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DELTA REPORT

10-K

PLSE - PULSE BIOSCIENCES, INC.

10-K - DECEMBER 31, 2023 COMPARED TO 10-K - DECEMBER 31, 2022

The following comparison report has been automatically generated

TOTAL DELTAS	2882
CHANGES	196
DELETIONS	1055
ADDITIONS	1631

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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 December 31, 2023

Or

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

For the transition period from to

Commission File Number 001-34899

Pulse Biosciences, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	PLSE	The Nasdaq Stock Market LLC

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

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

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

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

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

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

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

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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 June 30, 2023, 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. $124,067,534. 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 March 20, 2024: 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. 55,225,333

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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, Nano-pulse Stimulation, nsPFA, Nano-Pulse Stimulation, CellFX nsPFA, 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 and adoption rates, sales forecasts, 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 current 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.

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SUMMARY OF RISK FACTORS

Summary

Below is a summary of the principal factors that make an investment in Pulse Biosciences, Inc. speculative or risky. The following summary does not contain all of the information that may be important to you, and you should read the below summary in conjunction with the more detailed discussion of risks set forth under the heading "Risk Factors" in Part I, Item IA of this Annual Report on Form 10-K.

Risks Related to Our Financial Position and Need for Additional Capital

- We will need to obtain additional funding to finance our operations and complete the development and any commercialization of our products. If we do not receive substantial capital when needed, we may be forced to restrict our operations or delay, reduce or eliminate our product development programs.
- We depend heavily on the success of NPS to non-thermally clear targeted cells while sparing adjacent noncellular tissue. If we are unable to successfully develop and commercialize this patented technology, or experience significant delays in doing so, we may extend the period in which we will incur significant financial losses as an organization.
- We are almost entirely a development-stage company with very limited experience commercializing products. We have incurred significant losses since our inception. We anticipate that we will continue to incur losses for at least the next several years and may never generate profits from operations or maintain profitability.
- We will need to raise additional capital, which may result in further dilution to our investors, or incur additional indebtedness. The servicing of future debt may impair our liquidity position.

Risks Related to the Development and Commercialization of our Medical Products

- We can provide no assurance that our clinical product candidates, including our product candidates for the treatment of atrial fibrillation, our CellFX nsPFA Cardiac Clamp and our CellFX nsPFA 360° Cardiac Catheter, will obtain regulatory approval or that the results of clinical studies will be favorable.
- Medical device development and commercialization is a complex, time-consuming and expensive process. Our industry is fraught with risk and a high rate of failure.
- We have very limited sales and marketing experience and no experience commercializing our CellFX nsPFA Percutaneous Electrode System. We can give no assurances that our devices will be adopted by surgeons or other physicians to treat any medical condition..
- Regulatory requirements and timelines may affect the scope and timeline of our trials and the potential market for our product candidates, including the possibility of significant delays to any product launch.
- The medical device industry is characterized by intense competition, rapid technological changes, new product introductions and enhancements, and evolving industry standards. 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 our products or enhancements, our results of operations will suffer.
- If we experience any number of possible unforeseen events in connection with our clinical trials, potential marketing approval or commercialization of our product candidates could be delayed or prevented.
- If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory bodies, such as the U.S. Food and Drug Administration or the European Medicines Agency, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our medical devices.
- Regulatory requirements and timelines may affect the scope and timeline of our trials and the potential market for our product candidates.

Risks Related to Our Industry and Market

- We face substantial competition, which may result in others developing or commercializing products before or more successfully than we do.
- We compete against well-established incumbent technologies offering products in cardiology, oncology, and dermatology, as well as in minimally invasive procedures. 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.
- We may pursue business development opportunities to expand or enhance our pipeline of potential products, including through potential acquisitions of and/or collaborations with other entities or the acquisition of products unrelated to NPS technology, which may not achieve intended results or could increase the number of our outstanding shares or amount of outstanding debt or result in a change of control.

Legal, Tax, Regulatory and Compliance Risks

- Our ability to commercialize any of our product candidates is subject to substantial regulatory and legislative uncertainty, including as to pricing, reimbursement practices or other healthcare initiatives which could harm our business.
- We may face costly legal claims, in particular related to product liability and intellectual property infringement.
- We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

Risks Related to Our Intellectual Property, Cybersecurity and Data Privacy

- We rely upon patents to protect our technology. We may be unable to protect our intellectual property rights and we may be liable for infringing the intellectual property rights of others.

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- Our actual or perceived failure to comply with stringent and changing obligations related to data privacy and security could lead to regulatory investigations and actions, litigation, fines and penalties, disruptions to our business operations, reputational harm, loss of revenue and profits, and other adverse business impacts.
- We are exposed to risks related to cybersecurity and data privacy threats and incidents and we are subject to restrictions and changes in laws and regulations governing our data privacy and data protection, any of which could have a material adverse affect on our business.

Risks Related to Corporate Governance and Employee Relations

- Our future success depends on our ability to retain our Chief Executive Officer, our Chief Technology Officer, our Chief Strategy Officer, and other key executives and to attract, retain and motivate qualified personnel.
- Our Executive Chairman owns more than a majority of the voting power of the outstanding shares of our common stock and, as a result, investors may have limited ability to affect either the corporate governance of the Company or the taking of certain major decisions.

Risks Related to Owning Our Common Stock

- Substantial future sales of our shares of common stock in the public market, or the perception that these sales could occur, could cause the price of the shares to decline significantly, even if our business is doing well.
- The prices of our shares of common stock may be volatile and fluctuate substantially, which could result in substantial losses for our stockholders.
- 69% of our outstanding shares are owned by our executive Chairman, Robert Duggan, and his affiliates, which can reduce liquidity of our stock. Historically, our trading volume on Nasdaq has been low.

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™ 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 Nanosecond Pulsed-Field Ablation™ or nsPFA™ 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, or end-effectors, 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 primary efforts on the use of nsPFA energy and the CellFX platform in the treatment of atrial fibrillation ("AF").

Our Cardiac Program

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 electrophysiology. In December 2023, we initiated a clinical study in Prague, Czech Republic, to test our CellFX nsPFA 360° Cardiac Catheter in patients with AF and early acute data and remapping data from this study have been promising. More recently, we are currently have taken steps to initiate a clinical study of our CellFX nsPFA Cardiac Clamp in the Netherlands and, in January 2024, we filed a premarket notification 510(k) with the U.S. Food and Drug Administration (the “FDA”) for clearance to commercialize our novel CellFX nsPFA Cardiac Clamp in the United States. In parallel, we have taken initial steps towards a CE mark approval in Europe for the cardiac clamp. The results of preclinical testing of both in preclinical models. cardiac products have exceeded our expectations and much of the data have been published or presented at physician or industry conferences. 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.

CellFX nsPFA Cardiac Clamp

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.

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We believe our CellFX 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 In preclinical studies, our CellFX nsPFA Cardiac Clamp has consistently achieved transmural ablations in 1.25 seconds, independent of tissue type or thickness. Moreover, 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 CellFX nsPFA ablation given its nonthermal nature. Because Also, 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 We believe these advantages will be profoundly important to cardiac surgeons, treating AF, so it is we are working with leaders in the field to develop this technology quickly. In May 2023, we appointed Dr. Gan Dunnington as our Chief Medical Officer, Cardiac Surgery. Dr. Dunnington is a cardiothoracic surgeon and the Director of Cardiothoracic Surgery at St. Helena Hospital (Napa Valley). He specializes in minimally invasive complex cardiothoracic procedures for the treatment of AF. And, in October 2023, we appointed Dr. Niv Ad as our Chief Science Officer, Cardiac Surgery. Dr. Ad specializes in the surgical treatment of atrial fibrillation, minimally invasive heart surgery and other advanced heart surgery techniques and transcatheter therapies.

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 Since 2023, to prepare for human clinical use, including continued preclinical testing. In parallel we have been meeting with the continued testing of the device, we expect to meet with the U.S. Food and Drug Administration (the "FDA") FDA to discuss the regulatory requirements for a potential FDA 510(k) clearance or other approval to market our cardiac clamp in the United States. This will be done as part of In 2023, with guidance from the FDA's standard Q-submission process, also FDA, we completed a preclinical study, known as a pre-submission meeting. We expect that our first meeting on this topic Good Laboratory Practices or "GLP" study and, in January 2024, we filed a premarket notification 510(k) with the FDA will take place in the second quarter of 2023. for our novel CellFX nsPFA Cardiac Clamp.

CellFX nsPFA 360° Cardiac Catheter

We believe our cardiac catheter ablation device will have many of the same advantages that the cardiac ablation clamp has relative appears to have with respect 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 because of its safety profile and potential to improve efficacy. PFA differs from CellFX nsPFA technology in that the pulse widths are longer, typically in the 10's to 100's of microseconds. We believe CellFX 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 because it appears CellFX nsPFA technology 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 After seeing encouraging preclinical results, in December 2023, we initiated a clinical study in Prague, Czech Republic, to test our CellFX nsPFA 360° Cardiac Catheter in patients with AF and early acute data and remapping data from this study 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. been promising. 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 our cardiac catheter in the United States.

CellFX nsPFA Percutaneous Electrode System

Since early 2023, we have made tremendous progress in our percutaneous electrode program. After years of pre-clinical development and testing, as a supplemental point of validation of the Company's engineering capabilities, and to demonstrate our technology's unique mechanism of action on internal organs, in June 2023 we initiated a first-in-human study using our novel and proprietary nsPFA-enabled surgical end-effector, our percutaneous electrode. This study is being conducted by Professor Stefano Spiezia at the Ospedale del Mare in Naples, Italy, to help us better understand and confirm the mechanism of action and tissue response of nsPFA energy in internal organs as we advance into human cardiac tissue. Initially, ten subjects were treated and evaluated in the study. All of the initial patients in the study tolerated the procedure well with no reported pain or serious side effects. Ultrasound imaging 90 days post procedure showed that the treated portions of the nodules had been completely resorbed with no sign of scarring or fibrosis, which can be a side effect of other ablation modalities. Based on these positive initial results, in November 2023, we amended the thyroid study protocol to expand enrollment to focus on optimizing treatment parameters.

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In parallel, in November 2023, we filed a premarket notification 510(k) with the FDA for clearance to commercialize our novel CellFX nsPFA Percutaneous Electrode System in the United States. In March 2024, the Company received FDA 510(k) clearance for its CellFX nsPFA Percutaneous Electrode System for use in the ablation of soft tissue in percutaneous and intraoperative surgical procedures.

Having secured regulatory approval to market and sell the CellFX nsPFA Percutaneous Electrode System in the United States, we have initiated a limited market release, targeting a handful of select accounts.

The CellFX System Console

The CellFX System Console 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 end-effectors 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. AF and as part of the CellFX nsPFA Percutaneous Electrode System.

While we are not investing R&D resources in applications outside of cardiology and the treatment of AF, we We continue to believe nsPFA ablation, and as well as NPS technology more broadly, has the potential to provide superior outcomes across additional a variety of 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 165 197 issued patents and pending patent applications, and we have an exclusive license to 72 69 additional issued patents and pending patent applications. The vast majority of our granted patents have an expiration date between 2035 and 2041. 2042. 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 December 31, 2023, we had 61 56 employees, of which substantially all were located at our headquarters in Hayward, California. Of these employees, 39 half were engaged in research and development activities and 22 half were engaged in sales, operations, 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

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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 We 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 will 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 These 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 our 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.

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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;

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- 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.

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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 On May 31, 2023, the last day of the one-year period, the Company paid Mr. Duggan a fee of $1.0 million in consideration of the obligations set forth in the Letter Agreement. As of December 31, 2022 December 31, 2023, the amount there were no additional amounts owed to Mr. Duggan under the Letter Agreement was $0.6 million, recorded on the balance sheet under accrued expenses. Agreement.

In May 2023, the Company secured director and officer liability insurance from third-party insurance carriers through a brokered transaction.

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;

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- 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 significantrevenue 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. cardiology or elsewhere. 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. environment. There can be no assurance that our efforts will be successful, either

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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 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. requirements. 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 expect to 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 armed conflicts in Ukraine, Israel and Ukraine and the ongoing COVID-19 pandemic and resulting negative impact on elsewhere, which have negatively impacted 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

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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.

As a consequence of our corporate realignment, we 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. 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 Also, any 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 Nano-pulse Stimulation.

Our revenue to date has been generated entirely from the CellFX System, which consists of a console, handpieces connectors and tips, end-effectors, and both these products and all our potential products under development are based upon the same patented platform technology, Nano-Pulse 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 In 2021 to 2022, aesthetic and medical dermatologists have been were slow to adopt our products and even today they have used our products in only a small percentage of their eligible patients for a variety of reasons. patients. 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.

We intend to market the CellFX nsPFA Percutaneous Electrode System primarily to Otolaryngologists, Endocrine Surgeons, and Interventional Radiologists (“surgeons”) who may be slow or fail to adopt our products or who may use our products in only a small percentage of their eligible patients for a variety of reasons, including but not limited to:

- lack of experience with our products;
- lack of adequate reimbursement or cost to the patient;
- lack of conviction regarding evidence supporting cost benefits or cost effectiveness of our products over existing alternatives;
- lack of clinical data showing longer-term patient benefits;
- the possible introduction of new technologies competitive to our products; and
- liability risks generally associated with the use of new products and procedures.

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Moreover, our products, including our platform NPS technology, could be rendered obsolete or economically impractical by numerous factors, many of which are beyond our control, including but not limited to:

- entrance of new competitors into our markets;
- technological advancements of alternative technologies;
- loss of key relationships with suppliers, group purchasing organizations, or end-user customers;
- manufacturing or supply interruptions;
- product liability claims;
- our reputation and product market acceptance;
- loss of existing regulatory approvals or the imposition of new requirements to maintain such approvals or to receive new approvals; and
- product recalls or safety alerts.

We may fail to meet our publicly announced guidance or other expectations about our business and future operating results, which could cause our stock price to decline.

The Company may, from time to time, provide financial guidance about its business and future operating results. In developing this guidance, the Company's management must make certain assumptions and judgments about its future operating performance, including but not limited to projected hiring of sales professionals, growth of revenue in the relevant device markets, increase or decrease of its market share, costs of production of its recently introduced products, and stability of the macro-economic environment in the Company's key markets. Furthermore, analysts and investors may develop and publish their own projections of the Company's business, which may form a consensus about the Company's future performance. The Company's business results may vary significantly from such guidance or that consensus due to a number of factors, many of which are outside of the Company's control, and which could adversely affect its operations and operating results. Furthermore, if the Company makes downward revisions of its own previously announced guidance, or if the Company's publicly announced guidance of future operating results fails to meet expectations of securities analysts, investors or other interested parties, the price of the Company's common stock could decline.

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

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

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

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

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

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.

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

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

We have recently commenced revenue-producing operations in 2021; operations; however, we have been may be unsuccessful in earning significant revenues. We therefore intend to believe that developing the commercialization aspects of a company will take a substantial amount of capital and commitment of time and effort. We may seek development and marketing partners and license our technology to others in order to avoid our having to provide the marketing, manufacturing, and distribution capabilities within our organization. There can be no assurance that we will find any development and marketing partners or companies that are interested in licensing our technology. If we are unable to establish and maintain adequate sales, marketing, manufacturing, and distribution capabilities, independently or with others, we will not be able to generate product revenue, and may not become profitable.

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

We are highly dependent upon the principal members of our management team, including our Chief Executive Officer, 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

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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. In January 2022, we established an operating company in the Netherlands to further enhance our operations in Europe. However, in 2022 and 2023 we eliminated all of our full-time sales and marketing positions and, as of December 31, 2023, we had no U.S. or international sales force. We have had only just recently begun to hire employees to help market and sell our CellFX nsPDA Percutaneous Electrode System. As of March 2024, our U.S. sales and marketing team consisted of just two employees, a Vice President focusing on the surgical ablation market and a Global Senior Director focusing on the minimally invasive surgery market. We therefore have 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

We intend to hire and train a very limited number of March 1, 2023, following two reductions sales representatives and clinical specialists with backgrounds and experience in the relevant markets, especially those familiar with energy-based therapies and who have existing relationships with dermatologist. However, we expect that our sales force will require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. Furthermore, the use of our product will often require or benefit from direct support from us.

Our commercialization efforts depend on the efforts of our management and sales team, our third-party manufacturers and suppliers, physicians and medical clinics, and general economic conditions, among other factors, including the following:

- the effectiveness of our marketing and sales efforts in the United States and internationally;
- our success in educating surgeons and other physicians and patients about the benefits, administration and use of our products;
- the acceptance by physicians and patients of the safety and effectiveness of our products;
- the availability, perceived advantages, relative cost, relative safety, and relative efficacy of alternative and competing therapies; and
- our ability to achieve and maintain compliance with all regulatory requirements applicable to our products.

While few in number, we expect our direct sales representatives to develop long-lasting relationships with the surgeons they serve. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled direct sales representatives with significant technical knowledge in various areas, such as cardiology, minimally invasive surgery, and ablation technologies. New hires require training and take time to achieve full productivity. If we fail to train new hires adequately, or if we experience high turnover in our sales force in 2022 the future, we cannot be certain that new hires will become as productive as may be necessary to maintain or increase our sales. Also, if our direct sales representatives or third-party distributors fail to adequately promote, market and sell our products or decide to leave or cease to do business with us, our sales could significantly decrease or grow at a third elimination rate too slow to become profitable. In addition, our future sales will largely depend on our ability to increase our marketing efforts and adequately address our customers’ needs. If we are unable to adequately address our customers’ needs, it could negatively impact sales and market acceptance of positions in February 2023, our products, and we no longer had any employees engaged in may not generate sufficient revenue to become profitable. If we are unable to expand our sales and marketing activities on a fulltime basis. capabilities domestically and internationally, we may not be able to effectively commercialize our products, which would adversely affect our business, results of operations, and financial condition.

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

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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 If we are subject unable 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 manage the storage, discharge, handling, emission, generation, manufacture, and disposal of toxic or other hazardous substances used in the manufacture anticipated growth of our products. The failure to comply with past, present or business, our future laws could result in the imposition of fines, third-party property damage revenue 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 operating results 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.

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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.

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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. harmed.

From time to time, we may publish interim top-line or preliminary results from have experienced rapid growth in our clinical trials. Interim results from clinical trials business. Recent and future growth imposes significant added responsibilities on management, including the need to identify, recruit, train, and integrate additional employees. Rapid expansion in personnel could mean that we may announce are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues fewer experienced people carry out our research and more patient data become available. Preliminary or top-line results also remain subject to audit development activities, manufacture, market, and verification sell CellFX Systems and NPS therapies and procedures, that may which could result in inefficiencies and unanticipated costs, reduced quality, and disruptions to our operations. In addition, rapid and significant growth may strain our administrative and operational infrastructure, and the final data being materially different from failure to continue to upgrade our technical, administrative, operating, and financial control systems, or 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 occurrence 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 unexpected expansion difficulties, could have a material adverse effect on our business, financial condition and results of operations, and financial condition. The FDA our ability to timely execute our business plan. We may also change its clearance and approval policies, adopt additional regulations be unable to maintain the quality of, or revise existing regulations, or take other action which may prevent or delay approval or clearance delivery timelines of, our products under development. Any or satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. We may implement new enterprise software systems in a number of areas affecting a broad range of business processes and functional areas. The time and resources required to implement these actions new systems is uncertain and failure to complete this in a timely and efficient manner could harm our business. We cannot guarantee that any of the personnel, systems, procedures, and controls we put in place will be adequate to support the manufacture and distribution of our products. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

We must successfully educate and train surgeons and their staff on the proper use of the CellFX System; if our customers do not adopt our technology into their medical practices, or adopt our technology slower than expected, our business could suffer.

Although most surgeons may have adequate knowledge on how to use our novel CellFX System based on their clinical training and experience, we believe that the most effective way to introduce and build market demand for our products is by directly training surgeons and other physicians in the use of our products. Convincing them to dedicate the time and energy necessary for adequate training is challenging, and we cannot assure you that we will succeed in these efforts. If surgeons and other physicians are not properly trained, they may not use our products and, as a result, we may not maintain or grow our sales or achieve or sustain profitability. If surgeons and other physicians are not properly trained, they may also misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes, patient injury, negative publicity, or lawsuits against us, any of which could have a material significant 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:

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- 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 and results 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. operations.

Additionally, our strategy includes educating key opinion leaders in the industry. If these key opinion leaders determine that alternative technologies are more effective or that the benefits offered by our products are not sufficient to justify their higher cost, or if we encounter difficulty promoting adoption or others identify undesirable side effects caused by the CellFX System, establishing these systems as a number standard 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 care, our ability to achieve market acceptance of the CellFX System or of any future particular planned product, if approved.

We may find it difficult to enroll patients in products we introduce could be significantly limited and 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 business 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.

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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. suffer.

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, surgeons and other 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

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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 surgeons and other 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.

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 and Product-Related Risks

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, most 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 of ours, 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;

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- 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.

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 only preclinical experience using NPS technology in animal models of cardiac disease and very limited clinical experience treating AF with our CellFX nsPFA 360° Cardiac Catheter; 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 and the preliminary feasibility results we have seen in benign thyroid nodules might not be replicated in other areas of medicine, including the use of CellFX 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.

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 more follow-up data are gathered, patient enrollment continues and more patient data become available. Preliminary or top-line results, including our preliminary data from our feasibility thyroid nodule study, 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 or announced. 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;

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- 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.

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

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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.

Risks Related to Intellectual Property, Cybersecurity, Data Privacy, & Litigation

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;

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- 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.

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If our information technology systems or data, or those of third parties upon whom we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, regulatory investigations and actions; litigation (including class claims); fines and penalties; a disruption of our business operations such as our clinical trials; reputational harm; loss of revenue and profits; and other adverse consequences.

We depend on our information technology systems for the efficient functioning of our business, including the manufacture, distribution and maintenance of our products, as well as for accounting, data storage, compliance, purchasing, inventory management, and other related functions. We do not have redundant information technology in all aspects of our systems at this time. Despite the implementation of security and back-up measures, our information technology systems as well as those of our third-party partners, consultants, contractors, suppliers, and service providers, may be vulnerable to attack, damage and interruption from physical or electronic break-ins, accidental or intentional exposure of our data by employees or others with authorized access to our networks, computer viruses, malware, ransomware, malicious code, phishing attacks and other social engineering schemes, denial or degradation of service attacks, attacks by sophisticated nation-state and nation-state-supported actors, supply chain attacks, natural disasters, terrorism, war, telecommunication and electrical failure, denial of service, and other cyberattacks or disruptive incidents that could result in unauthorized access to, use or disclosure of, corruption of, or loss of sensitive, and/or proprietary data, including health-related and other personal information.

In the ordinary course of our business, we (and third parties upon whom we rely) may collect, receive, store, use, transfer, make accessible, protect, secure, dispose of, transmit, disclose or otherwise process proprietary, confidential and sensitive information, including personal data, such as health-related data and participant study related data, intellectual property, and trade secrets (collectively, “sensitive data”). We may share or receive sensitive data with or from third parties whose information security measures may not be adequate. In particular, the COVID-19 pandemic has caused us to modify our information technology practices including that our employees may work remotely which increases the risk of data breaches. Additionally, the prevalent use of mobile devices that access our sensitive data increases the risk of data breaches.

