director	March 31, 2023
/s/ Mitchell E. Levinson Mitchell E. Levinson	Chief Strategy Officer and Director	March 31, 2023
/s/ Shelley D. Spray Shelley D. Spray	Director	March 31, 2023
/s/ Manmeet S. Soni Manmeet S. Soni	Director	March 31, 2023
/s/ Mahkam Zanganeh Mahkam Zanganeh	Director	March 31, 2023
/s/ Richard A. van den Broek Richard A. van den Broek	Director	March 31, 2023
/s/ Timothy H. Mitsuoka Timothy H. Mitsuoka	Corporate Controller *(Principal Accounting Officer)*	March 31, 2023

List of Subsidiaries

Subsidiary	Jurisdiction of Incorporation	Ownership Position
NanoBlate Corp., a Delaware Corporation	Delaware	100%
BioElectroMed Corp., a California Corporation	California	100%
Pulse Biosciences BV	Netherlands	100%
2783162 Ontario Inc.	Ontario	100%

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-259330, 333-246346, 333-237577, 333-227974, 333-224800, 333-219104, and 333-219096 on Form S-3 and Registration Statement Nos. 333-264957, 333-256992, 333-254451, 333-237225, 333-229320, 333-222582, 333-221788, 333-218164, and 333-216897 on Form S-8 of our report dated March 31, 2023, relating to the financial statements of Pulse Biosciences, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2022.

/s/ *Deloitte & Touche LLP*

San Jose, California
March 31, 2023

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, Kevin P. Danahy, 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 31, 2023

By: /s/ Kevin P. Danahy
Kevin P. Danahy
Chief Executive Officer
(Principal Executive and Principal Financial 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, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned certifies, 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, as amended; and

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

Date: March 31, 2023

/s/ Kevin P. Danahy
Kevin P. Danahy
Chief Executive Officer
(Principal Executive and Principal Financial 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, except to the extent the Company specifically incorporates these certifications by reference therein.