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

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2021

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 x

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 x

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 x 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 x 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	x	Smaller reporting company	x
		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. ☐

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

Aggregate market value of registrant's common stock held by non-affiliates of the registrant on June 30, 2021, 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 $178,622,994. 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 25, 2022: 29,802,280

TABLE OF CONTENTS

		Page
PART I		
Item 1.	Business	3
Item 1A.	Risk Factors	18
Item 1B.	Unresolved Staff Comments	50
Item 2.	Properties	51
Item 3.	Legal Proceedings	51
Item 4.	Mine Safety Disclosures	51
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	52
Item 6.	Selected Financial Data	54
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	54
Item 7A.	Quantitative and Qualitative Disclosures about Market Risk	63
Item 8.	Financial Statements and Supplementary Data	64
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	93
Item 9A.	Controls and Procedures	93
Item 9B.	Other Information	93
Item 9C.	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	94
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	94
Item 11.	Executive Compensation	94
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	94
Item 13.	Certain Relationships and Related Transactions, and Director Independence	94
Item 14.	Principal Accounting Fees and Services	94
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	95
Item 16.	Form 10-K Summary	98
Signatures		99

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

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

SPECIAL NOTE ABOUT FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Annual Report") contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements relate to expectations concerning matters that are not historical facts. Words such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "might," "plans," "projects," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, statements related to our expected business, new product introductions, results of clinical studies, expectations regarding regulatory clearance and the timing of FDA or non-US filings or approvals including meetings with FDA or non-US regulatory bodies, procedures and procedure adoption, future results of operations, future financial position, our ability to generate revenues, our financing plans and future capital requirements, anticipated costs of revenue, anticipated expenses, the effect of recent accounting pronouncements, our investments, anticipated cash flows, our ability to finance operations from cash flows and similar matters, the impact of the recent COVID-19 coronavirus pandemic and related public health measures on our business, and statements based on current expectations, estimates, forecasts, and projections about the economies and markets in which we intend to operate and our beliefs and assumptions regarding these economies and markets. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. You should read the "Risk Factors" section of this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained herein. We do not assume any obligation to update any forward-looking statements.

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

Part I

Item 1. Business

Overview

Pulse Biosciences, Inc. is a novel bioelectric medicine company committed to health innovation using an entirely new and proprietary energy modality. The Company's CellFX® System is the first commercial product to harness the distinctive advantages of the Company's proprietary Nano-Pulse Stimulation™ ("NPS") technology. The CellFX System 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 non-cellular tissue, to treat a variety of medical conditions for which an optimal solution remains unfulfilled.

The CellFX® System

We have begun commercializing our proprietary CellFX System into the large and growing dermatology procedure market as our first commercial market. Powered by NPS technology, the CellFX System delivers nano second duration pulses of electrical energy to non-thermally clear targeted cells while sparing adjacent non-cellular tissue. This non-thermal specificity for cellular targets is a significant differentiator for the CellFX System compared to other energy devices used in dermatology and other medical specialties, such as radiofrequency ablation. The Company has validated the cell-specific effects of NPS technology with a series of completed and ongoing clinical studies of cellular lesions, which are skin conditions characterized by abnormal or undesired cellular structures located on, or in, the non-cellular dermal collagen.

In February 2021, the Company received 510(k) clearance from the U.S. Food and Drug Administration (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"); in June 2021, the Company received Health Canada approval for the CellFX System, which allows for marketing of the system in Canada; and in November 2021, the Company received approval for the CellFX System from the Therapeutic Goods Administration ("TGA"), and from the New Zealand Medicines and Medical Devices Safety Authority ("Medsafe") which allows for marketing of the system in Australia and New Zealand. The CE mark, Health Canada, TGA, and Medsafe approvals allow for use of the CellFX System in dermatological procedures requiring ablation and resurfacing of the skin for the reduction, removal, and/or clearance of cellular-based benign lesions, including Sebaceous Hyperplasia ("SH"), Seborrheic Keratosis ("SK"), and cutaneous non-genital warts.