While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our business operations, whether due to a loss, corruption or unauthorized disclosure of our trade secrets, personal information or other proprietary or sensitive information or other similar disruptions. The costs to us to attempt to protect against such breaches can be significant and could potentially require us to modify our business, including non-clinical and clinical trial activities. While we have implemented security measures designed to protect our information technology systems and to identify and remediate potential vulnerabilities, such measures may not be successful. We may not be able to detect vulnerabilities in our information technology systems because such threats and techniques used by threat actors change frequently are sophisticated in nature and may not be detected until after a security incident has occurred.

If we, or others upon whom we rely, experience or are perceived to have experienced a breach, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits and inspections), interruptions in our operations (including disruptions to our clinical trials), interruptions or restrictions on processing sensitive data (which could result in delays in obtaining, or our inability to obtain, regulatory approvals and significantly increase our costs to recover or reproduce the sensitive data), unauthorized, unlawful or accidental loss, corruption, access, modification, destruction, alteration, acquisition or disclosure of sensitive data, such as clinical trial data, reputational harm, litigation (including class-action claims), indemnification obligations, monetary fund diversions, financial loss and other harms. In particular, ransomware attacks are becoming increasingly prevalent and severe and can lead to significant disruptions to operations, loss of data and income, reputational harm and diversion of funds. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. Such theft could also lead to loss of intellectual property rights through disclosure of our proprietary business information, and such loss may not be capable of remedying. In addition, such a breach may require notification of the breach to relevant stakeholders. Such disclosures are costly and the disclosure or the failure to comply with such requirements could lead to adverse consequences. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

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

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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.

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.

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.

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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.

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 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. Such laws include:

- U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program, such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value, and the government can find a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the law or a specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government;
- HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH, and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;

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- the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by these physicians and their immediate family members;
- the CCPA requires covered companies to, among other things provide new disclosures to California consumers and afford such consumers new abilities to opt-out of certain sales of personal information. We cannot yet predict the impact of the CCPA or the recently approved CPRA on our business or operations, but it may require us to modify our data processing practices and policies and could cause us to incur substantial costs and expenses in an effort to comply;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and non-U.S. laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and state and non-U.S. laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

We have implemented 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 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

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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 We are subject to reform the U.S. healthcare system, may have a material adverse effect on us. environmental regulations and any failure to comply with applicable laws could subject us to significant liabilities and harm our business.

Proposals by We are subject to a variety of local, state, federal, and foreign government regulations relating to the federal government, state governments, regulators, storage, discharge, handling, emission, generation, manufacture, and third-party payors to control disposal of toxic or manage other hazardous substances used in 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 manufacture of our products. The adoption failure to comply with past, present or future laws could result in the imposition of proposals 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 control costs change how we manufacture our products, which could have a material adverse effect on our business.

We could be negatively impacted by actual or perceived violations of applicable anti-corruption law or our own internal policies designed to ensure ethical business practices.

We are subject to anti-bribery, anti-corruption, and anti-money laundering laws, including the U.S. Foreign Corrupt Practices Act of 1977, or FCPA, and similar anti-bribery laws in non-U.S. jurisdictions, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. As we grow our international presence and global operations, we will be increasingly exposed to trade and economic sanctions and other restrictions imposed by the United States, the European Union, and other governments and organizations.

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Anti-corruption laws, such as the FCPA and the U.K. Anti-Bribery Act, generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. The FCPA also imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments. Numerous other laws restrict, and in some cases prohibit, U.S. companies from directly or indirectly selling goods, technology or services to people or entities in certain countries. In addition, these laws require that we exercise care in structuring our sales and marketing practices and effecting product registrations in foreign countries. Compliance with these regulations is costly.

We participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under these anti-corruption laws. In addition, we cannot predict the nature, scope, or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. Although we have implemented company policies requiring our employees and consultants to comply with the FCPA and similar laws, such policies may not be effective at preventing all potential FCPA or other violations. There can be No assurance that none of our employees and agents, or those companies to which we outsource certain portions of our business operations, will not take actions that violate our policies or applicable laws, for which we may be ultimately held responsible. Our development of infrastructure designed to identify anti-corruption matters and monitor compliance is at an early stage. If we are not in compliance with these laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations, and liquidity. Likewise, any investigation of any potential violations of these laws by respective government bodies could also have an adverse impact on our reputation, our business, results of operations, 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; end-effectors;
- 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;

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- 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 armed conflicts, health epidemics and climate change 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.

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A majority percentage of our outstanding stock is held by Robert W. Duggan, Executive Chairman of our Board, who beneficially owns approximately 56% 69% 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 Four of our directors, including Mr. Duggan and Manmeet Soni, our Lead Independent Director and Audit Committee Chairman, 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% 69% 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.

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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 We 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.

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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 armed conflicts, health epidemics and global warming 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. markets. 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 However, in general the Company's deposits held with banks may exceed the amount of insurance provided on such deposits. Despite our low risk 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.

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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 1C. Cybersecurity

Cybersecurity Risk Management and Strategy

To combat ever-present cyber risks, the Company maintains a comprehensive cybersecurity program, which includes employee training, annual risk assessments and a comprehensive cybersecurity environment meant to detect, prevent, and limit unauthorized or harmful actions across our information technology environment. However, we operate in the medical device sector, which is subject to various cybersecurity risks that could adversely affect our business, financial condition, and results of operations,

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including intellectual property theft; fraud; extortion; harm to patients, customers, and employees; violation of privacy laws and other litigation and legal risk; and reputational risk.

We have implemented a risk-based approach to identify and assess the cybersecurity threats that could affect our business and information systems. We use recognized commercially reasonable measures, tools and methodologies to manage cybersecurity risk that are tested on a regular cadence. We also monitor and evaluate our cybersecurity posture on an ongoing basis through regular vulnerability scans, penetration tests and third-party reviews. Other key components of our cybersecurity program include, but are not limited to, asset management, encryption, data loss prevention technology, access controls, identity and access management (IAM), such as multi-factor authentication (MFA), vulnerability management, endpoint threat detection and response (EDR), logging and monitoring involving the use of security information and event management (SIEM), privileged access management (PAM), email and web gateway protection, multi-faceted backup and data recovery solutions, anti-malware, firewalls, IDS and IPS, auditing and monitoring, regular policy updates, security awareness training, anti-phishing campaigns, intrusion detection and prevention, vulnerability and patch management, and third-party risk management. We also subscribe to third-party threat intelligence tools and services that support monitoring, analyzing, and responding to emerging risks and threats. We require third-party service providers with access to personal, confidential, or proprietary information to implement and maintain comprehensive cybersecurity practices consistent with applicable legal standards, although currently we do not audit this. While we believe our cybersecurity practices are comparable to those of similarly situated companies, the Company does not currently audit its third-party service providers' cybersecurity practices, except through annual SOC-1 reviews and its regulatory and quality control auditing of vendors engaged in clinical trials or the manufacture of products used in the assembly of our medical devices. We also rely on industry leading third party service providers to provide the systems required to effectively run our clinical trials and require that these third-party service providers implement and maintain standard cybersecurity practices. We have business continuity plans that we regularly review and update in line with our evolving applications architecture. We believe our cybersecurity practices comply with applicable legal requirements, including those established by the FDA.

To date, we have not experienced any material security incidents or data breaches as a result of a compromise of our information systems and are not aware of any cybersecurity incidents that have had a material impact or are reasonably likely to materially affect our business strategy, operating results, or financial condition.

Cybersecurity Governance

One of the key functions of our board of directors is informed oversight of our compliance program, including the processes used to mitigate risks associated with cybersecurity threats. Our Board is responsible for monitoring and assessing strategic risk exposure generally, and our executive officers are responsible for the day-to-day management of the material risks we face. Our Board administers its enterprise-level oversight of risks associated with cybersecurity threats directly as a whole, as well as through delegation of responsibility to our Audit Committee, which serves and functions as the Board's primary oversight body to monitor the Company's cybersecurity and related information technology risk. The Audit Committee receives periodic reports from management personnel responsible for enterprise risk management, which also evaluates cybersecurity among other enterprise level risks on an annual basis. It also assesses the experience of management personnel responsible for preventing, mitigating, detecting, and remediating any cyber incidents, including applicable third-party providers. The Audit Committee also oversees the Company's disclosure of any cybersecurity incident deemed material as required by the SEC or any other governmental authority, as applicable.

At the operational level, the Company has established an information security team, including a Privacy and Security Council ("PSC"), consisting of representatives from IT, Legal, HR, and Finance, to help provide governance and strategic direction for managing cyber risks, maintaining IT regulatory compliance, and optimizing technology initiatives for alignment with our company goals and objectives. Pursuant to various policies adopted by the Company since 2021, including the Company's Privacy Policy, the Company's senior most IT employee, our Information Security Coordinator (our "ISC"), is a member of the PSC and has frontline responsibility for assessing, identifying and managing material risks from cybersecurity threats. The PSC convenes not less than annually, and meetings include updates on cybersecurity matters provided by the information security team.

Our ISC has expertise in the following areas which assist in assessing and managing applicable cybersecurity risk: 27 years of IT experience including endpoint detection, security, incident management and response, vulnerability management and response, event management and response, and network security segmentation. The ISC provides regular reports on ongoing risk and mitigation practices, including information about cyber risk management governance and status updates on various projects intended to enhance the overall cybersecurity posture of the Company, to our Chief Executive Officer, Chief Technology Officer, and General Counsel, who then report to the Audit Committee and the Board.

Our incident response plan designates our ISC as primarily responsible for identifying and evaluating any cybersecurity incident or suspected incident and reporting any such incidents to our General Counsel in order for management to evaluate materiality, and to report to our Audit Committee, our Board and make public disclosures, as applicable. Our General Counsel is responsible for routinely updating both the Board and the Audit Committee on the Company's cybersecurity personnel, practices and processes and, pursuant to our data breach response policy, which is updated from time to time, he must report to the Board in the event of any detected material incident and regularly update the Board on any mitigation and remediation steps being taken in connection with the Company's response. The Company has, from time to time, engaged external experts, including cybersecurity assessors, consultants, auditors, and legal counsel, in evaluating and testing our risk management systems and on a project-specific basis to assist us with projects that will improve our IT infrastructure, strengthen our products' security posture, and improve our cyber readiness. This enables us to leverage specialized knowledge and insights, ensuring our cybersecurity strategies and processes remain current.

Item2. 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.

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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 is not able to conclude that a liability is probable and cannot predict what the final outcome of Ms. Gardiner's arbitration proceeding will likely be. be or provide a reasonable estimate for the range of ultimate possible loss, if any. However, at this time, we believe that the final resolution of this matter will not adversely affect our consolidated position, results of operation, operations, or cash flows. flows and that a liability is not probable at this time.

Item 4. Mine Safety Disclosures

Not applicable.

Part 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 March 20, 2024, 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

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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 December 31, 2018, to December 31, 2022 December 31, 2023. Such returns are based on historical results and are not intended to suggest future performance.

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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™ 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™ or nsPFA™ 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. We The Company developed our its proprietary CellFX System,®, a novel nsPFA delivery platform, and commercialized the initial application of our its nsPFA technology to treat benign lesions of the skin. In parallel, we the Company has designed a variety of applicators, or end-effectors, 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 the Company decided in 2022 to focus our its primary efforts on the use of nsPFA energy and the CellFX platform in the treatment of atrial fibrillation ("AF" ("AF").

Our Cardiac Program

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 The Company has developed a cardiac ablation clamp for use in cardiac surgery and a cardiac ablation catheter for use in electrophysiology electrophysiology. In December 2023, we initiated a clinical study in Prague, Czech Republic, to test our CellFX nsPFA 360° Cardiac Catheter in patients with AF and early acute data and remapping data from this study have been promising. More recently, we are currently have taken steps to initiate a clinical study of our CellFX nsPFA Cardiac Clamp in the Netherlands and, in January 2024, we filed a premarket notification 510(k) with the U.S. Food and Drug Administration (the "FDA") for clearance to commercialize our novel CellFX nsPFA Cardiac Clamp in the United States. In parallel, we have taken initial steps towards a CE mark approval in Europe for the cardiac clamp. The results of preclinical testing of both in preclinical models. cardiac products have exceeded our expectations and much of the data have been published or presented at physician or industry conferences. 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 The Company's cardiac ablation clamp and cardiac ablation catheter both use the CellFX System to generate our proprietary pulses of electrical energy.

CellFX nsPFA Cardiac Clamp

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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 CellFX 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 In preclinical studies, our CellFX nsPFA Cardiac Clamp has consistently achieved transmural ablations in 1.25 seconds, independent of tissue type or thickness. Moreover, 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 CellFX nsPFA ablation given its nonthermal nature. Because Also, 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. In May 2023, we appointed Dr. Gan Dunnington as our Chief Medical Officer, Cardiac Surgery. Dr. Dunnington is a cardiothoracic surgeon and the Director of Cardiothoracic Surgery at St. Helena Hospital (Napa Valley). He specializes in minimally invasive complex cardiothoracic procedures for the treatment of AF. And, in October 2023, we appointed Dr. Niv Ad as our Chief Science Officer, Cardiac Surgery. Dr. Ad specializes in the surgical treatment of atrial fibrillation, minimally invasive heart surgery and other advanced heart surgery techniques and transcatheter therapies.

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. Since 2023, we have been meeting with the FDA to discuss the regulatory requirements for a potential 510(k) clearance or other approval to market our cardiac clamp in the United States. In 2023, with guidance from the FDA, we completed a preclinical study, known as a Good Laboratory Practices or "GLP" study and, in January 2024, we filed a premarket notification 510(k) with the FDA for our novel CellFX nsPFA Cardiac Clamp.

CellFX nsPFA 360° Cardiac Catheter

We believe our cardiac catheter ablation device will have many of the same advantages that the cardiac ablation clamp appears to have with respect 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 because of its safety profile and potential to improve efficacy. PFA differs from CellFX nsPFA technology in that the pulse widths are longer, typically in the 10's to 100's of microseconds. We believe CellFX nsPFA can offer similar safety advantages as PFA and may provide improved efficacy advantages based on the circumferential design of our catheter and because it appears CellFX nsPFA technology 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. After seeing encouraging preclinical results, in December 2023, we initiated a clinical study in Prague, Czech Republic, to test our CellFX nsPFA 360° Cardiac Catheter in patients with AF and early acute data and remapping data from this study have been promising. 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 our cardiac catheter in the United States.

CellFX nsPFA Percutaneous Electrode System

Since early 2023, we have made tremendous progress in our percutaneous electrode program. After years of pre-clinical development and testing, as a supplemental point of validation of the Company's engineering capabilities, and to demonstrate our technology's unique mechanism of action on internal organs, in June 2023 we initiated a first-in-human study using our novel and proprietary nsPFA-enabled surgical end-effector, our percutaneous electrode. This study is being conducted by Professor Stefano Spiezia at the Ospedale del Mare in Naples, Italy, to help us better understand and confirm the mechanism of action and tissue response of nsPFA energy in internal organs as we advance into human cardiac tissue. Initially, ten subjects were treated and evaluated in the study. All of the initial patients in the study tolerated the procedure well with no reported pain or serious side effects. Ultrasound imaging 90 days post procedure showed that the treated portions of the nodules had been completely resorbed with no sign of scarring or fibrosis, which can be a side effect of other ablation modalities. Based on these positive initial results, in November 2023, we amended the thyroid study protocol to expand enrollment to focus on optimizing treatment parameters.

In parallel, in November 2023, we filed a premarket notification 510(k) with the FDA for clearance to commercialize our novel CellFX nsPFA Percutaneous Electrode System in the United States. In March 2024, the Company received FDA 510(k) clearance for its CellFX nsPFA Percutaneous Electrode System for use in the ablation of soft tissue in percutaneous and intraoperative surgical procedures.

Having secured regulatory approval to market and sell the CellFX nsPFA Percutaneous Electrode System in the United States, we have initiated a limited market release, targeting a handful of select accounts.

The CellFX Console

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The CellFX Console 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 end-effectors 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 and as part of the CellFX nsPFA Percutaneous Electrode System.

We continue to believe nsPFA ablation, as well as NPS technology more broadly, has the potential to provide superior outcomes across a variety of medical disciplines and we may seek partnership opportunities to develop additional applications.

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, to fund our future operations through public or private equity offerings, debt financings, our at-the-market equity offering program, or to enter by entering into collaborations with third parties, to fund our future operations.

Over the past few years, Mr. Robert Duggan, our majority stockholder and Executive Director, 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 with Mr. Duggan pursuant to which Mr. Duggan he lent the Company $65 million to fund its product development operations. In April 2023, the 2022 Loan Agreement was terminated upon Mr. Duggan and the Company entering into a Securities Purchase Agreement whereby the shares were paid for through the cancellation of both the principal sum of $65.0 million and all accrued and unpaid interest owed at the time under the 2022 Loan Agreement, which totaled approximately $0.2 million. 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 conflicts in Ukraine and by Israel and the COVID pandemic, current banking environment, 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.

Stock-Based Compensation

Our stock-based compensation programs include stock options and an employee stock purchase program. We periodically issue stock options to officers, directors, employees, and consultants for their services to the Company. Such issuances vest and expire according to terms established at the issuance date. Stock-based payments to officers, directors and employees, including grants of employee stock options, are recognized in the financial statements based on their grant date fair values, which are estimated using the Black-Scholes option-pricing model. Stock-based compensation expense is charged to operations on a straight-line basis over the requisite service period. We have granted stock options with time-based, performance-based, and market-based vesting conditions.

For stock options with performance-based vesting conditions, we do not recognize compensation expense until it is probable that the performance-based vesting condition will be achieved. The analysis to determine such probability involves estimates and judgements from management. The estimate of expense may be revised periodically based on the probability of achieving the required performance targets.

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The vesting conditions for stock options with market-based vesting conditions relate to the achievement of certain market capitalization targets of the Company. The grant date fair value for these stock options was determined using a Monte Carlo simulation. The expense is recognized over the requisite service period for each tranche of the awards. The requisite service period is the service period derived from the Monte Carlo simulation model. If the market capitalization targets are met sooner than the derived service period, we will accelerate the recognition of stock-based compensation expense to reflect the cumulative expense associated with the vested shares. The Monte Carlo simulation requires the Company to make assumptions and judgements about the variables used in the calculation including the expected term, volatility of the Company's common stock, an assumed risk-free interest rate, and cost of equity. The assumptions used represent management's best estimates.

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 December 31, 2023 and 2021 2022

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

(in thousands)	Year Ended December 31, 2022	2021	$ Change	Year Ended December 31, 2023	2022	$ Change
Revenues:						
Product revenues	$ 700	$ 1,418	$ (718)	$ —	$ 700	$ (700)
Total revenues	700	1,418	(718)	—	700	(700)
Cost and expenses:						
Cost of revenues	11,944	1,968	9,976	—	11,944	(11,944)
Research and development	20,839	28,640	(7,801)	27,797	20,839	6,958
Sales and marketing	12,019	14,751	(2,732)	—	12,019	(12,019)
General and administrative	13,955	19,073	(5,118)	15,777	13,955	1,822
Total cost and expenses	58,757	64,432	(5,675)	43,574	58,757	(15,183)
Loss from operations	(58,057)	(63,014)	4,957	(43,574)	(58,057)	14,483
Other expense:						
Interest expense, net	(448)	(646)	198			
Total other expense	(448)	(646)	198			
Other income (expense):						

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Interest income (expense), net				1,364	(448)	1,812
Total other income (expense)				1,364	(448)	1,812
Loss from operations, before income taxes	(58,505)	(63,660)	5,155	(42,210)	(58,505)	16,295
Income tax benefit	—	—	—	—	—	—
Net loss	$ (58,505)	$ (63,660)	$ 5,155	$ (42,210)	$ (58,505)	$ 16,295

Revenues

Revenues decreased by $0.7 million to $0.7 million zero for the year ended December 31, 2022 December 31, 2023, from $1.4 million during compared to the same period in 2021. 2022. 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 decreased by $10.0 million $11.9 million to $11.9 million zero for the year ended December 31, 2022 December 31, 2023, from $2.0 million during compared to the same period in 2021 primarily 2022, driven by a $8.5 million inventory charge for the write-off recorded for of excessive and obsolete inventory in accordance with September 2022 due to the decision to shift our announced strategic shift to direction and advance our core NPS technology outside of dermatology. The Company has discontinued further sales in the dermatology market, which is currently the only market that the Company has regulatory clearance to market and sell into. As we are no longer selling the CellFX System, we are no longer incurring costs of revenues. Going forward, we will evaluate the classification of expenses as research and development or general and administrative in accordance with ASC Topic 730,*Research and Development*.

Research and Development

Research and development expenses consist of salaries compensation and other employee 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 increased by $7.8 $7.0 million to $27.8 million for the year ended December 31, 2023, compared to $20.8 million during the same period in 2022, from $28.6 primarily due to increases of $4.0 million in 2021 due to decreases of $3.6 paid services, $1.9 million in stock-based compensation, $2.0 million $0.7 million in compensation and other employee related expenses and $2.0 million $0.6 million in clinical trial supplies, partially offset by a decrease of $0.2 million in facilities and other outside research costs. Compensation and other employee related expenses decreased primarily due to the decrease IT cost allocations driven by our shift in headcount. focus.

Sales and Marketing

Sales and marketing expenses consist consisted of compensation and other employee related employee expenses for sales and marketing personnel, expenses associated with advertising and training, and marketing studies including our Controlled Launch program. The Company has discontinued further sales in the dermatology market and is performing research and development activities to advance its core NPS technology outside of dermatology. Because we have no current sales activities and we cannot market any products outside of dermatology, we will therefore classify costs previously booked as sales and marketing within general and administrative expenses. Sales and marketing expenses decreased by $2.7 $12.0 million to zero for the year ended December 31, 2023, compared to $12.0 million during the same period in 2022, from $14.7 million in 2021 primarily due to decreases of $2.0 million in stock-based compensation and $1.9 $8.0 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 $2.2 million in paid services and promotional activities, $0.7 million in stock-based compensation, $0.9 million in facilities and IT cost allocations driven by timing, whereby our shift in focus, and $0.1 million in supplies. As noted under the Company built up Cost of Revenues section, going forward, we will evaluate the sales force classification of expenses as research and development or general and administrative in the latter part of 2021 accordance with ASC Topic 730,*Research and* *early part of 2022, prior to the reduction in force in 2022.* *Development*.

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 increased by $5.1 $1.8 million to $15.8 million for the year ended December 31, 2023, compared to $14.0 million during the same period in 2022, from $19.1 primarily due to increases of $1.3 million in 2021 due to decreases of $3.8 facilities and IT cost allocations driven by our shift in focus, $1.0 million in stock-based compensation, $0.8 million in administrative costs driven by D&O insurance, $0.3 million and $0.9 million in compensation and other employee related expenses, and $0.2

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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, expenses. These were partially offset by an increase decreases of $1.3 million in severance costs paid services and $0.1 million in relation to the reduction in force. supplies.

Other Expense, Income (Expense), net

Interest expense income increased by $0.2 $1.8 million to $0.9 $2.5 million for the year ended December 31, 2022 December 31, 2023, from $0.7 million compared to $0.7 million during the same period in 2021 2022, driven by the 2022 Loan Agreement. increased returns on higher cash balances. Other expense increased decreased by $0.2 million $0.2 million to zero for the year ended December 31, 2023, compared to $0.2 million during the same period in 2022, driven primarily by a loss losses on disposal of assets. These were assets in 2022. This is offset by an increase in interest income expense of $0.6 $0.2 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 $1.1 million for the fiscal year ended December 31, 2021 December 31, 2023, filed compared to $0.9 million during the same period in 2022, driven by interest 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. 2022 Loan Agreement.

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. stock at $2.05 per share. 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 In May 2023, the Company delivered an irrevocable notice of redemption to warrant holders and, on June 16, 2023, it redeemed the last of the outstanding 2022 Rights Offering Warrants at a price of $0.01 per warrant share. Prior to the redemption date, warrants to purchase 7,250,897 shares were exercised, additional generating approximately $14.9 million of total gross proceeds to the Company. As of up to $15 million may be received December 31, 2023, there were no 2022 Rights Offering Warrants outstanding. Robert W. Duggan, the Company's majority stockholder and Executive Chairman, purchased approximately 56% of the shares offered 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 majority stockholder and 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 bore

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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 amended certain terms of the Loan Agreement. There were no changes to the interest rate, but the principal sum is now due repayment date was changed to September 30, 2024. However, on April 30, 2023, we entered into a Securities Purchase Agreement with Mr. Duggan, pursuant to which we agreed to issue and payable on September 30, 2024. The sell to Mr. Duggan 10,022,937 shares of our common stock, par value $0.001 per share, in a Private Placement, at a price per share of $6.51. These shares were paid for through the cancellation of the amounts then owed by the Company under the 2022 Loan Agreement, contains certain covenants the principal sum of $65.0 million and Events all accrued and unpaid interest outstanding, which totaled approximately $0.2 million as of Default. April 30, 2023. The parties completed the Private Placement on May 9, 2023 and, upon closing and satisfaction of the outstanding debt, the 2022 Loan Agreement terminated, without early termination fees or penalties being owed by the Company. No additional amounts are owed to Mr. Duggan under the 2022 Loan Agreement.

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

	Year Ended December 31,			Year Ended December 31,	
(in thousands)	2022	2021	2020	2023	2022
Net cash used in operating activities	$ (47,013)	$ (54,097)	$ (35,365)	$ (33,041)	$ (47,013)
Net cash provided by (used in) investing activities	$ (401)	$ 7,563	$ 10,044		
Net cash used in investing activities				$ (121)	$ (401)
Net cash provided by financing activities	$ 79,939	$ 62,685	$ 30,885	$ 16,388	$ 79,939
Net increase in cash and cash equivalents	$ 32,525	$ 16,151	$ 5,564		
Net (decrease) increase in cash and cash equivalents				$ (16,774)	$ 32,525

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 December 31, 2023, the Company we had cash and cash equivalents of $61.1 $44.4 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. Report on Form 10-K. 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 conflicts in Ukraine and by the COVID pandemic, Israel, together with the deterioration of the credit, banking and capital markets, could have an adverse impact on potential sources of future financing.

Operating Activities

During 2023, we used cash of $33.0 million in operating activities. The difference between cash used in operating activities and net loss consisted primarily of stock-based compensation, depreciation and amortization, accrued interest, and right-of-use assets, partially offset by increases in and accounts payable and accrued expenses.

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 2023, cash used in investing activities was $0.1 million, which was for the purchase of property and equipment.

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

Financing Activities

During 2021, 2023, cash provided from investing financing activities was $7.6 $16.3 million, primarily due to $14.8 million of which $8.0 million was provided proceeds from the maturities exercise of investments, partially offset by cash used for common stock warrants, $1.2 million of proceeds from the exercise of stock options, and $0.4 million from the sale of stock under our employee stock purchase of property and equipment.

Financing Activities plan.

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 December 31, 2023 and 2020, 2022, we incurred costs relating to the SRA equal to $0.2 million, $0.3 million zero and $0.6 $0.2 million, respectively. As of December 31, 2022 December 31, 2023, 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 December 31, 2023 (in thousands):

	Payments Due by Period					Payments Due by Period				
(in thousands)	Total	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 Years	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	$ 12,124	$ 1,910	$ 4,023	$ 4,308	$ 1,883

Off-Balance Sheet Arrangements

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We do At December 31, 2023, we did not have any transactions, obligations or relationships that constitute 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. arrangements.

JOBS Act Accounting Election In the ordinary course of business, we enter into standard indemnification arrangements. Pursuant to these arrangements, we indemnify, hold harmless, and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified party in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology, or from claims relating to our performance or non-performance under a contract. The maximum potential amount of future payments we could be required to make under these agreements is not determinable because it involves claims that may be made against us in future periods, but have not yet been made. To date, we have not incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

Through the end We also enter and have entered into indemnification agreements with our directors and officers that may require us to indemnify them against liabilities that arise by reason of 2021, their status or service as directors or officers, except as prohibited by applicable law. In addition, we were an emerging growth company as defined by the JOBS Act. Under the JOBS Act, we were given the option may have obligations to delay adopting new hold harmless and indemnify third parties involved with our fundraising efforts and their respective affiliates, directors, officers, employees, agents or revised accounting standards issued subsequent other representatives against any and all losses, claims, damages and liabilities related to claims arising against such parties pursuant to the enactment terms of the JOBS Act until agreements entered into between us and such time third parties in connection with such fundraising efforts. No liability associated with such indemnification agreements has been recorded 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. December 31, 2023.

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 December 31, 2023, we did not have any investments.

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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 December 31, 2023 and 2021, 2022, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit) equity, , and cash flows, for each of the three two years in the period ended December 31, 2022 December 31, 2023, 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 December 31, 2023 and 2021, 2022, and the results of its operations and its cash flows for each of the three two years in the period ended December 31, 2022 December 31, 2023, 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.

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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 The critical audit matters are matters matter communicated below is a matter arising from the current-period audit of the financial statements that were was communicated or required to be communicated to the audit committee and that (1) relate relates 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 The communication of critical audit matters. matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Stock-Based Compensation – Valuation of Market-based Options - Refer to Notes 2 and 6 to the financial statements

Critical Audit Matter Description

During 2023, the Company issued certain stock options with market-based vesting conditions. These vesting conditions relate to the achievement of certain market capitalization targets of the Company. Using a Monte Carlo simulation, the Company estimates the fair value of the market-based options on the grant date, with the associated stock-based compensation expense recognized over the requisite service period. The requisite service period is the service period derived from the Monte Carlo simulation model. The determination of the fair value of market-based options is estimated using the expected volatility, the risk-free interest rate, cost of equity, and the expected term.

Given the level of judgment involved by management, including the use of a specialist, to determine the grant date fair value of the market-based options, audit procedures required a high degree of subjective auditor judgment necessary in evaluating the complex valuation methodology used and an increased extent of effort, including the need to involve our fair value specialists.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to market-based options included the following, among others:

- We inspected stock option agreements and Board of Directors minutes to evaluate key terms and conditions of the market-based options granted.
- We tested the accuracy and completeness of the market-based options granted during the year by agreeing the underlying inputs, such as grant date, exercise price, and vesting conditions, among others, back to source documents, such as Board of Directors minutes and stock option agreements.
- With the assistance of our fair value specialists, we evaluated management's valuation of the market-based options by:
  - Evaluating the Monte Carlo simulation methodology and the reasonableness of the valuation assumptions, including the expected volatility, the risk-free interest rate, cost of equity, and the expected term.
  - Independently calculating a fair value estimate for the market-based options.

/s/ Deloitte & Touche LLP

San Jose, Francisco, California
March 31, 2023 28, 2024

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

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

	December 31,		December 31,	
	2022	2021	2023	2022
ASSETS				
Current assets:				
Cash and cash equivalents	$ 61,139	$ 28,614	$ 44,365	$ 61,139
Accounts receivable	—	61		
Inventory	—	5,824		
Prepaid expenses and other current assets	1,008	2,131	963	1,008

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Total current assets	62,147	36,630	45,328	62,147
Property and equipment, net	1,961	2,462	1,528	1,961
Intangible assets, net	2,551	3,216	1,886	2,551
Goodwill	2,791	2,791	2,791	2,791
Right-of-use assets	8,062	8,785	7,256	8,062
Other assets	365	365	365	365
Total assets	$ 77,877	$ 54,249	$ 59,154	$ 77,877
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	$ 1,573	$ 2,904	$ 1,836	$ 1,573
Accrued expenses	2,595	4,389	3,814	2,595
Deferred revenue	—	16		
Lease liability, current	896	774	1,058	896
Note payable, current	—	436		
Related party note payable, current	917	—	—	917
Total current liabilities	5,981	8,519	6,708	5,981
Lease liability, less current portion	9,144	10,040	8,086	9,144
Related party note payable, less current	65,000	—	—	65,000
Total liabilities	80,125	18,559	14,794	80,125
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		
Common stock, $0.001 par value; authorized – 500,000 shares; issued and outstanding – 55,144 shares and 37,235 shares at December 31, 2023 and 2022, respectively			55	37
Additional paid-in capital	292,420	271,861	381,220	292,420
Accumulated other comprehensive income (loss)	—	—	—	—
Accumulated deficit	(294,705)	(236,200)	(336,915)	(294,705)
Total stockholders' (deficit) equity	(2,248)	35,690		
Total stockholders' equity (deficit)			44,360	(2,248)
Total liabilities and stockholders' equity	$ 77,877	$ 54,249	$ 59,154	$ 77,877

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,			Year Ended December 31,	
	2022	2021	2020	2023	2022
Revenues:					

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Product revenues	$ 700	$ 1,418	$ —	$ —	$ 700
Total revenues	700	1,418	—	—	700
Cost and expenses:					
Cost of revenues	11,944	1,968	—	—	11,944
Research and development	20,839	28,640	26,444	27,797	20,839
Sales and marketing	12,019	14,751	7,256	—	12,019
General and administrative	13,955	19,073	16,265	15,777	13,955
Total cost and expenses	58,757	64,432	49,965	43,574	58,757
Loss from operations	(58,057)	(63,014)	(49,965)	(43,574)	(58,057)
Other income (expense):					
Interest income (expense), net	(448)	(646)	114	1,364	(448)
Total other income (expense)	(448)	(646)	114	1,364	(448)
Loss from operations, before income taxes	(58,505)	(63,660)	(49,851)	(42,210)	(58,505)
Income tax benefit	—	—	—	—	—
Net loss	(58,505)	(63,660)	(49,851)	(42,210)	(58,505)
Other comprehensive gain (loss):					
Unrealized gain (loss) on available-for-sale securities	—	1	(5)		
Comprehensive loss	$ (58,505)	$ (63,659)	$ (49,856)	$ (42,210)	$ (58,505)
Net loss per share:					
Basic and diluted net loss per share	$ (1.72)	$ (2.28)	$ (2.14)	$ (0.88)	$ (1.72)
Weighted average shares used to compute net loss per common share — basic and diluted	33,935	27,964	23,248	48,038	33,935

See accompanying notes to the consolidated financial statements.

PULSE BIOSCIENCES, INC.

Consolidated Statements of Stockholders' Equity (Deficit) Equity

(in thousands, except per share amount)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	(Deficit) Equity	Shares	Amount	Capital	Income (Loss)	Deficit	Equity (Deficit)
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						

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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)

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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	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	7,317	7	14,857	—	—	14,864	
Issuance of shares under employee stock purchase plan	188	1	485	—	—	486	188	1	485	—	—	486	
Issuance of shares upon exercise of warrants	14	—	26	—	—	26	14	—	26	—	—	26	
Stock-based compensation expense	—	—	5,191	—	—	5,191	—	—	5,191	—	—	5,191	
Net loss	—	—	—	—	(58,505)	(58,505)	—	—	—	—	(58,505)	(58,505)	
Balance, December 31, 2022	37,235	$ 37	$ 292,420	$ —	$ (294,705)	$ (2,248)	37,235	$ 37	$ 292,420	$ —	$ (294,705)	$ (2,248)	
Issuance of common stock as part of debt extinguishment, net of issuance costs of $6							10,023	10	65,233	—	—	65,243	

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Issuance of shares upon exercise of warrants, net of issuance costs of $9	7,238	7	14,821	—	—	14,828
Issuance of shares under employee stock purchase plan	347	1	394	—	—	395
Issuance of common stock upon exercise of stock options	301	—	1,171	—	—	1,171
Stock-based compensation expense	—	—	7,181	—	—	7,181
Net loss	—	—	—	—	(42,210)	(42,210)
Balance, December 31, 2023	55,144	$ 55	$ 381,220	$ —	$ (336,915)	$ 44,360

See accompanying notes to the consolidated financial statements.

PULSE BIOSCIENCES, INC.

Consolidated Statements of Cash Flows

(in thousands)

	Year Ended December 31,			Year Ended December 31,	
	2022	2021	2020	2023	2022
Cash flows from operating activities:					
Net loss	$ (58,505)	$ (63,660)	$ (49,851)	$ (42,210)	$ (58,505)
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation	690	480	430	542	690
Amortization of intangible assets	665	666	665	665	665
Stock-based compensation	5,191	14,601	10,075	7,181	5,191
Write-off of excessive and obsolete inventory	8,477	—	—	—	8,477
Net premium amortization and discount on available-for-sale securities	—	13	5		
Loss on disposal of fixed assets	185	—	119	13	185
Gain on U.S. Treasury securities	—	—	(8)		
Changes in operating assets and liabilities:					
Accounts receivable	61	(61)	—	—	61
Inventory	(2,653)	(5,824)	—	—	(2,653)
Prepaid expenses and other current assets	1,164	(1,374)	194	(65)	1,164
Other receivables	(41)	54	—	109	(41)
Right-of-use assets	723	653	509	806	723
Other long-term assets	—	—	129		
Accounts payable	(1,304)	1,160	(266)	263	(1,304)

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Accrued expenses	(1,794)	(937)	2,830	1,219	(1,794)
Deferred revenue	(16)	16	—	—	(16)
Lease liabilities	(774)	(542)	(196)	(896)	(774)
Accrued interest on related party note payable	917	—	—	(668)	917
Accrued interest on note payable	1	658	—	—	1
Net cash used in operating activities	(47,013)	(54,097)	(35,365)	(33,041)	(47,013)
Cash flows from investing activities:					
Purchases of property and equipment	(401)	(437)	(441)	(121)	(401)
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		
Net cash used in investing activities				(121)	(401)
Cash flows from financing activities:					
Proceeds from issuance of common stock under employee stock purchase plan	486	810	490	395	486
Proceeds from exercises of warrants	26	4,217	244	14,828	26
Proceeds from exercises of stock options	—	786	717	1,171	—
Proceeds from issuance of common stock	14,864	56,697	29,434	—	14,864
Proceeds from issuance of related party note	65,000	—	—	—	65,000
Proceeds from insurance loan agreement	—	1,939	—		
Issuance cost in relation to related party note extinguishment				(6)	—
Payments made on insurance loan agreement	(437)	(1,532)	—	—	(437)
Tax payments related to shares withheld for vested restricted stock units	—	(232)	—		
Net cash provided by financing activities	79,939	62,685	30,885	16,388	79,939
Net increase in cash and cash equivalents	32,525	16,151	5,564		
Net (decrease) increase in cash and cash equivalents				(16,774)	32,525
Cash and cash equivalents at beginning of period	28,614	12,463	6,899	61,139	28,614
Cash and cash equivalents at end of period	$ 61,139	$ 28,614	$ 12,463	$ 44,365	$ 61,139
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)		
Principal and accrued interest of related party note settled via issuance of common stock				$ (65,249)	$ —
Equipment purchases included in accounts payable and accrued expenses	$ (27)	$ 27	$ 20	$ —	$ (27)
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 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

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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 stock-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,

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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 was fully written off due to excessive and obsolete inventory. inventory and the Company does not plan to capitalize further inventory in relation to the dermatology market.

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 recognized revenue at a point in time when it satisfies satisfied performance obligations by transferring control of promised goods to its customers. The amount of revenue recognized is was equal to the consideration which the Company is was entitled to in exchange for the promised goods, excluding any amounts assessed by government authorities for taxes which might be have been collected from a customer. Sales contracts often involve involved the sale and delivery of multiple products, each of which typically represent represented a separate performance obligation in the contract. While the Company sells has sold these products on a stand-alone basis at their respective SSP, stand-alone selling prices ("SSP"), initial customer contracts will likely involve primarily involved the bundling of products which will be were delivered concurrently to the customer. In such instances, the full consideration of the contract will be was recognized upon shipment of the products. The Company generally requires required receipt of full payment prior to shipment, however, from time to time, payment terms may be were extended to customers upon which the Company will perform performed a necessary credit evaluation to ensure future collectability of the outstanding balance. The accounts receivable balance at December 31, 2023 is zero and the Company has therefore not recorded an allowance against the accounts receivable 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 accrued 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 During the year ended December 31,2023, the Company reduced the accrued warranty reserve is included within Accrued expenses on liability to zero. Based upon the consolidated balance sheets. Warranty expense is recorded as Company's shift in focus, there are a component limited number of Cost of Revenues consoles currently covered under the standard warranty. All inventory has been fully written off, therefore the only incremental costs to fulfill a warranty claim would be shipping costs, which will be immaterial in the consolidated statements of operations and comprehensive loss. nature.

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

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Beginning balance	$ 80	$ —	$ 50	$ 80
Add: Accruals for warranties issued during the period	42	80	—	42
Less: Adjustment for inventory at cost and excessive and obsolete inventory	(72)	—	(50)	(72)

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Ending balance	$ 50	$ 80	$ —	$ 50

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Stock-Based Compensation

The Company recognizes the cost of Company's stock-based compensation programs include stock options and an employee stock purchase program.

The Company periodically issues stock options to officers, directors, employees, and consultants for services rendered. Such issuances vest and expire according to terms established at the issuance date. Stock-based payments to officers, directors and employees, including grants of employee stock options, are recognized in the financial statements based upon on their grant date fair value. The fair value of stock options is determined as of the grant date values, which are estimated using the Black-Scholes option pricing option-pricing model. Stock-based compensation expense is charged to operations on a straight-line basis over the vesting period. The fair value of Restricted Stock Units ("RSU") awards is determined based on the number of units Company has 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 options with both time-based 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. For stock awards with performance-based vesting conditions, the Company does not recognize compensation expense until it is probable that the performance-based vesting condition will be achieved. The analysis to determine such probability involves estimates and judgements from management and the estimate of expense may be revised periodically.

The Company has also issued certain stock options with market-based vesting conditions. These vesting conditions relate to the achievement of certain market capitalization targets of the Company. The grant date fair value of for these performance stock options was determined using a Monte Carlo simulation. The expense 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 for each tranche of the fair value awards. The requisite service period is the service period derived from the Monte Carlo simulation model. If the market capitalization targets are met sooner than the derived service period, the Company will accelerate the recognition 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 to reflect the cumulative expense associated with the vested shares. The Monte Carlo simulation requires the Company to make assumptions and generally require significant analysis and judgment to develop. The Company determines judgements about the variables used in the calculation including the expected term, volatility factor based on its own historical volatility. The of the Company's common stock, an assumed risk-free interest rate, is based on and cost of equity. The assumptions used in 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 option-pricing model represent management's best estimates. If factors change and different assumptions are used, the simplified method to calculate Company's stock-based compensation expense could be materially different in the expected term, which is the average of the contractual term and vesting period. future.

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 both of the years ended December 31, 2022, 2023 2021and 2020 2022, 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

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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 2023 and 2021 2022, 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 if applicable its components, as part of the consolidated statements of operations and comprehensive loss. There were no adjustments to comprehensive loss during both of the years ended December 31, 2023 and 2022.

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,			Year Ended December 31,	
	2022	**2021**	**2020**	2023	2022
Common stock warrants	7,303,832	—	612,310	—	7,303,832
Common stock options	5,250,696	5,996,813	5,039,194	9,466,036	5,250,696
Restricted stock units	—	—	111,305		
Total	12,554,528	5,996,813	5,762,809	9,466,036	12,554,528

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 2023 and 2021 2022, 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.

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Recent Accounting Pronouncements Not Yet Adopted

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, October 2023, the FASB issued ASU No.2018 2023-18 06, *Collaborative Arrangements Disclosure Improvements– Clarifying: Codification Amendments in Response to the Interaction between Topic SEC's Disclosure Update and Simplification Initiative. This guidance affects a wide variety of topics in the Codification. The effective date for each amendment will be the date on which the removal of the respective related disclosures from Regulation S-808 X (Collaborative Arrangements) or Regulation S-K becomes effective. Early adoption is prohibited 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 amendments in this 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. applied prospectively. 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 expect the adoption of the new this standard had noto have a material impact on the Company's consolidated financial statements. statements and related disclosures.

In December 2019, November 2023, the FASB issued ASU 2019 2023-12, 07,*Income Taxes Segment Reporting* (Topic 740 280): Simplifying the Accounting for Income Taxes, which eliminates certain exceptions related Improvements to Reportable Segment Disclosures. The amendments in this ASU require disclosures, on an annual and interim basis, of significant segment expenses that are regularly provided to the general principles CODM, as well as the aggregate amount of other segment items included in ASC the reported measure of segment profit or loss. This ASU requires that a public entity disclose the title and position of the CODM and an explanation of how the CODM uses the reported measure(s) of segment profit or loss in assessing segment performance and deciding how to allocate resources. Public entities will be required to provide all annual disclosures currently required by Topic 740 280 in interim periods, and makes entities with a single reportable segment are required to provide all the disclosures required by the amendments to other areas with the intention of simplifying various aspects related to accounting for income taxes. The new standard in this ASU and existing segment disclosures in Topic 280. This ASU is effective for fiscal years beginning after December 15, 2023, 15,2020, including and interim periods therein; within fiscal years beginning after December 15, 2024, with early adoption permitted. The amendments in this ASU should be applied retrospectively to all prior periods presented in the financial statements. The Company adopted is currently evaluating the Topic 740 effective January 1,2021. The adoption did impact of this standard on its consolidated financial statements and related disclosures, and does not expect the standard will have a material impact on the Company's consolidated financial statements. statements and related disclosures.

In December 2023, the FASB issued ASU No.2023-09,*Income Taxes* (Topic 740): Improvements to Income Tax Disclosures. This ASU requires greater disaggregation of information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. This ASU applies to all entities subject to income taxes and is intended to help investors better understand an entity's exposure to potential changes in jurisdictional tax legislation and assess income tax information that affects cash flow forecasts and capital allocation decisions. This ASU is effective for annual periods beginning after December 15, 2024, with early adoption permitted. This ASU should be applied on a prospective basis although retrospective application is permitted. The Company is currently evaluating the impact the adoption of this ASU will have on its consolidated financial statements and related disclosures.

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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 The Company did not classify any of its investments within Level 2 inputs include commercial paper, corporate bonds and asset-backed securities. of the fair value hierarchy.

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.

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The following table sets forth the fair value of the Company's financial assets measured on a recurring basis (in thousands):

Assets	December 31, 2022 Classification	Level 1	Level 2	Level 3	Total	December 31, 2023 Classification	Level 1	Level 2	Level 3	Total
Money market funds	Cash and cash equivalents	$ 57,973	$ —	$ —	$ 57,973	Cash and cash equivalents	$ 41,184	$ —	$ —	$ 41,184
Total assets measured at fair value		$ 57,973	$ —	$ —	$ 57,973		$ 41,184	$ —	$ —	$ 41,184

Assets	December 31, 2021 Classification	Level 1	Level 2	Level 3	Total	December 31, 2022 Classification	Level 1	Level 2	Level 3	Total
Money market funds	Cash and cash equivalents	$ 23,675	$ —	$ —	$ 23,675	Cash and cash equivalents	$ 57,973	$ —	$ —	$ 57,973
Total assets measured at fair value		$ 23,675	$ —	$ —	$ 23,675		$ 57,973	$ —	$ —	$ 57,973

During the years ended December 31, 2022 2023 and 2021 2022, the Company did not record impairment charges related to its marketable investments. cash equivalents. During the years ended December 31, 2022 2023 and 2021 2022, 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 2023 or 2021 2022.