The CellFX System is a tunable, software-enabled, console-based platform, designed to accommodate the clinical workflow preferred by physicians. The CellFX System currently includes a multi-use handpiece and a suite of single-patient use treatment tips ranging from 1.5mm^2 to 10mm^2, enabling treatment of a variety of lesion sizes and depths. The treatment tips wirelessly connect to the CellFX System when plugged into the handpiece, allowing for the use of automated treatment settings based on the treatment tip used.

We have also designed an integrated cloud software infrastructure called CellFX CloudConnect™ to enable our innovative utilization-based business model to help align the interests of patients, practices, and the Company. CellFX CloudConnect makes possible the wireless connectivity between the physician's CellFX System, our e-commerce customer portal ("CellFX Marketplace"), practice management tools to track utilization data and other metrics, and our internal customer relationship management and enterprise resource planning software systems. CellFX CloudConnect also facilitates direct connectivity to the CellFX System to enable remote software updates, service, and maintenance functions. Because of this ability to streamline, be responsive, and reduce disruption to the clinician workflow, CellFX CloudConnect allows us to provide active high-touch support.

Our Proprietary Nano-Pulse Stimulation Technology Platform

Our proprietary CellFX System leverages our patented NPS technology platform. NPS technology is characterized by nanosecond duration pulses of electrical energy, each less than a millionth of a second long. When applied to targeted tissue, our NPS technology sends energy pulses to cells in order to alter the function of the internal cellular organelles, including the mitochondria and endoplasmic reticulum, without disrupting extracellular tissue. We believe this leads to regulated cell death, a process exhibited naturally by cells in the human body when they undergo stress and are unable to restore cellular homeostasis.

The CellFX System is designed to function on the basis of a unique non-thermal mechanism of action that likely results in a biophysical disruption brought about by the tunable speed and amplitude of our NPS pulses interacting with the physical structure of cells. While the CellFX System delivers pulses that directly affect the internal organelles of cells, these pulses do not have significant functional effect on non-cellular tissue, such as collagen, a protein that forms the structural foundation of the skin. In short, with our proprietary CellFX System, we can deliver a cell-focused effect that we believe leads to regulated cell death while preserving surrounding non-cellular tissue, a combination that may potentially lead to highly differentiated treatment applications.

Our Strategy

Our objective is to advance our NPS technology platform into medical specialty areas where an optimal solution remains unfulfilled. We are in the business of commercializing novel, proprietary, and differentiated products that have the potential to significantly improve patient outcomes in the markets we serve, as well as those we intend to serve in the future. To achieve this plan, we intend to:

- **Demonstrate the unique benefits of our proprietary CellFX System and its unique non-thermal mechanism of action across a number of compelling applications:**
  - The first introduction of the CellFX System focuses on serving dermatologists and other skin specialists as a new modality to address common benign skin conditions that are cellular in nature and often difficult to treat. We have conducted, and will continue to conduct, numerous clinical studies, including studies in SK, the most common benign raised pigmented lesion; SH, small skin-colored bumps, often oily in appearance and can appear in clusters; cutaneous non-genital warts; and back acne.

- **Continue commercialization efforts of our proprietary CellFX System and applications for its use across clinical indications already cleared or approved:**
  - In January 2021, the Company received CE marking approval for the CellFX System, which allows for marketing of the system in the European Union and, in June 2021, the Company received Health Canada approval for the CellFX System, which allows for marketing of the system in Canada. The CE mark and Health Canada approvals allow for indication of use of the CellFX System in dermatological procedures requiring ablation and resurfacing of the skin for the reduction, removal, and/or clearance of cellular-based benign lesions, including SH, SK, and cutaneous non-genital warts.
  - In February 2021, we received 510(k) clearance from the FDA for the CellFX System for general dermatologic procedures requiring ablation and resurfacing of the skin.
  - In November 2021, we received approval from Medsafe in Australia for indication of use of the CellFX System in dermatological procedures requiring ablation and resurfacing of the skin for the reduction, removal, and/or clearance of cellular-based benign lesions, including SH, SK, and cutaneous non-genital warts.
  - In November 2021, we received approval from the TGA in Australia for indication of use of the CellFX System in dermatological procedures requiring ablation and resurfacing of the skin for the reduction, removal, and/or clearance of cellular-based benign lesions, including SH, SK, and cutaneous non-genital warts.
  - In December 2021, we received approval from the Health Sciences Authority in Singapore for indication of the CellFX System in dermatological procedures requiring ablation and resurfacing of the skin for the reduction, removal, and/or clearance of cellular-based benign lesions, such as non-genital cutaneous warts and plantar warts.