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	December 31, 2023	2022
Leasehold improvements	$ 2,519	$ 2,519	$ 2,519	$ 2,519
Laboratory equipment	1,118	1,019	1,247	1,118
Furniture, fixtures and equipment	966	932	966	966
Software	289	202	272	289
Construction in progress	22	186	—	22
	4,914	4,858	5,004	4,914
Less: Accumulated depreciation and amortization	(2,953)	(2,396)	(3,476)	(2,953)
	$ 1,961	$ 2,462	$ 1,528	$ 1,961

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Depreciation expense for the years ended December 31, 2022, 2023 2021and 2020 2022, was $0.7 million, $0.5 million and $0.4 $0.7 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,		December 31,	
	2022	2021	2023	2022
Acquired patents and licenses	$ 7,985	$ 7,985	$ 7,985	$ 7,985
Less: Accumulated amortization	(5,434)	(4,769)	(6,099)	(5,434)
	$ 2,551	$ 3,216	$ 1,886	$ 2,551

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

Years ending December 31:		
2023	$ 665	
2024	665	$ 665
2025	665	665
2026	556	556
	$ 2,551	$ 1,886

Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,		December 31,	
	2022	2021	2023	2022
Compensation expense	$ 1,377	$ 2,932	$ 3,199	$ 1,377
Controlled launch (Note 8)	—	534		
Director and officer liability insurance (Note 12)	571	—	—	571
Clinical trial fees and costs	64	245	84	64
Professional fees	318	85	343	318
Warranty	50	80	—	50
Other	215	513	188	215
	$ 2,595	$ 4,389	$ 3,814	$ 2,595

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 2023, the Company determined that its goodwill was not impaired.

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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 2023 and 2021 2022. The Company's Board of Directors (the "Board") has the authority to issue preferred stock and to determine the rights, preferences, privileges, and restrictions, including voting rights, without any further vote or action by the Company's stockholders.

Common Stock

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

Private Placement Securities Purchase Agreement

On April 30, 2023, the Company entered into a Securities Purchase Agreement with Robert W. Duggan, the Company's majority stockholder and Executive Chairman, pursuant to which the Company agreed to issue and sell to Mr. Duggan 10,022,937 shares of the Company's common stock, par value $0.001 per share, in a Private Placement, at a price per share of $6.51. The parties completed the Private Placement on May 9, 2023, after satisfying all pre-closing conditions, and the Company issued the full number of shares to Mr. Duggan. The shares were paid for through the cancellation of the principal sum of $65.0 million borrowed by the Company pursuant to the 2022 Loan Agreement (See Note 13), together with all accrued and unpaid interest outstanding owed at the time of closing.

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. stock at a price of $2.05 per share. 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 In May 2023, the Company delivered an irrevocable notice of up redemption to $15 million warrant holders and, on may June 16, 2023, be received through it redeemed the exercise last 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 outstanding 2022 Rights Offering Warrants are exercisable immediately and expire on the fifth anniversary at a price 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 warrant share. See the volume weighted average price of the Company's common stock equals or exceeds 200% of the exercise price*Common Stock Warrants* section below 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. further details. Robert W. Duggan, the Company's largest majority stockholder and Executive Chairman, purchased approximately 56% of the shares offered in through 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

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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 were 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 On May 10, 2023, the year ended Company issued a press release announcing that on December 31, 2022 May 9, 2023 , a the terms for warrant redemption had been met. Pursuant to the redemption, the Company redeemed 66,175 warrants on the redemption date, June 16, 2023. Prior to the redemption date, warrants to purchase 7,250,897 shares were exercised, generating approximately $14.9 million of total of 13,240 warrants were exercised. gross proceeds to the Company. As of December 31, 2022 2023, there were 7,303,832 no 2022 Rights Offering Warrants outstanding.

A summary of total warrants activity for the year ended December 31, 2022 2023 is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Warrants outstanding at December 31, 2021	—	$ —	—			
Warrants outstanding at December 31, 2022				7,303,832	$ 2.05	4.43
Issued	7,317,072	2.05		—	—	
Exercised	(13,240)	2.05		(7,237,657)	2.05	
Expired/Redeemed	—	—		(66,175)	2.05	
Warrants outstanding and exercisable at December 31, 2022	7,303,832	$ 2.05	4.43			
Warrants outstanding at December 31, 2023				—	$ —	—

Equity Plans

2017 Equity Incentive Plan and 2017 Inducement Equity Incentive Plan

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

The 2017 Plan has a 10-year term, and provides for the grant of stock options, stock appreciation rights, restricted stock, 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 2023 and 2021, 2022, the number of shares of common stock available under the 2017 Plan increased by 1,188,657 1,200,000 and 1,022,002 1,188,657 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. Additionally, in December 2023, the number of shares of common stock available under the 2017 Plan increased by 1,375,000 shares as a result of a stockholder vote held at a special meeting of stockholders. As of December 31, 2022 2023, 2,368,716 231,763 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. And, in March 2024, the Board approved a second amendment to the Inducement Plan to reserve an additional 2,000,000 shares of the Company's common stock for issuance pursuant to the Inducement Plan. As of December 31, 2022 2023, 1,053,767 1,249,126 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 2023 is presented below:

	Stock Options Outstanding			Stock Options Outstanding		
	Number of shares	Weighted average exercise price	Weighted average remaining life (in years)	Number of shares	Weighted average exercise price	Weighted average remaining life (in years)
Balances — December 31, 2021	5,996,813	$ 15.77	7.33			
Balances — December 31, 2022				5,250,696	$ 12.67	6.24
Options granted	1,440,100	2.97		5,338,386	5.26	
Options exercised	—	—		(301,254)	3.89	
Options canceled	(1,472,385)	14.88		(316,494)	5.42	
Options expired	(713,832)	14.62		(505,298)	12.71	
Balances — December 31, 2022	5,250,696	$ 12.67	6.24			
Exercisable — December 31, 2022	3,479,531	$ 15.17	5.06			
Balances — December 31, 2023				9,466,036	$ 9.01	7.78
Exercisable — December 31, 2023				3,833,663	$ 13.67	5.56

Time-based Options

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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 2023 is presented below:

	Stock Options Outstanding			Stock Options Outstanding		
	Number of shares	Weighted average exercise price	Weighted average remaining life (in years)	Number of shares	Weighted average exercise price	Weighted average remaining life (in years)
Balances — December 31, 2021	4,796,716	$ 16.44	7.05			
Balances — December 31, 2022				4,730,394	$ 12.95	6.16
Options granted	1,240,100	2.59		2,390,386	4.7	
Options exercised	—	—		(301,254)	3.89	
Options canceled	(674,465)	16.73		(262,994)	6.06	
Options expired	(631,957)	15.05		(414,626)	13.01	
Balances — December 31, 2022	4,730,394	$ 12.95	6.16			
Exercisable — December 31, 2022	3,230,670	$ 15.39	5.07			
Balances — December 31, 2023				6,141,906	$ 10.48	7.07
Exercisable — December 31, 2023				3,390,035	$ 14.47	5.28

The intrinsic value of time-based options exercised during the years ended December 31, 2022, 2023 2021 and 2020 2022 was zero, $0.8 $0.9 million and $1.6 million, zero, respectively.

The fair value of the time-based options granted to employees and directors during the years ended December 31, 2022, 2023 2021 and 2020 2022 was $2.3 million, $15.1 $9.0 million and $6.7 $2.3 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/ strategic and 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 2023 is presented below:

	Stock Options Outstanding			Stock Options Outstanding		
	Number of shares	Weighted average exercise price	Weighted average remaining life (in years)	Number of shares	Weighted average exercise price	Weighted average remaining life (in years)
Balances — December 31, 2021	1,200,097	$ 13.11	8.44			
Balances — December 31, 2022				520,302	$ 10.08	7.02
Options granted	200,000	5.32		848,000	3.13	
Options exercised	—	—		—	—	
Options canceled	(797,920)	13.32		(53,500)	2.31	
Options expired	(81,875)	11.28		(90,672)	11.35	
Balances — December 31, 2022	520,302	$ 10.08	7.02			
Exercisable — December 31, 2022	248,861	$ 12.25	4.92			

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Balances — December 31, 2023	1,224,130	$	5.51	8.53
Exercisable — December 31, 2023	443,628	$	7.57	7.75

The fair value of the performance options granted to employees during the years ended December 31, 2022, 2023 2021and 2020 2022 was $2.0 million and $0.8 million, $2.5 million, respectively.

Market-based Options

Certain stock options awarded by the Company contain market conditions related to achievement of certain market capitalization targets. The options will vest and $5.5 million, respectively. become exercisable once the specific market capitalization target is fulfilled.

A summary of the market-based option activity under the 2017 Plan for the year ended December 31, 2023 is presented below:

	Stock Options Outstanding		
	Number of shares	Weighted average exercise price	Weighted average remaining life (in years)
Balances — December 31, 2022	—	$ —	—
Options granted	2,100,000	6.78	
Options exercised	—	—	
Options canceled	—	—	
Options expired	—	—	
Balances — December 31, 2023	2,100,000	$ 6.78	9.44
Exercisable — December 31, 2023	—	—	—

The fair value of the market-based options granted to employees during the year ended December 31, 2023 was $10.5 million. There were no market-based options granted during the year ended December 31, 2022.

The Company estimates the fair value of time-based and performance-based stock options on the grant date using the Black-Scholes option pricing model. The estimated fair value of these employee stock options is amortized on a straight-line basis over the requisite service period of the awards. The Company reviews, and when deemed appropriate, updates the assumptions used on a periodic basis. The fair value of time-based and performance-based stock options was estimated using the Black-Scholes option-pricing model utilizing following weighted-average assumptions:

	Year Ended December 31,	
	2023	2022
Expected term in years	5.0 - 8.0	5.3 - 6.8
Expected volatility	89 - 95%	83 - 88%
Risk-free interest rate	3.7 - 4.4%	1.9 - 3.2%
Dividend yield	—	—

The Company estimates the fair value of market-based stock options on the grant date using a Monte Carlo simulation model. The estimated fair value of these employee stock options is amortized over the requisite service period for each tranche of the awards. The requisite service period is the service period derived from the Monte Carlo simulation model. If the market capitalization targets are met sooner than the derived service period, the Company will accelerate the recognition of stock-based compensation expense to reflect the cumulative expense associated with the vested shares. The fair value of market-based stock options was estimated using the following weighted-average assumptions:

	Year Ended December 31,			Year Ended December 31,	
	2022	2021	2020	2023	2022
Expected term in years	5.3 - 6.8	5.3 - 6.1	5.3 - 6.1	4.0 - 6.3	—
Expected volatility	83 - 88%	78%	70%	90%	—
Risk-free interest rate	1.9 - 3.2%	0.9 - 1.4%	0.3 - 0.5%	3.4% - 3.8%	—

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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 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 waived the evergreen provision of the for 2017 2022 ESPP, the number of and 2023 and no additional shares of common stock available were reserved under the 2017 ESPP was increased by 383,250 shares. ESPP. During the years ended December 31, 2022 2023 and 2021 2022, the Company issued 188,097 347,681 and 91,378 188,097 shares of common stock under the 2017 ESPP, respectively. As of December 31, 2022 2023, 460,999 113,318 shares of common stock remained available for issuance under the 2017 ESPP.

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

	Year Ended December 31,	
	2023	2022
Expected term in years	0.5 - 1.0	0.5 - 1.0
Expected volatility	83%	83%
Risk-free interest rate	5.1% - 5.5%	0.6% - 3.5%
Dividend yield	—	—

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,	Year Ended December 31,

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	2022	2021	2020	2023	2022
Cost of revenues	$ 217	$ 129	$ —	$ —	$ 217
Research and development	1,563	5,211	4,013	3,491	1,563
Sales and marketing	733	2,749	1,187	—	733
General and administrative	2,678	6,512	4,875	3,690	2,678
Total stock-based compensation expense	$ 5,191	$ 14,601	$ 10,075	$ 7,181	$ 5,191

As of December 31, 2022 2023, 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,			Year Ended December 31,	
	2022	2021	2020	2023	2022
Time-based options	$ 4,467	$ 9,235	$ 8,739	$ 3,827	$ 4,467
Performance options	233	4,840	133		
RSU	—	—	86		
Performance-based options				1,977	233
Market-based options				1,130	—
ESPP	491	526	1,117	247	491
Total stock-based compensation expense	$ 5,191	$ 14,601	$ 10,075	$ 7,181	$ 5,191

At December 31, 2022 2023, there was $5.6 $9.7 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 4.19 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 the Company 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 the Company's reasonable satisfaction, that ODURF has met its obligations pursuant to the specified task order and statement of work. The principal investigator may transfer funds 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, 2023 2021and 2020 2022, we the Company incurred costs relating to the SRA equal to $0.2 million, $0.3 millionzero and $0.6 $0.2 million, respectively. As of December 31, 2022 2023, there are no unbilled SRAs left under the task orders.

8. Controlled Launch

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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 completed 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 Company did not record any sales and marketing expense in relation to the years Controlled Launch program for the year ended December 31, 2022 2023and 2021 the . The Company recorded $0.1 million and $1.8 million, respectively, an expense of $0.6 million for the year ended December 31, 2022. This expense was partially offset by $0.5 million of expense reversal for the return of certain CellFX Systems, resulting in a $0.1 million 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.

During the year ended December 31, 2023, the Company did not recognize any revenue in relation to the Controlled Launch program. During the year ended December 31, 2022, certain consultants completed the Controlled Launch program 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 program was relieved and recognized as revenue on a non-cash basis as a result of these purchases during the year ended December 31, 2022. See Note 9 for additional detail of revenue transactions.

9. Revenue

The In connection with its Controlled Launch program in dermatology, the Company recognizes recognized revenue at a point in time when it satisfies satisfied performance obligations by transferring control of promised goods to its customers. The amount of revenue recognized is was equal to the consideration which the Company is was 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 was 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. The Company has not recognized any revenue during the year ended December 31, 2023. Total revenue recognized for the years year ended December 31, 2022and 2021, was $0.7 million and $1.4 million, respectively, $0.7 million of which approximately $0.4 million and $1.1 million, respectively, $0.4 million 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.

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

Performance Obligations

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

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

Disposable treatment tips 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, which are also still available for existing customers, 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 During part of the Controlled Launch, customers purchased CUs; when the customer's balance of CUs on a specific system is was depleted, the system will would no longer function until the customer purchases purchased additional CUs. Customers can At that time, customers could purchase additional CUs via the Company's CellFX Marketplace which is was an online marketplace accessible directly from the CellFX System. Payment for CUs is was due upon order placement and the CUs are were immediately available for download to the console via CellFX CloudConnect. At that time, CUs represent represented a distinct performance obligation which is was satisfied when CUs are were made available for customers to download from the Company's CellFX CloudConnect, as customers can could use purchased CUs at any time at their discretion, and the Company does did not provide any ongoing service or other forms of involvement after the sale occurs. occurred.

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 In the Controlled Launch, the transaction price is was the consideration to which the Company expects expected to be entitled to in exchange for providing the promised goods to customers. Customer orders placed for cash contemplate contemplated 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 evaluated the possible impact of variable consideration in determining the transaction price, in particular the possibility of future returns or credits. Sales Still outstanding 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.* (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.

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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") CODM of the Company. The CODM reviews the results of the Company on a consolidated basis, however in basis. In prior year, when making certain operating decisions and assessing performance, the CODM will has additionally review reviewed 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,			Year Ended December 31,	
	2022	2021	2020	2023	2022
Systems	$ 560	$ 1,189	$ —	$ —	$ 560
Cycle units	140	229	—	—	140
Total consolidated revenue	$ 700	$ 1,418	$ —	$ —	$ 700

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

	Year Ended December 31,			Year Ended December 31,	
	2022	2021	2020	2023	2022
North America	$ 517	$ 1,182	$ —	$ —	$ 517
Rest of World	183	236	—	—	183
Total consolidated revenue	$ 700	$ 1,418	$ —	$ —	$ 700

11. Income Taxes

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

	Year Ended December 31,			Year Ended December 31,	
	2022	2021	2020	2023	2022
Domestic	$ (58,505)	$ (63,660)	$ (49,851)	$ (42,210)	$ (58,505)
Foreign	—	—	—	—	—
	$ (58,505)	$ (63,660)	$ (49,851)	$ (42,210)	$ (58,505)

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

	December 31,			December 31,	
	2022	2021	2020	2023	2022
Current					
Federal	$ —	$ —	$ —	$ —	$ —
State	3	3	3	—	3
Foreign	—	—	—	—	—
Total current	3	3	3	—	3
Deferred					
Federal	—	—	—	—	—
State	—	—	—	—	—
Foreign	—	—	—	—	—
Total deferred	—	—	—	—	—
Total provision for income taxes	$ 3	$ 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, 2023 2021and 2020. 2022.

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,			Year Ended December 31,	
	2022	2021	2020	2023	2022
Federal tax at statutory rate	21.0%	21.0%	21.0%	21.0%	21.0%
State tax at statutory rate	8.4	8.4	8.4	—	8.4
Research and development credits	0.9	1.9	2.1	3.7	0.9
Return to provision				2.6	—
Change in valuation allowance	(18.4)	(26.8)	(43.3)	(19.1)	(18.4)
Deferred adjustment	(5.3)	—	8.5	(1.6)	(5.3)
Change in tax rate	—	—	4.2	(5.8)	—
Uncertain Tax Position	(5.7)	(2.3)	—		
Uncertain tax position				—	(5.7)
Other	(0.9)	(2.2)	(0.8)	(0.8)	(0.9)
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 2023 and 2021 2022, are as follows (in thousands):

	December 31,		December 31,	
	2022	2021	2023	2022
Deferred tax assets				
Accruals	$ 3,404	$ 1,034	$ 1,502	$ 3,404
Net operating loss carryforwards	56,447	49,246	61,072	56,447
Tax credit carryforwards	7,111	6,611	9,815	7,111

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Stock-based compensation	8,784	12,188	7,704	8,784
R&D Capitalization	3,810	—		
Lease liability under ASC 842	2,948	3,182		
R&D capitalization			7,384	3,810
Lease liability			1,920	2,948
Fixed assets			7	—
Intangibles			99	—
Gross deferred tax assets	82,504	72,261	89,503	82,504
Valuation allowance	(79,779)	(69,006)	(87,853)	(79,779)
Total deferred tax assets	2,725	3,255	1,650	2,725
Deferred tax liabilities				
Intangibles	(117)	(365)	—	(117)
ROU asset under ASC 842	(2,593)	(2,862)		
Right-of-use asset			(1,650)	(2,593)
Fixed assets	(15)	(28)	—	(15)
Total deferred tax liabilities	(2,725)	(3,255)	(1,650)	(2,725)
Net deferred tax assets/(liabilities)	$ —	$ —	$ —	$ —

The Company's unrecognized tax benefits as of December 31, 2022, 2023 2021and 2020 2022 were $10.2 million and $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,			December 31,	
	2022	2021	2020	2023	2022
Unrecognized tax benefits at beginning of year	$ 5,140	$ 2,491	$ 1,470	$ 8,925	$ 5,140
Increases related to current year tax positions	2,055	2,649	1,021	1,575	2,055
Increases related to prior year tax positions	1,730	—	—	1,129	1,730
Decreases related to prior year tax positions				(1,459)	—
Unrecognized tax benefits at end of year	$ 8,925	$ 5,140	$ 2,491	$ 10,170	$ 8,925

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 2023 and does not anticipate any significant change within twelve months of this reporting date.

The Company's valuation allowance increased by $8.1 million in the year ended December 31, 2023 and 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 2023, the Company had federal and state net operating loss ("NOL") carryforwards of $199.9 $222.0 million and $204.6 $204.4 million, respectively, which begin to expire in 2034. Of the total federal NOL carryforward of $199.9 $222.0 million, approximately $174.3 $196.4 million is carried forward indefinitely but is limited to 80% of the taxable income.

As of December 31, 2022 2023, the Company had approximately $5.8 $8.6 million and $5.5 $8.1 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 2023, the Company was not under examination by the Internal Revenue Service or any state tax jurisdiction.

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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 2023.

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 majority stockholder and 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 On May 31, 2023, the last day of the one-year period, the Company paid Mr. Duggan a fee of $1.0 million in consideration of the obligations set forth in the Letter Agreement. As of December 31, 2023 31,2022, the amount , there were no additional amounts owed to Mr. Duggan under the Letter Agreement was $0.6 million, recorded on Agreement.

On June 9,2022, the balance sheet under accrued expenses. Company 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 one2022 Rights Offering Warrant to purchase one share of common stock at a price of $2.05 per share. Robert W. Duggan, the Company's majority stockholder and Executive Chairman, purchased approximately 56% of the shares offered through the 2022 Rights Offering.

On September 20, 2022, the Company and Robert W. Duggan, the Company's 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. On April 30, 2023, the Company (Note entered into a Securities Purchase Agreement with Mr. Duggan, pursuant to which the Company agreed to issue and sell to Mr. Duggan 10,022,937 shares of the Company's common stock, par value $0.001 per share, in a Private Placement, at a price per share of $6.51. These shares were paid for through the cancellation of the amounts then owed by the Company under the 2022 Loan Agreement, the principal sum of $65.0 million and all accrued and unpaid interest outstanding, which totaled approximately $0.2 million as of April 30, 2023. Upon closing of the Private Placement and satisfaction of the outstanding debt, the 2022 Loan Agreement terminated, without early termination fees or penalties being owed by the Company. No additional amounts are owed to Mr. Duggan under the 2022 Loan Agreement. See Note 13). for further details.

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 Company's majority stockholder and 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 2022Loan Agreement bears bore 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 amended certain terms of the2022 Loan Agreement. There were no changes to the interest rate, but the principal sum is now due and payable on repayment date was

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changed to September 30, 2024. During the year ended December 31, 2022, 2023, the Company made cash payments of $1.7 million for accrued interest on the loan, and recorded $0.9 an additional $1.1 million of interest expense in relation to the 2022 Loan Agreement.

Insurance Loan Agreement

On May April 30, 2023, 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 entered into a Securities Purchase Agreement with Mr. Duggan, pursuant to which the Company made agreed to issue and sell to Mr. Duggan 10,022,937 shares of the Company's common stock, par value $0.001 per share, in a down payment Private Placement, at a price per share of $0.7 million and financed $6.51. These shares were paid for through the balance cancellation of $1.9 million via an Insurance Loan Agreement. The Insurance the amounts then owed by the Company under the 2022 Loan Agreement, had an annual the principal sum of $65.0 million and all accrued and unpaid interest rate outstanding, which totaled approximately $0.2 million as of 3.69% April 30, 2023. The parties completed the Private Placement on May 9, 2023 and, required monthly payments through upon closing and satisfaction of the outstanding debt, the February 2022upon which the Insurance Loan Agreement was paid in full. During terminated, without early termination fees or penalties being owed by the year ended Company. December 31, 2022, No additional amounts are owed to Mr. Duggan under the Company recorded $1.0 thousand of interest expense in relation to the Insurance2022 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, 2023 2021and 2020 2022, rent expense, including common area maintenance charges, was $2.1 million, $1.9 $2.3 million and $1.7 $2.1 million, respectively.

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

	Year Ended December 31,		Year Ended December 31,	
Assets:	2022	2021	2023	2022
Right-of-use assets	$ 8,062	$ 8,785		
Operating right-of-use assets			$ 7,256	$ 8,062

	Year Ended December 31,		Year Ended December 31,	
Liabilities:	2022	2021	2023	2022
Current operating lease liabilities	$ 896	$ 774		
Non-current operating lease liabilities	9,144	10,040		
Lease liability, current			$ 1,058	$ 896
Lease liability, less current portion			8,086	9,144
Total lease liabilities	$ 10,040	$ 10,814	$ 9,144	$ 10,040

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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

	Year Ended December 31,	
	2023	2022
Cash paid for operating lease liabilities	$ 1,845	$ 1,806

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

Year ending December 31:		
2023	$ 1,845	
2024	1,910	$ 1,910
2025	1,977	1,977
2026	2,046	2,046
2027	2,117	2,117
2028		2,191
Thereafter	4,074	1,883
Total lease payments	13,969	12,124
Less imputed interest	(3,929)	(2,980)
Total lease liabilities	$ 10,040	$ 9,144

Weighted-average remaining lease term and discount rate, as of December 31, 2022, 2023, were as follows:

Weighted-average remaining lease term	6.83 5.83
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 is not able to conclude that a liability is probable and cannot predict what the final outcome of Ms. Gardiner's arbitration proceeding will likely be. be or provide a reasonable estimate for the range of ultimate possible loss, if any. However, at this time, we believe that the final resolution of this matter will not adversely affect our consolidated position, results of operation, operations, or cash flows. flows and that a liability is not probable at this time.

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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.

In February 2023, the Company eliminated an additional seven positions and incurred a discrete restructuring related charge of $0.1 million which was fully recorded in February 2023 and the related expenses are included within total cost and expenses on the consolidated statement of operations for the year ended December 31, 2023. This charge represents the total amount incurred in connection with the activity.

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, 2023 2021and 2020 2022.

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.

17. Subsequent Events

In March 2024, the Company received FDA 510(k) clearance for its CellFX nsPFA Percutaneous Electrode System for use in the ablation of soft tissue in percutaneous and intraoperative surgical procedures. Having secured regulatory approval to market and sell the CellFX nsPFA Percutaneous Electrode System in the United States, we have initiated a limited market release, targeting a handful of select accounts.

In March 2024, the Board approved a second amendment to the Company's Inducement Plan to reserve an additional 2,000,000 shares of the Company's common stock for issuance pursuant to the Inducement Plan.

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

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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 December 31, 2023.

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 December 31, 2023, 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.None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not Applicable.

Part PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information responsive**BOARD OF DIRECTORSAND COMMITTEES OF THE BOARD**

Board and Committee Meetings

Our Board of Directors and its committees meet throughout the year on a set schedule, hold special meetings as needed, and act by written consent from time to time. During fiscal year 2023, our Board of Directors held seven meetings, and each director attended at least 75% of the aggregate of (i) the total number of meetings of our Board of Directors held during the period for which he or she has been a director and (ii) the total number of meetings held by all committees of our Board of Directors on which he or she served during the periods that he or she served.

The names of our directors, their ages as of December 31, 2023, and certain other information about them are set forth below:

Name	Age	Position
Robert W. Duggan	79	Executive Chairman of the Board of Directors
Manmeet S. Soni	46	Director
Shelley D. Spray	59	Director
Darrin R. Uecker	58	Director and Chief Technology Officer

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Richard A. van den Broek	57	Director
Mahkam Zanganeh, D.D.S.	53	Director

The principal occupations and positions and directorships for at least the past five years of our directors, as well as certain information regarding their individual rience, qualifications, attributes, and skills that led our Board of Directors to conclude that they should serve on the Board of Directors, are described below.

There are no family relationships among any of our directors or executive officers.

Robert W. Duggan was appointed to our Board of Directors, as its Chairman, in November 2017, and he has served as the Executive Chairman of our Board of Directors since September 2022. Mr. Duggan is currently co-Chief Executive Officer of Summit Therapeutics Inc., a company developing Ivonescimab for the treatment of lung cancer and other medicinal therapies intended to improve quality of life, increase potential duration of life, and resolve serious unmet medical needs, as well as its Executive Chairman, a position he has held since February 2020, and its majority stockholder. Since 2016, Mr. Duggan has also been Chief Executive Officer of Duggan Investments, Inc., a venture capital and public equity investment firm primarily focused on patient-friendly breakthrough solutions to complex diseases of aging. From September 2007 through its acquisition by AbbVie Inc. in May 2015, Mr. Duggan was a member of the board of directors of Pharmacyclics, Inc., a developer of small-molecule medicines for the treatment of cancers. Mr. Duggan was also the Chairman and Chief Executive Officer of Pharmacyclics, from September 2008 to May 2015, as well as its largest investor. From 1990 to 2003, Mr. Duggan was Chairman of the Board of Directors of Computer Motion, Inc. and, from 1997 to 2003, he served as its Chief Executive Officer. In June 2003, Computer Motion merged with Intuitive Surgical Inc. After Intuitive Surgical's acquisition of Computer Motion, from 2003 to 2011, Mr. Duggan served on the board of directors of Intuitive Surgical. Mr. Duggan received a U.S. Congressman's Medal of Merit from Ron Paul in 1985 and in 2000 he was named a Knight of the Legion D'Honor by President Jacques Chirac of France. He is a member of the University of California at Santa Barbara Foundation board of trustees.

Mr. Duggan was appointed as a director because of his significant combined service as Chief Executive Officer of multiple innovative health care companies and career spanning over 30 years as a venture investor and advisor for a broad range of companies, and extensive expertise in vision, strategic development, planning, finance, and management.

Manmeet S. Soni was appointed to our Board of Directors in November 2017. Since October 2023, Mr. Soni has been the Chief Operating Officer of Summit Therapeutics, Inc. Prior to this, item Mr. Soni was the President, Chief Operating Officer, and Chief Financial of Reata Pharmaceuticals, Inc., a pharmaceutical company focused on developing small molecule therapeutics for the treatment of severe life-threatening diseases. Mr. Soni joined Reata in August 2019, as Chief Financial Officer, Executive Vice President and was promoted in June 2020 to Chief Operating Officer and Chief Financial Officer, Executive Vice President of Reata. Prior to joining Reata Pharmaceuticals, Mr. Soni was the Senior Vice President and Chief Financial Officer of Alnylam Pharmaceuticals Inc. from May 2017 to August 2019. From March 2016 to February 2017, Mr. Soni served as Executive Vice President, Chief Financial Officer and Treasurer of ARIAD Pharmaceuticals, Inc., a biopharmaceutical company, when ARIAD was acquired by Takeda Pharmaceutical Company Limited. Mr. Soni continued as an employee of ARIAD through May 2017. Previously, he served as Chief Financial Officer of Pharmacyclics, Inc., a biopharmaceutical company, until its acquisition by AbbVie in May 2015, after which he supported AbbVie during the post-acquisition transition through September 2015. Prior to joining Pharmacyclics, Mr. Soni worked at Zeltiq Aesthetics Inc., a publicly held medical technology company as Corporate Controller. Prior to Zeltiq, Mr. Soni worked at PricewaterhouseCoopers in the life science and venture capital group. Prior to that, he worked at PricewaterhouseCoopers India providing audit and assurance services. Mr. Soni has served as a member of the board of directors of Summit Therapeutics Inc., since December 2019. Mr. Soni has also served as a member of the board of directors of Arena Pharmaceuticals, Inc. from Dec 2018 to June 2021. Mr. Soni is incorporated herein a Certified Public Accountant and Chartered Accountant from India.

Mr. Soni was appointed as a director because of his extensive experience in the life sciences industry and his financial and accounting expertise.

Shelley D. Spray has served as a director since November 2021. Ms. Spray currently serves as Chief Education & Brand Officer of Summit Therapeutics Inc. Ms. Spray has had over 25 years of experience in the healthcare industry holding multiple executive roles, including Chief Marketing Officer of Aesthera Corporation (acquired by reference Solta Medical), where she focused on growth strategies and commercialization of their Isolaz photopneumatic system from 2006 to 2008, and Vice President of Worldwide Marketing at Xlumena Inc. (acquired by Boston Scientific), where she led the development of its launch strategy for its endoscopic ultrasound guided transluminal system. Before this, Ms. Spray was Vice President of Worldwide Marketing at Intuitive Surgical (NASDAQ: ISRG) where she led early commercialization strategies into the U.S. and international markets. In the late 1990s, Mr. Spray was Vice President and General Manager of the Radiosurgery and StealthNet Divisions of Medtronic, Inc. At Medtronic, she rebuilt infrastructure, redefined divisional focus, and developed B2B and B2C strategies for minimally invasive brain tumor treatments. Ms. Spray has been honored with many awards including a prestigious Telly Award and a Business Week Magazine Bronze award for product development and design. Ms. Spray received a B.S. in Business, Magna Cum Laude, Beta Gamma Sigma, from Arizona State University and graduated from the Competitive Strategic Marketing Program of Columbia University's Executive School of Business.

Ms. Spray was appointed as a director because of her extensive experience in product development and marketing in the life science field.

Darrin R. Uecker has been a director since September 2015 and our Chief Technology Officer since September 2022. Previously, he served as our Chief Executive Officer for seven years, as the Company developed and launched its first product, the CellFX System. Mr. Uecker has over 25 years of experience in the medical device field. From January 2014 to September 2015, Mr. Uecker was the President and Chief Operating Officer of Progyny, Inc., a company that developed Eeva™, the world's first automated time-lapse system for embryo selection during in-vitro fertilization. From June 2009 to January 2014, Mr. Uecker was the Chief Executive Officer and President as well as a Director of Gynesonics, Inc., a company that developed a novel medical device for the treatment of symptomatic uterine fibroids using ultrasound guided radiofrequency ablation. Prior to that, Mr. Uecker served in a variety of executive level roles, including as a Senior Vice President at CyperHeart, Inc. (June 2008 to June 2009), a company that developed an external beam radiation platform for the treatment of heart arrhythmias, a Senior Vice President at Conceptus, Inc. (May 2007 to June 2008), and as Chief Technology Officer at RITA Medical Systems, Inc. (January 2004 to January 2007), a medical device oncology company focused on ablative therapies. Mr. Uecker holds a M.S. degree in Electrical and Computer Engineering from the University of California at Santa Barbara.

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Mr. Uecker was appointed as a director due to his practical experience and leadership in technical, research and development gained in leadership roles with life science companies developing technologies.

Richard A. van den Broek was appointed to our definitive proxy statement Board of Directors in August 2020. Mr. van den Broek currently serves as managing partner of HSMR Advisors, LLC, a position he has held since February 2004, and has served as a director of Cogstate Ltd since 2009. Mr. van den Broek previously served on the boards of directors of Pharmacyclics, Inc. from December 2009 to April 2015, Response Genetics, Inc., from December 2010 to September 2015, Special Diversified Opportunities, Inc., from March 2008 to October 2015, and Celldex Therapeutics, Inc., from December 2014 to December 2016. Mr. van den Broek received an A.B. from Harvard University and is a Chartered Financial Analyst.

Mr. van den Broek was appointed as a director because of his extensive experience in the biotechnology sector and deep understanding of the global pharmaceutical market.

Mahkam "**Maky**" **Zanganeh, D.D.S.** was appointed as a director in February 2017, and is currently co-Chief Executive Officer of Summit Therapeutics Inc., as well as the Founder/CEO of Maky Zanganeh and Associates, which provides consulting and executive management services to businesses in the areas of product development, research, transactions, and commercialization. Previously, from August 2012 to September 2015, she served as the Chief Operating Officer of Pharmacyclics Inc. She also served as Chief of Staff and Chief Business Officer of Pharmacyclics from December 2011 to July 2012 and Vice President, Business Development, from August 2008 to November 2011. Prior to joining Pharmacyclics, Dr. Zanganeh served as President Director General (2007-2008) for the French government bio-cluster project initiative in France, establishing alliances and developing small life science businesses regionally. From September 2003 to August 2008, Dr. Zanganeh served as Vice President of Business Development for Robert W. Duggan & Associates. Dr. Zanganeh also served as worldwide Vice President of Training & Education (2002-2003) and President Director General for Europe, Middle East and Africa (1998-2002) for Computer Motion Inc. Dr. Zanganeh received a DDS degree from Louis Pasteur University in Strasbourg, France and an MBA from Schiller International University in France.

Dr. Zanganeh was appointed as a director because of her years of executive and operational experience in the life sciences industry.

Board Committees

Presently, our Board of Directors has an Audit Committee, a Compensation Committee, and a Nominating and Corporate Governance Committee, each of which has the composition and the responsibilities described below. The Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee all operate under charters approved by our Board of Directors, which charters are available on the Investors Relations page of our website at www.pulsebiosciences.com under "Corporate Governance." Our Board of Directors, from time to time, establishes additional committees to address specific needs.

The following table sets forth (i) the three standing committees of our Board of Directors, (ii) the current members of each committee, and (iii) the number of meetings held by each committee in fiscal year 2023:

Name	Audit	Compensation	Nominating and Corporate Governance
Robert W. Duggan			X
Manmeet S. Soni	X	X	X
Shelley D. Spray	X		
Richard A. van den Broek	X	X	
Number of meetings held during 2023	5	4	0

Our Corporate Governance Guidelines set out that all directors are expected to attend our annual meeting of stockholders. All of the current Board members who were members of the Board at our 2023 annual stockholder meeting attended the meeting.

Audit Committee

Our Audit Committee oversees our corporate accounting and financial reporting process and assists the Board of Directors in monitoring our financial systems and our legal and regulatory compliance. Our Audit Committee is responsible for, among other things:

- reviewing and monitoring our corporate financial reporting and the external audit;
- providing to our Board of Directors the results of its observations and recommendations derived therefrom;
- outlining to our Board of Directors improvements made, or to be made, in internal accounting controls;
- selecting and supervising the independent auditors;
- overseeing our comprehensive compliance program;
- preparing the Audit Committee's report required by the SEC rules to be included in this Proxy Statement; and
- providing to our Board of Directors such additional information and materials as it may deem necessary to make our Board of Directors aware of significant financial, reporting and compliance matters that require the attention of our Board of Directors.

The members of our Audit Committee are Ms. Spray and Messrs. Soni and van den Broek and Mr. Soni serves as our Audit Committee chair. Our Board of Directors has determined that each member of our Audit Committee is independent within the meaning of the independent director guidelines of The Nasdaq Stock Market. We believe that the composition of our Audit Committee meets the requirements for independence under, and the functioning of our Audit Committee complies with, all applicable requirements of The Nasdaq Stock Market and SEC rules and regulations. In addition, our Board of Directors has determined that each of Messrs. Soni and van den Broek and Ms. Spray

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meets the financial literacy requirements under the rules of The Nasdaq Stock Market and the SEC and that Mr. Soni qualifies as an Audit Committee financial expert as defined under SEC rules and regulations.

Compensation Committee

Our Compensation Committee oversees our corporate compensation policies, plans and programs. Our Compensation Committee is responsible for, among other things:

- reviewing and approving, or commending to our Board of Directors for approval, corporate goals and objectives relevant to our Chief Executive Officer's compensation, evaluating the Chief Executive Officer's performance in light of those goals and objectives, and determining and approving, or recommending to our Board of Directors for approval, the Chief Executive Officer's compensation based on this evaluation and such other factors as the Compensation Committee or our Board of Directors, as applicable, deem appropriate;
- reviewing and approving, or making recommendations to our Board of Directors with respect to, non-Chief Executive Officer compensation, and incentive-compensation and equity-based plans that are subject to our Board of Director's approval;
- providing oversight of our compensation policies and plans and benefits programs, and overall compensation philosophy;
- administering our equity compensation plans for its executive officers and employees and the granting of equity awards pursuant to such plans or outside of such plans; and
- preparing the report of the Compensation Committee required by the rules and regulations of the SEC.

The members of our Compensation Committee are Messrs. Soni, Duggan and van den Broek. Mr. Soni serves as the chair of our Compensation Committee. Our Board of Directors has determined that each member of our Compensation Committee is independent within the meaning of the independent director guidelines of The Nasdaq Stock Market. We believe that the composition of our Compensation Committee meets the requirements for independence under, and the functioning of our Compensation Committee complies with, all applicable requirements of The Nasdaq Stock Market and SEC rules and regulations.

Nominating and Corporate Governance Committee

Our Nominating and Corporate Governance Committee oversees and assists our Board of Directors in reviewing and recommending corporate governance policies and nominees for election to our Board of Directors. Our Nominating and Corporate Governance Committee is responsible for, among other things:

- reviewing and making recommendations to our Board of Directors on matters concerning corporate governance;
- reviewing and making recommendations to our Board of Directors on matters regarding the composition of our Board of Directors;
- identifying, evaluating and nominating candidates for our Board of Directors; and
- recommending appointments to committees of our Board of Directors and chairpersons for such committees.

The members of our Nominating and Corporate Governance Committee are Messrs. Duggan and Soni. Mr. Soni serves as chair of our Nominating and Corporate Governance Committee. Our Board of Directors has determined that each member of our Nominating and Corporate Governance Committee is independent within the meaning of the independent director guidelines of The Nasdaq Stock Market.

Director Compensation

Employee directors are not compensated for providing Board of Director services in addition to their regular employee compensation.

For 2023, Annual Meeting the non-employee members of Stockholders the Board of Directors were compensated as follows:

Cash compensation: Each non-employee member of the Board received the following cash compensation (the "Retainer Cash Payments"):

- an annual retainer for each member of the Board of $40,000 paid in equal quarterly installments;
- the members of our Audit, Compensation and Nominating and Corporate Governance Committees were eligible to receive an additional annual retainer of $10,000, $6,500, and $5,000, respectively, for their service on each Committee;
- the Chair of the Audit, Compensation and Nominating and Corporate Governance Committees were eligible to receive annual retainers of $20,000, $12,750, and $10,000, respectively; and
- the Chairman of the Board was eligible to receive an additional annual retainer of $27,300.

In March 2023, the Board of Directors amended the Company's Outside Director Compensation Policy to provide the Lead Independent Director with an annual service fee of $80,000, payable on a quarterly basis consistent with the amended policy.

We reimbursed our non-employee directors for all reasonable out-of-pocket expenses incurred in the performance of their duties as directors.

Pursuant to our compensation policy for independent directors, each non-employee director may elect to convert all or a portion of his or her Retainer Cash Payments into a number of options (the "Retainer Option," and such election, a "Retainer Option Election"). The number of shares subject to a Retainer Option will be equal to (i) the product of (A) the dollar value of the aggregate Retainer Cash Payments that the non-employee director elects to forego over the course of a specified period covered by a Retainer Option Election in favor of receiving a Retainer Option multiplied by (B) three, divided by (ii) the fair market value of a share on the date of grant of the Retainer Option, provided that the number of shares covered by such Retainer Option shall be rounded to the nearest whole share.

Equity Compensation: Pursuant to our compensation policy for independent directors, each new non-employee director receives a stock option grant to purchase 32,500 shares of our common stock under the terms of the then in effect equity compensation plan. These initial awards will vest over three years, with one-third of the shares subject to the option vesting on the one-year anniversary of the date of grant, and the remaining shares vesting monthly over the following two years, provided such non-employee

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director continues to serve as a director through each vesting date. In addition, each non-employee director is eligible to automatically received an annual stock option grant to purchase 20,000 shares of our common stock on the date of the annual meeting beginning on the date of the first annual meeting that is held after such non-employee director receives his or her initial award, provided such non-employee director continues to serve as a director through such date. Such annual awards vest monthly over one year, provided such non-employee director continues to serve as a director through each vesting date.

In the event of a "change in control," the participant non-employee director will fully vest in and have the right to exercise awards as to all shares underlying such awards and all restrictions on awards will lapse, and all performance goals or other vesting criteria will be deemed achieved at 100% of target level and all other terms and conditions met, provided the non-employee director remains a director through the date of such change in control.

The following table sets forth information concerning compensation paid or earned for services rendered to us by the non-employee members of our Board of Directors for the fiscal year ended December 31, 2023. Information about the compensation paid to Messrs. Uecker and Levinson is included in the section entitled, "Executive Compensation" and excluded from the table below:

Name	Fees earned or paid in cash ($)	Option Awards ($)(1)	Total ($)
Robert W. Duggan	—	$ 199,196	$ 199,196
Manmeet S. Soni	$ 42,678	$ 207,657	$ 250,335
Shelley D. Spray	$ 34,185	$ 83,977	$ 118,162
Richard A. van den Broek	—	$ 151,439	$ 151,439
Mahkam Zanganeh	—	$ 116,102	$ 116,102

(1) Amounts shown represent the aggregate grant date fair value of the option awards computed in accordance with FASB ASC Topic 718. These amounts do not correspond to the actual value that will be realized. The assumptions used in the valuation of these awards are consistent with the valuation methodologies specified in the notes to our financial statements.

The aggregate number of shares subject to stock options outstanding and exercisable at December 31, 2023 for each non-employee director is as follows:

Name	Aggregate Number of Stock Options Outstanding as of December 31, 2023	Aggregate Number of Stock Options Exercisable as of December 31, 2023
Robert W. Duggan	314,987	251,419
Manmeet S. Soni	288,885	222,548
Shelley D. Spray	87,547	40,924
Richard A. van den Broek	160,775	105,614
Mahkam Zanganeh	259,746	223,374

Section16(a) Beneficial Ownership Reporting Compliance

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires that our executive officers and directors and other persons who beneficially own more than 10% of a registered class of our equity securities file with the SEC reports of ownership and reports of changes in ownership of shares and other equity securities. Such executive officers and directors and other persons who beneficially own more than 10% of a registered class of our equity securities are required by the SEC to furnish us with copies of all Section 16(a) reports filed by such reporting persons.

Based solely on our review of such forms furnished to us or written representations provided to us by the reporting person, we are aware of no late Section 16(a) reports required to be filed by our executive officers, directors and other persons who beneficially own more than 10% of a registered class of our equity securities in the year ended December 31, 2023 other than: (i) in May 2023, Mr. Levinson filed the Form 4 reporting his receipt of a fully vested option for 2,000 shares a few days late, (ii) in June 2023, Mr. Levinson filed the Form 4 reporting his warrant exercise a few days late; and (iii) in May 2023, the Forms 4 reporting the Board retainer options were reported a few days late.

EXECUTIVE OFFICERS

Biographical information for our current executive officers, including their ages as of December 31, 2023, is set forth below, except Mr. Uecker's biography, which is included above, under the heading "Board of Directors and Committees of the Board."

Kevin P. Danahy, age 53, has served as our Chief Executive Officer since September 2022, and previously he served as our Chief Commercial Officer. Mr. Danahy has more than 20 years of senior management experience building and managing strategic commercial organizations for medical technology companies. Prior to joining Pulse Biosciences, Mr. Danahy most recently served as President of Solmetex, a medical device company focused on manufacturing environmental waste management products for the dental industry, from January 2019 to February 2022. From August 2017 to January 2019, Mr. Danahy held roles at Zimmer Biomet (NYSE: ZBH), a global medical device company with a comprehensive portfolio of robotic technologies, including Vice President of Global Emerging Technologies and Specialty Sales, in which he was responsible for leading the global launch and commercialization of Zimmer's new bionic surgical arm technology. Before his time at Zimmer, Mr. Danahy served as Sr. Director at Intuitive Surgical, where he successfully transformed the sales leadership training program. Early in his career, he served in commercial leadership roles at both Medtronic and Johnson & Johnson. Mr. Danahy holds an M.S. degree from Tufts University.