- **Continue with our Controlled Launch and build a foundation of clinical and commercial advocacy among this group of clinics to propel the first wave of early adopters:**
  - In February 2021, we initiated controlled launch programs in the United States and the European Union and in June 2021 we initiated a controlled launch program in Canada (collectively, our “Controlled Launch”). We expect our Controlled Launch participants will influence the first wave of early adopters when it comes to their CellFX purchase decisions and integrating the CellFX into a successful aesthetic dermatology practice.
  - In the fourth quarter of 2021, we completed the first two commercial sales of the CellFX System.
  - As of December 31, 2021, we onboarded a total of seventy CellFX Controlled Launch Program participants across the U.S., Europe, and Canada, completing program enrollment. As of December 31, 2021, twenty-nine Controlled Launch Program participants opted to purchase their CellFX System and six clinics opted out of the program.

- **Expand utilization of the CellFX System with new applications and procedure optimization:**
  - The sale of each CellFX System and the sale of cycle units required to operate the CellFX System are both revenue-generating events. The treatment of each lesion requires cycle units which the treating physicians will need to periodically replenish, creating additional revenue-generating events. Providing additional evidence and/or regulatory clearances for new clinical conditions is expected to increase the potential for physicians to increase their procedure volumes and associated procedure fees, which in turn should increase the number of cycle units purchased for the existing installed base and increase the likelihood that additional physicians will purchase a CellFX System based on its expanded utility and revenue-generating potential within their practice.
  - We expect to continue to conduct clinical studies and make regulatory submissions on an ongoing basis to broaden the approved uses of the CellFX System. Specific indication labeling will allow the Company to provide educational and promotional materials to our physician customers to enable them to promote specific applications to their patients. Based on the local regulations of each geographic market, the Company may also engage in cooperative marketing and advertising, under appropriate circumstances.

- In December 2021, upon completion of all treatments in an investigational device exemption ("IDE") pivotal comparison study to evaluate the treatment of SH using the CellFX System, we submitted a 510(k) to add the treatment of SH to the CellFX System's indications for use in the United States. In February 2022, we received an Additional Information ("AI") letter from the FDA in response to the 510(k) submitted. In the AI letter, the FDA stated it did not believe the Company provided sufficient clinical evidence at this time to support the expanded indication for use, and that the Company had not met the primary endpoints of the SH IDE study. The Company anticipates meeting with the FDA to discuss the contents of the AI letter and potential next steps, which may require additional clinical data and potentially a new 510(k) submission.

- **Leverage the CellFX branding of cellular mechanism to drive expansion in dermatology and set the stage for future applications beyond dermatology:**

  - While we are prioritizing cash-pay applications in the immediate term, the Company intends to invest in continued research with non-melanoma skin cancer and other medical applications to expand users and usage. This includes evaluating reimbursement strategies and options for selected applications.
  - The significant investments in scientific and clinical programs in dermatology we have made over the last several years have given us unique insights and a deeper understanding of our cell-based, tissue-sparing platform technology that should inform and accelerate the use of NPS in other application areas within and outside of dermatology. This includes early pre-clinical work in areas such as otolaryngology, cardiology, and oncology.

Aesthetic Dermatology Procedure Market

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

Based on the ability of our NPS mechanism to clear cellular structures while sparing the structural foundation of the skin, we believe there is a significant opportunity for the CellFX System in the growing aesthetic and medical dermatology market. In the United States, according to the 2019 Survey on Dermatologic Procedures by the American Society for Dermatologic Surgery ("ASDS"), dermatologists performed nearly 14 million cosmetic and medically-necessary procedures, with 4.1 million cosmetic procedures performed using energy-based devices – an 18% increase from 2018 and a 106% increase from 2012. ASDS has also reported that consumers ranked their dermatologist as the #1 influencer of skin procedure decisions. We have worked closely with top KOLs in the aesthetic and medical dermatology field to identify those procedures and skin conditions in which the CellFX System and its unique NPS mechanism of action would offer a high value proposition.