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Mitchell E. Levinson, age 63, was appointed as our Chief Strategy Officer in August 2021 and is responsible for leading the Company's new product development efforts and advancing our Percutaneous Electrode Program. He served on our Board of Directors from March 2019 to May 2023 and from January 2015 to November 2017. From October 2018 to August 2022, Mr. Levinson was a board member and Chief Technology Officer of Cerebrotech Medical Systems, Inc., a neurotechnology device company focused on the development of portable neurotechnology solutions that he co-founded in 2010. Mr. Levinson also served as President and Chief Executive Officer of Cerebrotech Medical Systems from December 2010 to October 2018. Prior to 2010, Mr. Levinson was the start-up Chief Executive Officer for Zeltiq Aesthetics Inc. where he became its first employee in 2005 and served as its president and its Chief Executive Officer from September 2005 until September 2009. He continued with Zeltiq as Chief Scientific Officer from September 2009 through December 2010. From March 2000 to September 2005, he served as Vice President of Research and Development of Thermage, Inc. (later renamed Solta Medical Inc.), a company engaged in cosmetic tissue tightening devices. He is the inventor of over 50 issued and numerous pending U.S. patents. Mr. Levinson earned his B.S. in Mechanical Engineering from University of California at San Diego and holds an M.S in Computer Systems from the University of Phoenix.

CORPORATE GOVERNANCE

Overview

Our Board of Directors oversees our Chief Executive Officer and other senior management in the competent and ethical operation of our business and affairs and assures that the long-term interests of the stockholders are being served. Our Board of Directors has adopted corporate governance guidelines that address items such as the qualifications and responsibilities of our directors and director candidates and corporate governance policies and standards applicable to us in general. We believe that good governance leads to high board effectiveness, promotes the long-term interests of our stockholders, strengthens the accountability of our Board of Directors and management, and improves our standing as a trusted member of the communities we serve.

Board Leadership Structure

Our Board of Directors believes that the roles of Chairman and Chief Executive Officer may be filled by the same or different individuals. This allows our Board of Directors to have the flexibility to determine whether the two roles should be combined or separated based upon the needs of the Company and our Board of Directors' assessment of our leadership, from time to time. Our Board of Directors believes that, at this time, it is in the best interests of our Company and our stockholders to separate these roles and for Kevin P. Danahy to serve as our Chief Executive Officer and for Robert W. Duggan, our majority stockholder, to serve as Executive Chairman of the Board of Directors.

Our Board of Directors has determined that the separation of the roles of Executive Chairman of the Board of Directors and Chief Executive Officer is appropriate at this time as it allows both our Chief Executive Officer and Executive Chairman to focus on management responsibilities and corporate strategy, while allowing our Executive Chairman to also focus on leadership of the Board of Directors, providing feedback and advice to the Chief Executive Officer and providing a channel of communication between the members of our Board of Directors and the Chief Executive Officer. The Executive Chairman of the Board of Directors presides over all Board meetings and works with the SEC within 120 days after the end Chief Executive Officer to develop agendas for meetings of the fiscal year covered Board of Directors. He also works with the Board of Directors to drive decisions about particular strategies and policies and, in concert with the independent committees of the Board of Directors, facilitates a performance evaluation process of the Board of Directors.

Additionally, in March 2023, our Board of Directors appointed Manmeet S. Soni as its Lead Independent Director. As Lead Independent Director, Mr. Soni serves as a liaison between the Executive Chairman of the Board of Directors and the other independent directors and is responsible for leading any meetings of the independent directors, among other things. In the absence of both our Executive Chairman and our Lead Independent Director at a meeting of the Board of Directors, Mr. Danahy presides over the meeting, whereas during executive sessions of the independent directors, an independent director in attendance presides over the meeting and provides feedback from the executive session to the Executive Chairman, Chief Executive Officer and other senior management.

The Board of Director's Role in Risk Oversight

Our management has day-to-day responsibility for identifying risks facing us, including implementing suitable mitigating processes and controls, assessing risks in relation to Company strategies and objectives, and appropriately managing risks in a manner that serves the best interests of the Company, our stockholders, and other stakeholders. Our Board of Directors is responsible for ensuring that an appropriate culture of risk management exists within the Company and for setting the right "tone at the top," overseeing our aggregate risk profile, and assisting management in addressing specific risks.

Generally, various committees of our Board of Directors oversee risks associated with their respective areas of responsibility and expertise. For example, our Audit Committee oversees, reviews and discusses with management and the Company's independent auditor risks associated with our internal controls and procedures for financial reporting and the steps management has taken to monitor and mitigate these exposures; our Audit Committee also oversees the management of other risks, including those associated with credit risk, and it oversees our comprehensive compliance program, which covers subjects such as privacy, anti-kickback compliance, and our prohibitions against insider trading. Our Compensation Committee oversees the management of risks associated with our compensation policies, plans and practices. Our Nominating and Corporate Governance Committee oversees the management of risks associated with director independence and the composition and organization of the Board of Directors.

Management and other employees report to the Board of Directors and/or to the relevant committees, from time to time, on risk-related issues.

Director Independence

Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our Board of Directors has determined that each of Dr. Zanganeh, Ms. Spray, and Messrs. Duggan, Soni, and van den Broek, representing five of our six currently serving directors, is "independent" as that term is defined under the rules of The Nasdaq Stock Market and none of these directors has or has had a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Our Board of Directors has also determined that Messrs. Soni and van den Broek and Ms. Spray, who comprise our Audit Committee, Messrs. Soni, Duggan and van den Broek, who comprise our Compensation Committee, and Messrs. Soni and Duggan, who comprise our Nominating and Corporate Governance Committee, satisfy the

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independence standards for those committees established by applicable SEC rules, including Rule 10A-3 of the Exchange Act, and the rules of The Nasdaq Stock Market. In making this Annual Report determination, our Board of Directors considered the relationships that each non-employee director has or has had with our Company and all other facts and circumstances that our Board of Directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

The Board of Directors believes that the independence of the members of the Board of Directors satisfies the independence standards established by applicable SEC rules and the rules of The Nasdaq Stock Market.

Director Nominations

Candidates for nomination to our Board of Directors are selected by the Nominating and Corporate Governance Committee in accordance with the Committee's charter, and our Certificate of Incorporation and bylaws. The Nominating and Corporate Governance Committee evaluates all candidates in the same manner and using the same criteria, regardless of the source of the recommendation.

The Nominating and Corporate Governance Committee may retain recruiting professionals to assist in identifying and evaluating candidates for director nominees. Our Board of Directors has adopted Corporate Governance Guidelines and the Nominating and Corporate Governance Committee has adopted Policies and Procedures for Director Candidates which set out, among other things, that the Nominating and Corporate Governance Committee considers factors such as character, integrity, judgment, diversity of experience (including age, gender, international background, race and professional experience), independence, area of expertise, length of service, potential conflicts of interest, other commitments and the like. The Nominating and Corporate Governance Committee considers the following minimum qualifications to be satisfied by any nominee to the Board of Directors: the highest personal and professional ethics and integrity; proven achievement and competence in the nominee's field and the ability to exercise sound business judgment; skills that are complementary to those of the existing members of the Board of Directors; the ability to assist and support management and make significant contributions to our success; and an understanding of the fiduciary responsibilities that is required of a member of the Board of Directors and the commitment of time and energy necessary to diligently carry out those responsibilities.

Based on Form 10-K. the Nominating and Corporate Governance Committee's recommendation, the Board of Directors selects director nominees and recommends them for election by our stockholders, and also fills any vacancies that may arise between annual meetings of stockholders.

As a publicly held corporation based in California and listed on The Nasdaq Stock Market, the Company is subject to certain laws and listing requirements that mandate gender and other diversity on its board of directors, such as requirements to have a minimum number of directors from underrepresented communities. These requirements can be found at Nasdaq Listing Rule 5605(f)(4) and California Corporations Code sections 301.3 and 301.4. Currently, the Company is not in compliance with all of these requirements. However, the Nominating and Corporate Governance Committee considers director candidates with these requirements in mind and director recruitment efforts are continuing.

Moreover, the Nominating and Corporate Governance Committee will consider director candidates who are proposed by our stockholders in accordance with our bylaws, our Nominating and Corporate Governance Committee's Policies and Procedures for Director Candidates and other procedures established, from time to time, by the Nominating and Corporate Governance Committee. If you would like the Nominating and Corporate Governance Committee to consider a prospective director candidate, please follow the procedures in our bylaws and submit the candidate's name and qualifications to: Corporate Secretary, Pulse Biosciences, Inc., 3957 Point Eden Way, Hayward, CA 94545.

In April 2023, Mitchell Levinson, our Chief Strategy Officer, agreed not to stand for reelection to our Board of Directors so that we could more readily recruit onto the Board an independent director with cardiology experience. The Nominating and Corporate Governance Committee concurred with Mr. Levinson's decision, which was not the result of any disagreement or concern about the Company or his service as a director.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that is applicable to all of our employees, officers, and directors. Our code of business conduct and ethics is available on the Investor Relations page of our website at www.pulsebiosciences.com under "Corporate Governance." We will post amendments to, or waivers of, our code of business conduct and ethics on the same website.

Communication with the Board of Directors

Any stockholder communication with our Board of Directors or individual directors should be directed to Pulse Biosciences, Inc., c/o Corporate Secretary, 3957 Point Eden Way, Hayward, CA 94545. The Corporate Secretary will forward these communications, as appropriate, directly to our director(s). The independent directors of the Board of Directors review and approve the stockholder communication process periodically in an effort to enable an effective method by which stockholders can communicate with the Board of Directors.

Item11. Executive Compensation

Information responsive Compensation Committee Report

The following report of the Compensation Committee shall not be deemed to this item is be "soliciting material" or to otherwise be considered "filed" with the SEC, nor shall such information be incorporated herein by reference into any future filing under the Securities Act of 1933 (the "Securities Act") or the Exchange Act except to our definitive the extent that the Company specifically incorporates it by reference into such filing.

Our Compensation Committee has reviewed and discussed the Compensation Discussion and Analysis contained in this proxy statement with respect management. Based on this review and discussion, our Compensation Committee recommended to our 2023 Annual Meeting Board of Stockholders Directors that the Compensation Discussion and Analysis be included in this proxy statement.

Members of the Compensation Committee

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Manmeet S. Soni (Chair)
Robert W. Duggan
Richard A. van den Broek

Overview of Compensation Program

This Compensation Discussion and Analysis describes the material elements of compensation awarded to, be filed earned by or paid to each of our executive officers named in the Compensation Table under “Remuneration of Executive Officers” (the “named executive officers” or “NEOs”) who served during the year ended December 31, 2023. This compensation discussion primarily focuses on the information contained in the following tables and related footnotes and narrative for the last completed fiscal year. We also describe compensation actions taken after the last completed fiscal year to the extent that it enhances the understanding of our executive compensation disclosure. The principles and guidelines discussed herein would also apply to any additional executive officers that the Company may hire in the future.

The Compensation Committee of the Board has responsibility for overseeing, reviewing and approving executive compensation and benefit programs in accordance with the SEC within 120 days after Compensation Committee’s charter. The members of the end Compensation Committee are Manmeet Soni, Robert Duggan and Richard van den Broek.

The principal duties and responsibilities of the Compensation Committee include:

- reviewing, modifying and approving our overall compensation strategy and policies, including: (a) reviewing and approving corporate goals and objectives relevant to the compensation of our executive officers and other senior management, as appropriate; (b) evaluating and approving, or recommending to the Board for approval, compensation plans and programs advisable for us, including modifications and terminations to those plans and programs; (c) establishing policies with respect to equity compensation arrangements; (d) assessing the adequacy and competitiveness of our executive compensation programs among comparable companies in our industry; and (e) reviewing and approving the terms of any employment agreements, severance arrangements, change-of-control protections and any other compensatory arrangement for our executive officers and other senior management, as appropriate;
- establishing and approving individual and corporate goals and objectives of our named executive officer and our other executive officers and senior management and evaluating performance of our named executive officer and our other executive officers and senior management, as appropriate, in light of these stated objectives;
- reviewing and approving the type and amount of compensation to be paid or awarded to Board members; and
- adopting, amending, administering, and terminating our equity compensation plans, bonus plans, deferred compensation plans, and similar programs.

Since 2016, from time to time, the Compensation Committee has obtained advice from third parties regarding peer group compensation and other attributes of executive compensation. In 2020, the Compensation Committee engaged Compensia as its compensation consultant. During our fiscal year ended on December 31, 2021, the Compensation Committee continued its engagement of Compensia to review our executive and director compensation policies and practices and to conduct a competitive market analysis of executive and director compensation. We engaged Compensia once again in November 2023 to conduct a competitive market analysis of executive compensation. In 2023 and 2024, Compensia provided the following assistance to the Compensation Committee:

- reviewed and updated the compensation peer group of comparable public companies for purposes of evaluating the compensation levels of our executive officers and non-employee directors;
- analyzed the compensation levels and practices of the companies in our compensation peer group;
- reviewed the competitiveness of compensation paid to our executive officers, including base salary, annual cash incentive awards and long-term incentive awards;
- reviewed and provided input on the design of the annual and long-term incentive compensation programs offered to our executive officers and other members of senior management; and
- provided ad hoc advice and support, including related to the severance and change of control provisions in our employment agreements, aggregate equity utilization (burn rate and overhang) and broad-based employee cash and equity compensation.

The Compensation Committee does not believe that its relationship with Compensia or the work of Compensia on behalf of the Compensation Committee has raised any conflict of interest. The Compensation Committee reviews these factors on an annual basis.

Generally, the Compensation Committee’s process for setting executive compensation comprises two related elements: the determination of compensation levels; and the establishment of performance objectives for the current year. The Compensation Committee generally makes adjustments to annual compensation, determines bonuses and equity awards and establishes new performance objectives at one or more meetings held near the beginning of the fiscal year. The Compensation Committee also considers matters related to individual compensation, such as compensation for new executive officer hires, as well as high-level strategic issues, such as the effectiveness of our compensation strategy, potential modifications to that strategy and new trends, plans or approaches to compensation, at various meetings throughout the year.

For executive officers other than our Chief Executive Officer, the Compensation Committee solicits and considers such executive officers’ performance evaluations and recommendations submitted to the Compensation Committee by our Chief Executive Officer. In addition, the Compensation Committee conducts an evaluation of the performance of both our Chief Executive Officer and our Chief Technology Officer, as he is also a director on our Board of Directors, and determines any adjustments to their compensation as well as awards to be granted. Based on those discussions and the exercise of its discretion, the Compensation Committee, without members of management present, discusses and ultimately approves the compensation of our executive officers. For all executive officers and directors, when making its compensation decisions, the Compensation Committee may review and consider, as appropriate, materials such as financial reports and projections, operational data, tax and accounting information, tally sheets that set forth the total compensation that may become payable to executive officers in various hypothetical scenarios, executive officer and director share ownership information, company share performance data, analyses of historical executive officer compensation levels and current company-wide compensation levels and

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recommendations of Compensia, the Compensation Committee's compensation consultant, including analyses of executive officer and director compensation paid at the companies comprising the compensation peer group. The Compensation Committee may also form and delegate authority to subcommittees as it deems appropriate.

Executive Compensation

The following is a discussion and analysis of compensation arrangements of our named executive officers. This discussion contains forward looking statements that are based on our current plans, considerations, expectations, and determinations regarding future compensation programs. Actual compensation programs that we adopt may differ materially from currently planned programs as summarized in this discussion.

We seek to ensure that the total compensation paid to our executive officers is reasonable and competitive. Compensation of our executives is structured around the achievement of individual performance and near-term corporate targets as well as long-term business objectives.

Our named executive officers for fiscal year 2023 were our principal executive officer and our next two most highly compensated executive officers who were serving as executive officers as of December 31, 2023, namely:

- Kevin P. Danahy, our Chief Executive Officer;
- Darrin R. Uecker, our Chief Technology Officer and a director; and
- Mitchell E. Levinson, our Chief Strategy Officer.

In December 2022, the Compensation Committee concluded that none of the Company's 2022 corporate objectives had been achieved and decided to award no 2022 cash bonuses.

In March 2023, to encourage employee retention through the Company's change in strategic focus, the Compensation Committee awarded all Company employees, other than our Chief Executive Officer and Chief Technology Officer, a spot bonus equal to 8% of each employee's base salary. Each of these bonuses was paid in three equal installments on June 30, 2023, September 30, 2023, and December 31, 2023, provided the recipient remained an employee through the applicable payment date.

In September 2023, the Board of Directors awarded $300,000, as a 2023 bonus prepayment, to each of our Chief Executive Officer and Chief Technology Officer in recognition of the Company's exceptional progress towards successfully completing its 2023 corporate objectives. Thereafter, in December 2023, the Compensation Committee concluded that 100% of the Company's 2023 corporate objectives had been achieved and decided to award 2023 cash bonuses in full, which bonuses were paid in 2024 other than the prepayments in September 2023.

Summary Compensation Table

The following table provides information regarding the compensation of our principal executive officer, and our next two most highly compensated executive officers, who were serving as executive officers of the Company as of December 31, 2023.

Name and principal position	Year	Salary ($)	Bonus ($)	Stock Awards ($)(1)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Kevin P. Danahy	2023	433,333	399,973 (2)	—	5,029,724	1,420	5,864,450
Chief Executive Officer	2022	350,038	—	—	1,912,015 (3)	1,203	2,263,256
Darrin R. Uecker	2023	433,333	399,973 (2)	—	4,555,302	1,420	5,390,028
Chief Technology Officer and Director	2022	485,909	—	—	—	1,326	487,235
Mitchell E. Levinson	2023	369,563	213,582 (4)	—	1,109,997	1,420	1,694,562
Chief Strategy Officer and Director	2022	360,000	—	—	—	1,338	361,338

(1) Amounts shown represent the aggregate grant date fair value of the restricted stock units and option awards computed in accordance with FASB ASC Topic 718. These amounts do not correspond to the actual value that will be realized by our named executive officers. The assumptions used in the valuation of these awards are consistent with the valuation methodologies specified in the notes to our financial statements.

(2) Reflects prepayment of 2023 bonus potential by the Company's Board of Directors.

(3) Reflects Mr. Danahy's new hire option award and the award he received upon his appointment as our Chief Executive Officer.

(4) Reflects 2023 retention bonus.

Outstanding Equity Awards at Fiscal Year-End

The following table presents certain information concerning equity awards held by our principal executive officer and our next two most highly compensated executive officers who were serving as executive officers of the Company as of December 31, 2023.

	Option Awards	Stock Awards

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Name	Number of securities underlying outstanding options (#)			Option exercise price ($/sh)	Option expiration date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	**Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)**	**Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)**
	Exercisable	Unexercisable	Unexercisable and Unearned						
Kevin P. Danahy	25,000 (1)	—	75,000 (1)	6.41	2/14/2032	—	—	—	—
	—	—	50,000 (1)	6.41	2/14/2032	—	—	—	—
	112,500	—	337,500 (1)	1.53	9/23/2032	—	—	—	—
	50,000	—	50,000 (2)	6.41	2/14/2032	—	—	—	—
	—	—	50,000 (3)	6.41	2/14/2032	—	—	—	—
	—	—	500,000 (3)	6.44	4/29/2033	—	—	—	—
	—	—	200,000 (3)	7.08	7/12/2033	—	—	—	—
	—	—	460,000 (6)	4.38	11/1/2033	—	—	—	—
Darrin R. Uecker	281,534	—	—	4.00	9/20/2025	—	—	—	—
	195,000	—	—	30.99	6/7/2027	—	—	—	—
	187,286	—	—	30.99	6/7/2027	—	—	—	—
	27,375	—	27,375 (2)	24.03	3/22/2031	—	—	—	—
	37,500	—	— (5)	10.66	5/18/2030	—	—	—	—
	—	—	500,000 (3)	6.44	4/29/2033	—	—	—	—
	—	—	200,000 (3)	7.08	7/12/2033	—	—	—	—
	—	—	330,000 (6)	4.38	11/1/2033	—	—	—	—
Mitchell E. Levinson	20,000	—	— (2)	18.69	5/20/2031	—	—	—	—
	45,987	—	— (2)	18.69	5/20/2031	—	—	—	—
	6,201	—	12,404 (2)	21.12	8/19/2031	—	—	—	—
	35,000	—	— (4)	18.25	3/18/2029	—	—	—	—
	4,716	—	9,434 (2)	21.12	8/19/2031	—	—	—	—
	15,000	—	— (4)	13.03	5/16/2029	—	—	—	—
	15,901	—	— (4)	10.66	5/18/2030	—	—	—	—
	20,000	—	— (4)	10.66	5/18/2030	—	—	—	—
	16,378	—	16,377 (2)	21.12	8/19/2031	—	—	—	—
	8,750	—	26,250 (2)	2.92	3/22/2033	—	—	—	—
	4,425	—	13,275 (2)	8.02	5/8/2033	—	—	—	—
	—	—	100,000 (3)	7.08	7/12/2033	—	—	—	—
	—	—	100,000 (6)	4.38	11/1/2033	—	—	—	—

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	2,000	—	— (5)	5.81	4/17/2033	—	—	—	—

(1) Grant consisting of 100% time-based vesting option grants.

(2) Performance-based vesting stock option grants of which a portion of the performance criteria have been achieved.

(3) Performance-based vesting stock option grants of which no performance criteria have been achieved.

(4) Board service grants pursuant to the Company's Amended and Restated Outside Director Compensation Policy.

(5) Fully vested stock option grants.

(6) Stock options will vest in full automatically upon the earlier to occur of (i) the six (6) year anniversary of the grant date, and (ii) the 1-year anniversary of a Change in Control, as defined by the Company's 2017 Equity Incentive Plan; provided, however, that no Change in Control shall be found to exist for purposes of vesting of the Awards if the primary purpose of the persons investing in the Company is principally to provide working capital financing, and not to acquire a controlling interest in the Company, notwithstanding whether the sum of such investment, after the financing, equals or exceeds 50% of the ownership of the Company.

Pay Versus Performance

As required by Section 953(a) of the Dodd-Frank Wall Street Reform and Consumer Protection Act and Item 401(v) of Regulation S-K, we are providing the following information about the relationship between executive compensation actually paid (as defined by SEC rules) and certain financial performance of the Company. The Compensation Committee did not consider the pay versus performance information presented in this section when making its compensation decisions for either of the years shown. For further information about how we align executive compensation with the Company's performance, please refer to the Compensation Discussion and Analysis, above. The amounts in the tables below are calculated in accordance with SEC rules and do not represent amounts actually earned or realized by our NEOs.

The following table sets forth the compensation for our principal executive officers (our "PEOs") and the average compensation for certain of our other NEOs, each as reported in the Summary Compensation Table and with certain adjustments to reflect Compensation Actually Paid ("CAP"), as defined under the SEC rules. The table also provides information with respect to Cumulative Total Shareholder Return ("TSR") and Net Income.

Year	Summary Compensation Table Total for PEO	Compensation Actually Paid to PEO	Average Summary Compansation Table Total for Non-PEO NEOs	Average Summary Compansation Actually Paid to Non-PEO NEOs	Value of Initial Fixed $100 Investment Based On: Total Shareholder Return(3)	Net Loss (in thousands)
(a)	(b)	(c)	(d)	(e)	(f)	(h)
2023	$ 12,949,040	$ (1,279,489)	$ 3,779,506	$ 2,946,661	$ 51.30	$ (42,210)
2022	$ 1,005,904	$ (766,432)	$ 1,052,964	$ (837,429)	$ 11.61	$ (58,505)
2021	$ 2,286,036	$ 1,312,304	$ 1,062,416	$ 765,510	$ 62.07	$ (63,660)

(1) Mr. Kevin Danahy, our Chief executive Officer, was our PEO for 2023. Our non-PEO NEOs for 2023 were Mr. Darrin Uecker, our Chief Technology Officer, and Mr. Mitchell Levinson, our Chief Strategy Officer.

(2) The amounts shown for Compensation Actually Paid have been calculated in accordance with 402(v) of Regulation S-K and do not reflect compensation actually earned, realized, or received by the PEOs and non-PEO NEOs. The amounts reflect the Summary Compensation Table with certain adjustments as detailed in the table below.

	2023		2022		2021	
	PEO	Non-PEO NEO	PEO	Non-PEO NEO	PEO	Non-PEO NEO
Summary Compensation Table ("SCT") Total	$ 5,864,450	$ 3,542,295	$ 1,005,904	$ 1,052,964	$ 2,286,036	$ 1,062,416
(Subtract): Aggregate value for stock awards and option awards included in SCT amounts for the covered fiscal year	$ (5,029,724)	$ (2,832,649)	$ (519,615)	$ (1,392,400)	$ (1,774,614)	$ (930,748)
Add: Fair value at year end of awards granted during the covered fiscal year that were outstanding and unvested at the covered fiscal year end	$ 4,032,260	$ 2,267,040	$ 999,900	$ 415,914	$ 954,621	$ 633,842
(Subtract): Year-over-year change in fair value at covered fiscal year end of awards granted in any prior fiscal year that were outstanding and unvested at the covered fiscal year end	$ (4,878,900)	$ (132,033)	$ -	$ (842,516)	$ -	$ -
Add: Vesting date fair value of awards granted and vested during the covered fiscal year	$ -	$ 150,324	$ -	$ -	$ -	$ -

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(Subtract): Change as of the vesting date (from the end of the prior fiscal year) in fair value of awards granted in any prior fiscal year for which vesting conditions were satisfied during the covered fiscal year	$ (157,125)	$ (24,246)	$ (94,673)	$ (71,392)	$ (153,739)	$ -
(Subtract): Fair value at end of prior fiscal year of awards granted in any prior fiscal year that failed to meet the applicable vesting conditions during the covered fiscal year	$ (1,110,450)	$ (24,069)	$ (2,157,948)	$ -	$ -	$ -
	$ (1,279,489)	$ 2,946,661	$ (766,432)	$ (837,429)	$ 1,312,304	$ 765,510

(3) Total Shareholder Return assumes $100 was invested in our Common Shares on December 31, 2020.

Analysis of the Information Presented in the Pay Versus Performance Tables

We do not link our PEO and NEO compensation to the Company's financial and stock price performance. Instead we link a significant portion of their compensation to the achievement of key product development milestones.

For purposes of this disclosure, there were no financial performance measures used to link Company performance to Compensation Actually Paid to our PEOs and non-PEO NEOs in 2023.

All information provided under the "Pay Versus Performance" heading will not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing, except to the extent the Company specifically incorporates such information by reference.

Employment Agreement with Kevin P. Danahy (Chief Executive Officer)

We entered into an employment agreement with Mr. Danahy on February 9, 2022, when he joined the Company as our Chief Commercial Officer. We then amended Mr. Danahy's employment agreement on September 20, 2022, when the Board appointed him as our Chief Executive Officer. Mr. Danahy's employment agreement, as amended, has no specific term and constitutes at-will employment. His current annual base salary is $525,000. Presently, Mr. Danahy is eligible for an annual target bonus equal to 70% of his annual base salary, subject to achievement of performance objectives. Mr. Danahy is also eligible to participate in employee benefit plans maintained from time to time by us of general applicability to other senior executives.

Mr. Danahy's original employment agreement provided him the right to receive an option to purchase up to 300,000 shares of our common stock (the "Danahy Start Date Option"). On September 20, 2022, Mr. Danahy and the Company entered into an amendment agreement (the "Danahy Amendment"), pursuant to which he received an additional option to purchase up to 450,000 shares of our common stock (the "Danahy CEO Option"). Under Mr. Danahy's employment agreement, as amended, the Danahy Start Date Option will vest according to the following schedule provided he continues to provides services to the Company as a Service Provider, as defined by the Company's equity plans, through each such vesting date: (a) 1/3 of the option shares granted (100,000 option shares) will vest in four equal installments on each of the first four annual anniversaries of his Start Date, *i.e.*, February 9, 2022, (b) 1/3 of the option shares (100,000 option shares) will vest upon the achievement of performance objectives established in good faith by the Compensation Committee, with vesting targets set at 25% (*i.e.*, 25,000 option shares each) on each of the first four annual anniversaries of the Start Date, (c) 1/6 of the option shares (50,000 option shares) will vest in two equal installments on each of the third and fourth annual anniversaries of the Start Date, and (d) 1/6 of the option shares (50,000 option shares) will vest upon in two equal installments on each of the third and fourth annual anniversaries of the Start Date upon the achievement of performance objectives established in good faith by the Compensation Committee. In contrast, the Danahy CEO Option has time-based vesting provisions and will vest in equal installments over four years on each anniversary of the amendment date, subject to his continuing service to the Company. However, pursuant to his employment agreement, if Mr. Danahy's employment is involuntary terminated within twelve months following a Company "change of control," as such term is defined in his applicable option agreements, 100% of his unvested equity awards then outstanding will fully vest and become exercisable. If his employment is involuntarily terminated not in connection with a Company change of control, then the vesting of his outstanding equity awards that would normally vest over the following twelve-month period will immediately accelerate and fully vest prior to his termination.

If we terminate Mr. Danahy's employment other than for "cause," death, or disability or if he resigns for "good reason," as defined in his employment agreement, then, subject to his execution of a release of claims in our favor and Mr. Danahy's compliance with certain restrictive covenants set forth in his employment agreement Mr. Danahy is entitled to receive (i) continuing payments of his then-current base salary for a period of twelve months following his termination of employment, less applicable withholdings, (ii) accelerated vesting as to that portion of his then outstanding and unvested options that would have vested had he remained an employee for twelve months following his termination date, or accelerated vesting of 100% of his unvested options if he is involuntarily terminated within twelve months following a Company "change of control," as defined by his employment agreement, and (iii) reimbursement of premiums to maintain group health insurance continuation benefits pursuant to "COBRA" for Mr. Danahy and his respective dependents until the earlier of (A) Mr. Danahy or his eligible dependents become covered under similar plans, or (B) the date upon which Mr. Danahy ceases to be eligible for coverage under COBRA.

As defined in Mr. Danahy's employment agreement, as amended, "cause" means Mr. Danahy's (i) conviction of, or plea of nolo contendere to, a felony or any crime involving fraud, embezzlement or any other act of moral turpitude, (ii) gross misconduct, (iii) unauthorized use or disclosure of any proprietary information or trade secrets of the Company or any other party to whom Mr. Danahy owes an obligation of nondisclosure as a result of Mr. Danahy relationship with the Company; (iv) willful breach of any obligations under any written agreement or covenant with the Company that is injurious to the Company; or (v) continued failure to perform his employment duties after

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Mr. Danahy has received a written demand of performance from the Company which specifically sets forth the factual basis for the Company's belief that Mr. Danahy has not substantially performed his duties and has failed to cure such non-performance to the Company's satisfaction within 30 business days after receiving such notice.

As defined in Mr. Danahy's employment agreement, as amended, "good reason" means Mr. Danahy's resignation within 30 days following the expiration of any Company cure period (discussed below) following the occurrence of one or more of the following, without Mr. Danahy's express written consent: (i) the assignment to Mr. Danahy of any duties beyond the generally recognized scope of employment of a company chief executive officer or the reduction of Mr. Danahy's duties or the removal of Mr. Danahy from his position and responsibilities as chief executive officer, either of which must result in a material diminution of Mr. Danahy's authority, duties, or responsibilities with the Company in effect immediately prior to such assignment; provided, however, if Mr. Danahy is provided with an alternative executive type position within the Company or its subsidiaries at the same or better compensation as proved herein or that a reduction in duties, position or responsibilities solely by this Annual Report virtue of the Company being acquired and made part of a larger entity will not constitute "good reason"; (ii) a material reduction in Mr. Danahy's base salary (except where there is a reduction applicable to the management team generally of not more than 10% of Mr. Danahy's base salary); or (iii) a material change in the geographic location of Mr. Danahy's primary work facility or location; provided, that a relocation of less than 50 miles from Mr. Danahy's then present work location will not be considered a material change in geographic location. Mr. Danahy will not resign for good reason without first providing the Company with written notice of the acts or omissions constituting the grounds for "good reason" within 90 days of the initial existence of the grounds for "good reason" and a reasonable cure period of not less than 30 days following the date of such notice and such grounds for "good reason" have not been cured during such cure period.

In the event any payment to Mr. Danahy pursuant to his employment agreement would be subject to the excise tax imposed by Section 4999 of the Code as a result of a payment being classified as a parachute payment under Section 280G of the Code, Mr. Danahy will receive such payment as would entitle him to receive the greatest after-tax benefit, even if it means that we pay him a lower aggregate payment so as to eliminate the potential excise tax imposed by Section 4999 of the Code.

Mr. Danahy has also entered into our standard inventions assignment, confidentiality and non-competition agreement and our standard indemnification agreement for officers and directors.

Employment Agreement with Darrin R. Uecker (Chief Technology Officer)

We entered into an employment agreement with Mr. Uecker on Form 10-K. September 8, 2015, when he joined the Company as our President and Chief Executive Officer. We then amended Mr. Uecker's employment agreement on October 5, 2016, in advance of our initial public offering of shares. We again amended Mr. Uecker's employment agreement on September 20, 2022, when the Board appointed him as our Chief Technology Officer, so that he could focus his efforts on new product development in cardiology. Mr. Uecker's employment agreement, as amended, has no specific term and constitutes at-will employment. His current annual base salary is $525,000. Presently, Mr. Uecker is eligible for an annual target bonus equal to 70% of his annual base salary, subject to achievement of performance objectives. Mr. Uecker is also eligible to participate in employee benefit plans maintained from time to time by us of general applicability to other senior executives.

Mr. Uecker's employment agreement provided him the right to receive an option to purchase shares of our common stock equal to 3% of our fully diluted equity as of September 8, 2015 (the "Uecker Start Date Option"), and the right to receive an option to purchase shares of our common stock subsequent to the completion of the then planned IPO such that, including the Uecker Start Date Option, Mr. Uecker would hold options to purchase shares equal to 3% of our post-IPO fully diluted equity (the "IPO Option"). On October 5, 2016, Mr. Uecker and our Company entered into an amendment agreement (the "Uecker Amendment"), pursuant to which Mr. Uecker agreed to forgo receipt of the IPO Option until our stockholders approve a new equity incentive plan or an increase in the number of shares available under our 2015 Equity Incentive Plan. Pursuant to the Uecker Amendment, in exchange for Mr. Uecker forgoing receipt of the IPO Option, Mr. Uecker received (i) an option grant to purchase 187,286 shares of our common stock, which is a number of shares equal to the number of shares he would have been entitled to receive upon completion of the IPO, and (ii) a restricted stock grant with a grant date fair value equal to the product of (A) (i) the exercise price per share of the deferral grant, less (ii) $4.00 per share, multiplied by (B) 187,286. In the event of a change in control that precedes the aforementioned option grant while Mr. Uecker is still an employee of our Company, Mr. Uecker would be entitled to receive a cash bonus equal to the consideration he would have received as a holder of a vested option to purchase 187,286 shares of our common stock at an exercise price of $4.00 per share. Pursuant to Mr. Uecker's employment agreement, if we experience a change of control, as such term is defined in Mr. Uecker's applicable option agreement, and Mr. Uecker remains an employee through the date of such change of control, the Uecker Start Date Option and IPO Option, to the extent outstanding and unvested, will fully vest and become exercisable. The Uecker Start Date Option and IPO Option will be exercisable for a 10-year period after the start date of employment.

If we terminate Mr. Uecker's employment other than for "cause," death, or disability or if he resigns for "good reason," as defined in his employment agreement, then, subject to his execution of a release of claims in our favor and Mr. Uecker's compliance with certain restrictive covenants set forth in his employment agreement Mr. Uecker is entitled to receive (i) continuing payments of Mr. Uecker's then-current base salary for a period of 12 months following his termination of employment, less applicable withholdings, (ii) accelerated vesting as to that portion of Mr. Uecker's then outstanding and unvested options that would have vested had Mr. Uecker remained an employee for twelve months following his termination date, and (iii) reimbursement of premiums to maintain group health insurance continuation benefits pursuant to "COBRA" for Mr. Uecker and his respective dependents until the earlier of (A) Mr. Uecker or his eligible dependents become covered under similar plans, or (B) the date upon which Mr. Uecker ceases to be eligible for coverage under COBRA.

As defined in Mr. Uecker's employment agreement, as amended, "cause" means Mr. Uecker's (i) conviction of, or plea of nolo contendere to, a felony or any crime involving fraud, embezzlement or any other act of moral turpitude, (ii) gross misconduct, (iii) unauthorized use or disclosure of any proprietary information or trade secrets of the Company or any other party to whom Mr. Uecker owes an obligation of nondisclosure as a result of Mr. Uecker relationship with the Company; (iv) willful breach of any obligations under any written agreement or covenant with the Company that is injurious to the Company; or (v) continued failure to perform his employment duties after Mr. Uecker has received a written demand of performance from the Company which specifically sets forth the factual basis for the Company's belief that Mr. Uecker has not substantially performed his duties and has failed to cure such non-performance to the Company's satisfaction within 30 business days after receiving such notice.

As defined in Mr. Uecker's employment agreement, as amended, "good reason" means Mr. Uecker's resignation within 30 days following the expiration of any Company cure period (discussed below) following the occurrence of one or more of the following, without Mr. Uecker's express written consent: (i) the assignment to Mr. Uecker of any

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duties beyond the generally recognized scope of employment of a company chief technology officer or the reduction of Mr. Uecker's duties or the removal of Mr. Uecker from his position and responsibilities as chief techology officer, either of which must result in a material diminution of Mr. Uecker's authority, duties, or responsibilities with the Company in effect immediately prior to such assignment; provided, however, if Mr. Uecker is provided with an alternative executive type position within the Company or its subsidiaries at the same or better compensation as proved herein or that a reduction in duties, position or responsibilities solely by virtue of the Company being acquired and made part of a larger entity will not constitute "good reason"; (ii) a reduction in Mr. Uecker's base salary (except where there is a reduction applicable to the management team generally of not more than 10% of Mr., Uecker's base salary); or (iii) a material change in the geographic location of Mr. Uecker's primary work facility or location; provided, that a relocation of less than 50 miles from Mr. Uecker's then present work location will not be considered a material change in geographic location. Mr. Uecker will not resign for good reason without first providing the Company with written notice of the acts or omissions constituting the grounds for "good reason" within 90 days of the initial existence of the grounds for "good reason" and a reasonable cure period of not less than 30 days following the date of such notice and such grounds for "good reason" have not been cured during such cure period.

In the event any payment to Mr. Uecker pursuant to his employment agreement would be subject to the excise tax imposed by Section 4999 of the Code as a result of a payment being classified as a parachute payment under Section 280G of the Code, Mr. Uecker will receive such payment as would entitle him to receive the greatest after-tax benefit, even if it means that we pay him a lower aggregate payment so as to eliminate the potential excise tax imposed by Section 4999 of the Code.

Mr. Uecker has also entered into our standard inventions assignment, confidentiality and non-competition agreement and our standard indemnification agreement for officers and directors.

Employment Agreement with Mitchell E. Levinson (Chief Strategy Officer)

We entered into an employment agreement with Mr. Levinson on August 19, 2021, when he joined the Company as our Chief Strategy Officer. The employment agreement has no specific term and constitutes at-will employment. Mr. Levinson's current annual base salary is $389,380. Presently, Mr. Levinson is eligible for an annual target bonus equal to 50% of his annual base salary, prorated for the year of hire, subject to achievement of performance objectives set and measured in the good faith of our board of directors. Mr. Levinson is eligible to participate in employee benefit plans maintained from time to time by us of general applicability to other senior executives.

Immediately prior to his appointment as an executive officer, Mr. Levinson resigned from our board of director's Sciences and Technology Committee and Compensation Committee, and the Science and Technology Committee has since been dissolved. Mr. Levinson continues to serve as a Company director, however, because he is no longer considered to be an independent director, he no longer receives compensation for his board service.

Mr. Levinson's employment agreement provided him the right to receive an option to purchase up to 65,510 shares of our Common (the "Levinson Start Date Option"). The Levinson Start Date Option is exercisable for a 10-year period after the start date of employment. Subject to certain accelerated vesting provisions as described herein, the options provided by the Levinson Start Date Option will vest as follows: (a) 50% of the option shares granted (32,755 option shares) will vest in three equal installments (10,918 option shares) on the second, third and fourth anniversary of the start date and (b) 50% of the option shares (32,755 option shares) will vest upon the achievement of performance objectives established in good faith by the Compensation Committee of the board of directors, with vesting targets set at 25% (8,188 option shares) on each annual anniversary of the Start Date. All vesting is subject to Mr. Levinson's continuing to be a Service Provider (as defined in our 2017 Equity Incentive Plan) through each applicable vesting date and vesting target achievement determination date.

If we terminate Mr. Levinson's employment other than for "cause," death, or disability or if he resigns for "good reason" as defined in his employment agreement, then, subject to his execution of a release of claims in our favor and Mr. Levinson's compliance with certain restrictive covenants set forth in his employment agreement, Mr. Levinson is entitled to receive (i) continuing payments of Mr. Levinson's then-current base salary for a period of 6 months following his termination of employment (3 months if the involuntary termination or resignation for good reason occurs within less than one year from the start date), less applicable withholdings, (ii) Mr. Levinson's annual target bonus for the year of termination, prorated for the portion of the year served assuming 100% achievement, , (iii) reimbursement of premiums to maintain group health insurance continuation benefits pursuant to "COBRA" for Mr. Levinson and his respective dependents until the earlier of (A) Mr. Levinson or his eligible dependents become covered under similar plans, or (B) the date upon which Mr. Levinson ceases to be eligible for coverage under COBRA, and (iv) accelerated vesting as to that portion of Mr. Levinson's then outstanding and unvested options that would have vested had he remained an employee for twelve months following his termination date, except in the event of involuntary termination following a Company change of control. If the involuntary termination occurs within the twelve (12) month period following a Company change of control, then (i) if the employment term as of the date of such termination is less than one year from the Start Date, then 50% of the unvested portion of Mr. Levinson's then outstanding equity awards will immediately vest prior to his termination, and (ii) if the employment term as of the date of such termination is one year or more from the start date, then the unvested portion of Mr. Levinson's then outstanding equity awards will immediately vest prior to his termination.

As defined in his employment agreement, "cause" means Mr. Levinson's (i) conviction of, or plea of nolo contendere to, a felony or any crime involving fraud, embezzlement or any other act of moral turpitude, (ii) gross misconduct, (iii) unauthorized use or disclosure of any proprietary information or trade secrets of the Company or any other party to whom he owes an obligation of nondisclosure as a result of his relationship with the Company; (iv) willful breach of any obligations under any written agreement or covenant with the Company that is injurious to the Company; or (v) his continued failure to perform his employment duties after he has received a written demand for performance from the Company which specifically sets forth the factual basis for the Company's belief that he has not substantially performed his duties and has failed to cure such non-performance to the Company's satisfaction within thirty (30) business days after receiving such notice.

As defined in his employment agreement, "good reason" means Mr. Levinson's resignation within thirty (30) days following the expiration of any Company cure period (discussed below) following the occurrence of one or more of the following, without his express written consent: (i) the assignment to Mr. Levinson of any duties beyond the generally recognized scope of employment of a company Chief Strategy Officer or the reduction of his duties or the removal of Mr. Levinson from his position and responsibilities as Chief Strategy Officer, either of which must result in a material diminution of his authority, duties, or responsibilities with the Company in effect immediately prior to such assignment; provided, however, if the he is provided with an alternative executive type position within the Company or its subsidiaries at the same or better compensation as proved herein or that a reduction in duties, position or responsibilities solely by virtue of the Company being acquired and made part of a larger entity will not

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constitute “Good Reason”; (ii) a reduction in Mr. Levinson’s base salary (except where there is a reduction applicable to the management team generally of not more than 10% of Executive’s base salary); or (iii) a material change in the geographic location of Executive’s primary work facility or location; provided, that a relocation of less than fifty (50) miles from Executive’s then present work location will not be considered a material change in geographic location. Executive will not resign for Good Reason without first providing the Company with written notice of the acts or omissions constituting the grounds for “Good Reason” within ninety (90) days of the initial existence of the grounds for “Good Reason” and providing a cure period of not less than thirty (30) days following the date of such notice and such grounds for “Good Reason” have not been cured during such cure period.

In the event any payment to Mr. Levinson pursuant to his employment agreement would be subject to the excise tax imposed by Section 4999 of the Code as a result of a payment being classified as a parachute payment under Section 280G of the Code, Mr. Levinson will receive such payment as would entitle him to receive the greatest after-tax benefit, even if it means that we pay him a lower aggregate payment so as to eliminate the potential excise tax imposed by Section 4999 of the Code.

Mr. Levinson has also entered into our standard inventions assignment, confidentiality and non-competition agreement and our standard indemnification agreement for officers and directors.

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 The following table sets forth certain information as of March 20, 2024 with respect to the beneficial ownership of our 2023 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end common stock by (i) each person we believe beneficially holds more than 5% of the fiscal year covered outstanding shares of our common stock based solely on our review of SEC filings or information provided to us by this Annual Report such person; (ii) each director and nominee; (iii) each named executive officer listed in the table entitled, “Summary Compensation Table” under the section entitled, “Executive Compensation;” and (iv) all directors and executive officers as a group. As of March 20, 2024, there were 55,225,333 shares of our common stock issued and outstanding. Unless otherwise indicated, all persons named as beneficial owners of our common stock have sole voting power and sole investment power with respect to the shares indicated as beneficially owned. Unless otherwise noted below, the address of each stockholder listed on Form 10-K. the table is c/o Pulse Biosciences, Inc., 3957 Point Eden Way, Hayward, California 94545.

Name of beneficial owner	Number of Shares Owned(1)	Right to Acquire Shares(2)	Total Beneficial Ownership	Percent of Class(3)
5% Stockholders:				
Robert W. Duggan(4)	37,827,813	162,439	37,990,252	68.6 %
Named executive officers and directors:				
Kevin P. Danahy	35,887	212,500	248,387	(*)
Robert W. Duggan(4)	37,827,813	162,439	37,990,252	68.6 %
Mitchell E. Levinson(5)	100,229	194,358	294,587	(*)
Manmeet S. Soni	—	307,218	307,218	(*)
Shelley D. Spray	—	99,560	99,560	(*)
Darrin R. Uecker	151,461	742,382	893,843	1.6 %
Richard A. van den Broek	—	200,473	200,473	(*)
Mahkam Zanganeh, D.D.S.(6)	752,985	217,130	970,115	1.7 %
All executive officers and directors as a group (8 people)	38,868,375	2,136,060	41,004,435	71.5 %

(*) Represents beneficial ownership of less than 1% of the outstanding shares of our common stock.