Regarding prevalence of our intended initial dermatologic applications (SH, SK, and cutaneous non-genital warts), based on third-party surveys conducted among aesthetic physicians, an average of 200 patients per month in both the United States and the European Union who visit aesthetic dermatology practices present with each of our initial dermatologic applications. Further, these surveys reported that patients place greater value on lesion removal procedures over other popular aesthetic procedures they currently receive and are willing to pay cash to treat multiple lesions in a single visit.

Initial Aesthetic Dermatology Applications

Sebaceous Hyperplasia

SH is a common benign condition of sebaceous glands in adults of middle age or older. SH occurs when the sebaceous glands become enlarged, creating small, shiny, yellowish lesions or bumps, usually 2-4 millimeters in diameter and typically on the face. In a 2019 marketing study conducted with U.S. dermatologists (n=304), physicians reported seeing on average 42 patients per week with SH, with 65% left untreated due to the lack of desirable outcomes with traditional treatment methods (*e.g.*, electrocautery).

Results from our clinical trials have demonstrated that NPS has a unique ability to clear cellular structures located within the dermis of the skin, such as enlarged sebaceous glands that cause SH, without damaging the dermal foundation, making it a potentially unique and highly effective treatment modality for SH lesions and similar targets residing deeper within the dermis of the skin.

In our multi-center clinical studies to date, we have treated more than 1,000 SH lesions in more than 260 patients. As studies are ongoing, results to date indicate that NPS technology is effective for the treatment of SH. Over 80% of treated SH lesions were rated clear or mostly clear by investigators at the 60-day post treatment follow-up evaluation. In our latest study in which we evaluated whether the use of lower energy settings would maintain efficacy, results demonstrated that lower NPS energy levels maintained high efficacy while improving overall cosmetic effects, as well as higher patient satisfaction, compared to our first studies.

In January 2021, we completed all treatments in an IDE pivotal study to compare the safety and efficacy of the CellFX System to a comparator group, Electrodessication for the treatment of SH lesions. In December 2021, we submitted a 510(k) to add the treatment of SH to the CellFX System's indications for use in the United States. In February 2022, we received an AI letter from the FDA in response to the 510(k) submitted. In the AI letter, the FDA stated it did not believe the Company provided sufficient clinical evidence at this time to support the expanded indication for use, and that the Company had not met the primary endpoints of the SH IDE study. The Company anticipates meeting with the FDA to discuss the contents of the AI letter and potential next steps, which may require additional clinical data and potentially a new 510(k) submission.

Notwithstanding the AI letter and the FDA's preliminary assessment, we believe that the successful treatment of SH lesions reflects a valuable commercial opportunity for the CellFX System in an area of unmet need and substantiates the unique ability of NPS pulses to penetrate the dermis and clear deeper cellular structures without damaging the surrounding dermis. In Europe, Canada, Australia, and New Zealand, the CellFX System is approved for the treatment of sebaceous hyperplasia, seborrheic keratosis and non-genital warts.

Seborrheic Keratosis

SK is one of the most common non-cancerous skin growths in older adults. SK usually appear as a brown, black, or light tan growth on the face, chest, shoulders, or back and has a waxy, scaly, slightly elevated appearance. SK are normally painless, and patients often seek to have them removed if they become irritated by clothing or for cosmetic reasons. Based on 2019 marketing research, dermatologists in the United States report seeing 84 patients with SK each week, with 52% left untreated despite having available treatment options (*e.g.*, cryosurgery).

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

Cutaneous, Non-Genital Warts

Non-genital warts are an extremely common benign skin disease caused by infection of epidermal cells with the human papillomavirus ("HPV"), resulting in cell proliferation and a thickened, warty papule on the skin. Common warts are most often seen on the hands and present as skin-colored papules with a rough scaly surface. Flat warts are most often seen on the backs of the hands and on the legs. They appear as slightly elevated small plaques that are skin-colored or light brown. Plantar warts occur on the soles of the feet and look like very thick callouses.