(1) Excludes shares that may be acquired through the exercise of outstanding stock options or the vesting of restricted stock units or other equity awards

(2) Represents shares issuable within 60 days after December 31, 2023 upon exercise of exercisable options; however, unless otherwise indicated, these shares do not include any equity awards awarded after December 31, 2023.

(3) For purposes of calculating the Percent of Class, shares that the person or entity had a right to acquire are deemed to be outstanding when calculating the Percent of Class of such person or entity.

(4) Based on information obtained from Mr. Duggan. Includes 351,565 shares owned by Genius Inc. and 492,069 shares owned by Blazon Corporation, both of which Mr. Duggan is the sole stockholder.

(5) Includes (a) 9,135 shares owned by Andrea Bloom, Mr. Levinson’s spouse, and (b) 10,741 shares owned by four other immediate family members.

(6) Includes (a) 27,000 shares owned by Mahin Zanganeh, Dr. Zanganeh’s mother, (b) 14,000 shares are owned by Mahshad Zanganeh, Dr. Zanganeh’s sister, and (c) 107,074 shares owned by a dependent minor.

Equity Compensation Plan Information

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The following table presents information about our equity compensation plans as of December 31, 2023:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	**Weighted average exercise price of outstanding options, warrants and rights ($)**	Number of securities remaining available for future issuance under equity compensation plans excluding securities reflected in column (a)
Equity compensation plans approved by security holders(1)	8,749,143	8.93	1,457,133
Equity compensation plans not approved by security holders(2)	700,893	10.04	1,249,126

(1) Includes the following plans: the 2017 Equity Incentive Plan (the "Equity Incentive Plan") and the 2017 Employee Stock Purchase Plan (the "ESPP"). Our Equity Incentive Plan provides that the number of shares available for issuance thereunder will be increased on the first day of each fiscal year beginning with the 2018 fiscal year in an amount equal to the least of (i) 1,200,000 shares, (ii) 4% of the outstanding shares of our common stock as of December 31 of the immediately preceding year, or (iii) such number of shares as determined by our Board of Directors. On January 1, 2023, the number of shares available for issuance under the Equity Incentive Plan increased by 1,200,000 shares pursuant to these provisions and, on December 19, 2023, the number of shares available for issuance under the Equity Incentive Plan increased by 1,375,000 shares pursuant to a special stockholder vote. These increases are reflected in the table above. On January 1, 2024, the number of shares available for issuance under the Equity Incentive Plan increased by an additional 1,200,000 shares pursuant to the Equity Incentive Plan's provisions. This increase is not reflected in the table above. Our ESPP provides that the number of shares available for issuance thereunder will be increased on the first day of each fiscal year beginning with the 2018 fiscal year in an amount equal to the least of (i) 450,000 shares, (ii) 1.5% of the outstanding shares of our common stock as of December 31 of the immediately preceding year, or (iii) such number of shares as determined by our Board of Directors. In December 2022, our Board of Directors elected not to permit an increase to the number of shares available for issuance under our ESPP. However, on January 1, 2024, the number of shares available for issuance under the ESPP increased by 450,000 shares pursuant to the ESPP's provisions.

(2) Consists of the Company's 2017 Inducement Equity Incentive Plan (the "Inducement Plan"), which was adopted by our Board of Directors. We initially reserved 1,000,000 shares of our common stock for issuance pursuant to equity awards granted under the Inducement Plan. On May 20, 2021, the Board approved an amendment to the Inducement Plan to increase the number of shares reserved for issuance by an additional 1,000,000 shares. This increase is reflected in the table above. In March 2024, the Board approved a second amendment to the Inducement Plan to reserve an additional 2,000,000 shares of the Company's common stock for issuance pursuant to the Inducement Plan. This increase is not reflected in the table above.

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

Information responsive Policies and Procedures for Related Party Transactions

We have adopted a formal written policy that our executive officers, directors, nominees for election as directors, beneficial owners of more than 5% of any class of our common stock, and any member of the immediate family of any of the foregoing persons are not permitted to enter into a related party transaction with us, where the aggregate amount involved will or may be expected to exceed $120,000 in any calendar year, without the prior consent of our Audit Committee, subject to the pre-approval exceptions described below. If advance approval is not feasible, then the related party transaction will be considered at the Audit Committee's next regularly scheduled meeting. In approving or rejecting any such proposal, our Audit Committee considers the facts and circumstances available and deemed relevant by our Audit Committee, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related party's interest in the transaction. Our Audit Committee has reviewed certain types of related party transactions that it has deemed pre-approved even if the aggregate amount involved will exceed $120,000, including employment of executive officers, director compensation, certain transactions with other organizations at which a related party's only relationship is as a non-executive employee, director or beneficial owner of less than 10% of that organization's shares, transactions where all stockholders receive proportional benefits, transactions involving competitive bids, regulated transactions, and certain banking-related services.

Related Party Transactions

In addition to the compensation arrangements, including employment, termination of employment and change in control arrangements discussed in this item Proxy Statement in the sections titled "Director Compensation" and "Executive Compensation," we describe below transactions and series of similar transactions, since the beginning of our last fiscal year, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed $120,000; and
- any of our directors, nominees for director, executive officers, or holders of more than 5% of our outstanding capital stock, or any immediate family member of, or person sharing the household with, any of these individuals or entities, had or will have a direct or indirect material interest.

D&O Insurance

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 agreed with the Company to personally provide indemnity coverage for a one-year period. The Company paid a fee of $1.0 million to Mr. Duggan on May 31, 2023, the last day of the one-year period, in consideration of the obligations set forth in the Letter Agreement.

In May 2023, the Company secured director and officer liability insurance from third-party insurance carriers through a brokered transaction.

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Duggan Term Loan

In September 2022 we entered into the 2022 Loan Agreement with Robert W. Duggan, our majority stockholder and Executive Chairman, in connection with Mr. Duggan lending the principal sum of $65.0 million to the Company. The Loan Agreement bore 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 amended certain terms of the Loan Agreement. There were no changes to the interest rate, but the principal sum repayment date was changed to September 30, 2024. During the year ended December 31, 2023, we made cash payments of $1.7 million for accrued interest on the loan, and recorded an additional $1.1 million of interest expense in relation to the 2022 Loan Agreement. On April 30, 2023, we entered into a Securities Purchase Agreement with Mr. Duggan, pursuant to which the Company agreed to issue and sell to Mr. Duggan 10,022,937 shares of the Company's common stock, par value $0.001 per share, in a Private Placement, at a price per share of $6.51. These shares were paid for through the cancellation of the amounts then owed by us under the 2022 Loan Agreement, the principal sum of $65.0 million and all accrued and unpaid interest outstanding, which totaled approximately $0.2 million as of April 30, 2023. The parties completed the Private Placement on May 9, 2023 and, upon closing and satisfaction of the outstanding debt, the 2022 Loan Agreement terminated, without early termination fees or penalties being owed by us. No additional amounts are owed to Mr. Duggan under the 2022 Loan Agreement.

Financings

Mr. Duggan oversubscribed in the rights offerings conducted by the Company in 2022. In the rights offering that closed in June 2022, Mr. Duggan purchased 5,764,188 shares of Company common stock and warrants to purchase up to an additional 5,764,188 shares of Company common stock.

As of March 20, 2024, Mr. Duggan is incorporated herein the beneficial owner of approximately 69% of our outstanding common stock.

Registration Rights Agreements

We are party to registration rights agreements and securities purchase agreements which provide, among other things, that certain holders of our outstanding common stock, including Robert W. Duggan and Mahkam Zanganeh, have the right to demand that we file a registration statement or request that their shares of our common stock be covered by reference a registration statement that we are otherwise filing.

Other Transactions

We have granted stock options to our definitive proxy statement executive officers and our directors. See the sections titled "Director Compensation" and "Executive Compensation" for a description of these stock options. In the ordinary course of business, we enter into offer letters and employment agreements with respect our executive officers. We have also entered into indemnification agreements with each of our directors, officers, and other executives. The indemnification agreements and our certificate of incorporation and bylaws require us to indemnify our 2023 Annual Meeting of Stockholders directors and officers to be filed with the SEC within 120 days after the end of the fiscal year covered fullest extent permitted by this Annual Report on Form 10-K. Delaware law.

Item 14. Principal Accounting Fees and Services

Information responsive**Policy on Audit Committee's Pre-Approval of Audit and Permissible Non-Audit Services of Independent Registered Public Accounting Firm**

The Audit Committee reviews and pre-approves all audit and permissible non-audit services provided by our independent registered public accounting firm. These services may include audit services, audit-related services and tax services, as well as specifically designated non-audit services which, in the opinion of the Audit Committee, will not impair the independence of the independent registered public accounting firm. Pre-approval generally is provided for up to one year, and any pre-approval is detailed as to the particular service or category of services and generally is subject to a specific budget. The independent registered public accounting firm and our management are required to periodically report to the Audit Committee regarding the extent of services provided by the independent registered public accounting firm in accordance with this item is incorporated herein pre-approval, including the fees for the services performed to date. In addition, the Audit Committee also may pre-approve particular services on a case-by-case basis, as necessary or appropriate.

Auditor Fees

The following table sets forth the approximate aggregate fees billed to us by reference to our definitive proxy statement with respect to our Deloitte & Touche LLP in fiscal years 2023 Annual Meeting and 2022 (in thousands):

Fee Category	2023	2022
Audit fees	$ 733	$ 610
Audit-related fees	34	30
All other fees	34	26
Total	$ 801	$ 666

Audit Fees consisted of Stockholders to be filed professional services rendered in connection with the SEC within 120 days after the end audit of the fiscal year covered by this our annual financial statements included in our Annual Report on Form 10-K. 10-K and quarterly review of our financial statements included in our Quarterly Reports on Form 10-Q. This category also includes advice on accounting matters that arose during the audit or the review of interim financial statement.

Audit-Related Fees consisted of professional services for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and are not reported under "Audit Fees." These include services rendered in connection with comfort letters related to our ATM offering and consents related to registration statements.

Tax Fees consisted of a Section 382 study.

All Other Fees consisted of expense reimbursements and the subscription to an online technical tool.

The Audit Committee has concluded that the provision of the non-audit services listed above was compatible with maintaining the independence of Deloitte & Touche LLP.

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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

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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
10.24+	Amendment to Employment Agreement, between Kevin Danahy and Pulse Biosciences, Inc., dated May 4, 2023	8-K	001-37744	10.1	May 5, 2023
10.25+	Amendment to Employment Agreement, between Darrin Uecker and Pulse Biosciences, Inc., dated May 5, 2023	8-K	001-37744	10.2	May 5, 2023
10.26+*	Third Amendment to Employment Agreement, between Kevin Danahy and Pulse Biosciences, Inc., dated March 2024				
10.27+*	Fourth Amendment to Employment Agreement, between Darrin Uecker and Pulse Biosciences, Inc., dated March 2024				
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).				
97.1*	Section 10D Clawback Policy				
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.

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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 March 28, 2024

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 28, 2024
/s/ Robert W. Duggan Robert W. Duggan	Executive Chairman of the Board of Directors	March 31, 2023 28, 2024
/s/ Darrin R. Uecker Darrin R. Uecker	Chief Technology Officer and Director	March 31, 2023 28, 2024
/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 28, 2024
/s/ Manmeet S. Soni Manmeet S. Soni	Director	March 31, 2023 28, 2024
/s/ Mahkam Zanganeh	Director	March 31, 2023 28, 2024

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Mahkam Zanganeh

/s/ Richard A. van den Broek Richard A. van den Broek	Director	March 31, 2023 28, 2024
/s/ Timothy H. Mitsuoka Timothy H. Mitsuoka	Corporate Controller *(Principal Accounting Officer)*	March 31, 2023 28, 2024

Exhibit 10.26

PULSE BIOSCIENCES, INC.

THIRD AMENDMENT TO EMPLOYMENT AGREEMENT

This third amendment (this "**Amendment**") is entered into effective as of March 26, 2024, by and between Kevin Danahy ("**Executive**") and Pulse Biosciences, Inc. (the "**Company**," and together with Executive, the "**Parties**").

WHEREAS, the Parties entered into an employment agreement dated February 9, 2022 (as previously amended, the "**Employment Agreement**");

WHEREAS, the Parties desire to amend certain provisions of the Employment Agreement related to Executive's base compensation and bonus target;

NOW, THEREFORE, in considerations of the promises, mutual covenants, and above recitals, including Executive's eligibility to receive substantially increased base compensation, the sufficiency of which is hereby acknowledged, Executive and the Company hereby agree as follows:

1. Amendments. Sections 3(a) and (b) of the Employment Agreement, titled "Compensation," are hereby amended and restated in their entirety as follows:

"(a) Base Salary. During the Employment Term, effective March 1, 2024, the Company will pay Executive an annual salary of $525,000.00 as compensation for Executive's services (the "**Base Salary**"). The Base Salary will be paid periodically (but not less frequently than bi-monthly) in accordance with the Company's normal payroll practices and be subject to the usual required withholdings. Executive's salary will be subject to review and adjustments will be made based upon the Company's normal performance review practices.

(b) Annual Bonus. Executive will be eligible to receive an annual bonus of up to 70.00% of Executive's base salary (the "Target Bonus") less applicable withholdings, calculated in a manner consistent with the Company's normal practices, upon the attainment of annual designated corporate goals and milestones, in each case set and measured in the good faith discretion of the Board at a time consistent with the other executives of the Company. Executive's eligibility, and the terms and conditions, for the Target Bonus will be documented and issued to Executive if and when approved by the Board. If awarded, the Target Bonus will be paid prior to the later of (i) the fifteenth (15th) day of the third (3rd) month following the close of the Company's fiscal year in which the Target Bonus is earned or (ii) March 15 following the calendar year in which the Target Bonus is earned, provided that the Employment Term extends through the date of payment."

2. Full Force and Effect. To the extent not expressly amended hereby, the Employment Agreement shall remain in full force and effect.

3. Counterparts. This Amendment may be executed in counterparts, all of which together shall constitute one instrument, and each of which may be executed by less than all of the parties to this Amendment.

4. Governing Law. This Amendment will be governed by the laws of the State of California (with the exception of its conflict of laws provisions).

IN WITNESS WHEREOF, each of the Parties has executed this Amendment, in the case of the Company by its duly authorized officer, effective as of the Amendment

PULSE BIOSCIENCES, INC.	EXECUTIVE
/s/ Darrin Uecker	/s/ Kevin Danahy
By: Darrin Uecker	By: Kevin Danahy
Its: Director & Chief Technology Officer	Date: March 27, 2024
Date: March 27, 2024	

Exhibit 10.27

PULSE BIOSCIENCES, INC.

FOURTH AMENDMENT TO EMPLOYMENT AGREEMENT

This fourth amendment (this "**Amendment**") is entered into effective as of March 26, 2024, by and between Darrin Uecker ("**Executive**") and Pulse Biosciences, Inc. (the "**Company**," and together with Executive, the "**Parties**").

WHEREAS, the Company and Executive entered into an employment agreement dated September 8, 2015 (as amended, the "**Employment Agreement**");

WHEREAS, the Parties desire to amend certain provisions of the Employment Agreement related to Executive's base compensation and bonus target;

NOW, THEREFORE, in considerations of the promises, mutual covenants, and above recitals, including Executive's eligibility to receive substantially increased base compensation, the sufficiency of which is hereby acknowledged, Executive and the Company hereby agree as follows:

1. Amendments. Sections 3(a) and 3(e) of the Employment Agreement, titled "Compensation," are hereby amended and restated in their entirety as follows:

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"(a) Base Salary. During the Employment Term, the Company will pay Executive an annual salary of $525,000.00 as compensation for Executive's services (the "**Base Salary**"). The Base Salary will be paid periodically (but not less frequently than bi-monthly) in accordance with the Company's normal payroll practices and be subject to the usual required withholdings. Executive's salary will be subject to review and adjustments will be made based upon the Company's normal performance review practices. . . .

(e) Annual Bonus. Executive will be eligible to receive an annual bonus of up to 70.00% of Executive's base salary (the "Target Bonus") less applicable withholdings, calculated in a manner consistent with the Company's normal practices, upon the attainment of annual designated corporate goals and milestones, in each case set and measured in the good faith discretion of the Board at a time consistent with the other executives of the Company. Executive's eligibility, and the terms and conditions, for the Target Bonus will be documented and issued to Executive if and when approved by the Board. If awarded, the Target Bonus will be paid prior to the later of (i) the fifteenth (15th) day of the third (3rd) month following the close of the Company's fiscal year in which the Target Bonus is earned or (ii) March 15 following the calendar year in which the Target Bonus is earned, provided that the Employment Term extends through the date of payment."

2. Full Force and Effect. To the extent not expressly amended hereby, the Employment Agreement as previously amended shall remain in full force and effect.

3. Counterparts. This Amendment may be executed in counterparts, all of which together shall constitute one instrument, and each of which may be executed by less than all of the parties to this Amendment.

4. Governing Law. This Amendment will be governed by the laws of the State of California (with the exception of its conflict of laws provisions).

IN WITNESS WHEREOF, each of the Parties has executed this Amendment, in the case of the Company by its duly authorized officer, effective as of the Amendment

PULSE BIOSCIENCES, INC.	EXECUTIVE
/s/ Kevin Danahy	/s/ Darrin Uecker
By: Kevin Danahy	By: Darrin Uecker
Its: Chief Executive Officer	Date: March 27, 2024
Date: March 27, 2024	

Exhibit 21.1

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. 333-273944, 333-259330, 333-246346, 333-237577, 333-227974, 333-224800, 333-219104, and 333-219096 on Form S-3 and Registration Statement Nos. 333-271808, 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, 28, 2023 2024, 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 2023.

/s/ Deloitte & Touche LLP

San Jose, California
March 31, 2023 28, 2024

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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 28, 2024

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

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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 2023 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 28, 2024

/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.

Exhibit 97.1

Incentive-Based Compensation Clawback Policy

Effective November 2023

Pulse Biosciences, Inc. ("Company") has adopted this clawback policy (the "Policy") as a supplement to any other clawback policies in effect now or in the future at the Company. To the extent this Policy applies to compensation payable to a covered person, it shall be the only clawback policy applicable to such compensation and no other clawback policy shall apply. However, notwithstanding the last sentence, if another Company policy provides that a greater amount of compensation shall be subject to clawback, such other policy shall apply, but only, to the amount in excess of the amount subject to clawback under this Policy.

This Policy shall be interpreted to comply with the clawback rules found in 229 C.F.R. §240.10D and Nasdaq Listing Rule 5608, which will take effect on October 2, 2023 (collectively, the "Rule"). To the extent this Policy is in any manner deemed inconsistent with the Rule, this Policy shall be treated as retroactively amended to be compliant with the Rule.

1. Definitions. As used in the Policy, the following capitalized terms shall have the meanings set forth in this Section 1. Terms used herein shall at all times be interpreted in accordance with 229 C.F.R. §240.10D-1(d) and any other guidance that may be issued under the Rule.

(a) "Executive Officer" shall mean the Company's president, principal financial officer, principal accounting officer, any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive Officers of the Company's subsidiaries are deemed Executive Officers of the Company if they perform such policy making functions for the Company. Identification of an Executive Officer for purposes of this Policy includes, at a minimum, Executive Officers identified pursuant to 17 C.F.R. §229.401(b).

(b) "Financial Reporting Measure" means measures, including but not limited to stock price and total shareholder return, that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures. A Financial Reporting Measure need not be presented within the financial statements or included in a filing with the Securities Exchange Commission.

(c) "Incentive-Based Compensation" means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of one or more Financial Reporting Measures.

2. Application of the Policy. This Policy shall only apply in the event that the Company is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct one or more errors in a previously issued financial statements that is or are material to such financial statements, or that would result in a material misstatement if the error or errors were corrected in the current period or left uncorrected in the current period.

3. Recovery Period. The Incentive-Based Compensation subject to clawback is the Incentive-Based Compensation Received during the three completed fiscal years immediately preceding the date that the Company is required to prepare an accounting restatement as described in Section 2, provided that the person served as an Executive

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Officer at any time during the performance period applicable to the Incentive-Based Compensation in question. The date that the Company is required to prepare an accounting restatement shall be determined pursuant to 229 C.F.R. §240.10D-1(b)(1)(ii).

(a) For purposes of this Policy, Incentive-Based Compensation is deemed "Received" in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if the payment or grant of the Incentive-Based Compensation occurs after the end of such period.

(b) Notwithstanding anything to the contrary, this Policy shall only apply if the Incentive-Based Compensation is Received on or after October 2, 2023.

(c) To the extent applicable, 229 C.F.R. §240.10D-1(b)(1)(i) shall govern certain circumstances under which the Policy will apply to Incentive-Based Compensation Received during a transition period arising due to a change in the Company's fiscal year.

4. Erroneously Awarded Compensation. The amount of Incentive-Based Compensation subject to clawback pursuant to this Policy ("Erroneously Awarded Compensation") is the amount of Incentive-Based Compensation Received that exceeds the amount of Incentive-Based Compensation that otherwise would have been Received had it been determined based on the restated amounts and shall be computed without regard to any taxes paid. For Incentive-Based Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in an accounting restatement:

(a) the amount shall be based on a reasonable estimate of the effect of the accounting restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was received; and

(b) the Company must maintain documentation of the determination of that reasonable estimate and provide such documentation to the exchange on which the Company's shares are listed.

5. Recovery of Erroneously Awarded Compensation. The Company shall recover reasonably promptly any Erroneously Awarded Compensation except to the extent that the conditions of paragraphs (a), (b), or (c) below apply. The Compensation Committee of the Company's Board of Directors (the "Committee") shall determine the repayment schedule for each amount of Erroneously Awarded Compensation in a manner that complies with the Rule's "reasonably promptly" requirement. Such determination shall be consistent with any applicable legal guidance, by the SEC, judicial opinion, or otherwise. The determination of "reasonably promptly" may vary from case to case and the Committee is authorized to adopt additional rules to further describe what repayment schedules satisfy this requirement.

(a) Erroneously Awarded Compensation need not be recovered if the direct expense paid to a third party to assist in enforcing the Policy (e.g., reasonable legal expenses and consulting fees) would exceed the amount to be recovered and the Committee makes a determination that recovery would be impracticable. However, before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Erroneously Awarded Compensation, establish that the direct costs of recovery exceed the recovery amounts, document such reasonable attempt(s) to recover, and provide such documentation to the exchange on which the Company's shares are listed.

(b) Erroneously Awarded Compensation need not be recovered if recovery would violate home country law, provided such law was adopted prior to November 28, 2022. Before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on violation of home country law, the Company shall obtain an opinion of home country counsel, acceptable to the exchange on which the Company's shares are listed, that recovery would result in such a violation and shall provide such opinion to such exchange.

(c) Erroneously Awarded Compensation need not be recovered if recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company or its subsidiaries, to fail to meet the requirements of Sections 401(a)(13) or 411(a) of the Internal Revenue Code of 1986, as amended, and regulations thereunder.

6. Committee decisions. Decisions of the Committee with respect to this Policy shall be final, conclusive, and binding on all Executive Officers subject to this Policy, unless determined to be an abuse of discretion.

7. No Indemnification. Notwithstanding anything to the contrary in any other policy of the Company or any agreement between the Company and an Executive Officer, no Executive Officer shall be indemnified by the Company against the loss of any Erroneously Awarded Compensation.

8. Agreement to Policy by Executive Officers. The Committee shall take reasonable steps to inform Executive Officers of this Policy and obtain their acknowledgement of this Policy, which steps may include the inclusion of this Policy as an attachment to any award that is or has been accepted by the Executive Officer.

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