During 2020, we initiated a 62-patient, multi-center, clinical, pivotal study evaluating the safety and efficacy of the CellFX System for the treatment of non-genital cutaneous warts. Results from this study showed favorable outcomes of up to 75% clearance rate for warts on the hands, leg, knee, and neck, with rapid skin recovery and a low rate of residual skin effects. During 2021 we completed enrollment of 150 patients in an IDE pivotal comparison study to assess the treatment of cutaneous non-genital warts using the CellFX System. We are currently analyzing the study data and are anticipating a 510(k) submission during the second quarter of 2022.

Future Dermatology Application Feasibility Studies

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

Basal Cell Carcinoma

During 2021 we completed enrollment of 30 patients as part of an FDA Investigational Device Exemption (“IDE”) feasibility study to assess the treatment of Basal Cell Carcinoma (“BCC") using the CellFX System. BCC is the most frequently occurring form of cancer in the US, with an estimated 3.6 million diagnosed cases every year, according to the Skin Cancer Foundation. The current treatment of BCC is wide margin surgical excision, which can result in undesirable scarring. We believe that NPS technology and the CellFX System can be used to treat smaller BCC lesions with improved outcomes in cosmetically sensitive areas, such as on the face, and we believe that this new application would be beneficial to a large number of patients.

The objective of the feasibility study is to demonstrate that the CellFX System can safely be used to eliminate BCC lesions with a potentially superior cosmetic outcome when compared to wide margin excision. During the study, BCC lesions are treated with the CellFX System and approximately 60 days following the treatment, the treatment area is examined for the cosmetic outcome. The lesion is then be excised using the current standard of care wide margin excision procedure and analyzed by the study pathologist to determine whether there are any remaining basal cells present in the treatment area. This study has been completely enrolled and the data is being analyzed.

Dermatofibroma

Dermatofibroma are small, benign lesions typically found on the extremities, especially the lower legs. These persistent and sometimes painful growths are fairly common, with dermatologists reporting seeing as many as 30 patients presenting with them per week. However, the current treatment rate is low, due primarily to the lack of available treatments. The current standard of care, surgical excision, is used infrequently because it typically results in undesirable scaring. There are currently no energy-based devices that are regularly used to treat dermatofibroma and for this reason we believe this could potentially be a large market opportunity and a viable CellFX procedure performed with the currently available treatment tips.

Safety Profile of Our NPS Technology Platform

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

Commercialization Strategy

To launch the CellFX System, we selected approximately 70 centers across the United States, Canada and the European Union to be the first physicians to receive the system in their respective markets and geographies through our Controlled Launch program. An objective of our ongoing Controlled Launch program has been to turn participating clinics into high utilization commercial customers that will serve as important reference clinics for future commercial customers. We initially expected clinics to complete the program requirements within three to five months. However, the average time for clinics that have completed the Controlled Launch program has been seven months. We continue to gain valuable information from the Controlled Launch process. While the real-world delivery of NPS technology through the CellFX System has proven to clear benign lesions in clinical studies, we have learned that the market development for benign lesions and the integration of this procedure into the practice workflow will require a higher touch model to generate the system utilization we are expecting. We now expect clinics to continue to move through the program throughout 2022, as they complete the program requirements.

We have deployed a sales and marketing team comprised of professionals with experience in delivering products and applications into the dermatology market and have long-standing relationships with the KOLs, clinics, and customers in this market. The field sales team has been converting Controlled Launch participants to purchases, as well as engaging in direct commercial sales of the CellFX System.

Controlled Launch participants that have opted to purchase the CellFX System for commercial use have performed CellFX procedures since becoming commercial users and, in the aggregate, have increased the number of treatment sessions per month. Currently, our commercial clinics are averaging ten patient treatment sessions per month with their CellFX System. Our goal for the end of 2022 is to increase utilization to forty patient treatment sessions per month at our current commercial clinics. To drive this increased utilization and emphasis on education, training and marketing at our current accounts, we have implemented changes to our commercial leadership, restructured our commercial field organization and modified our strategy in support of our utilization focus and reduced emphasis on new system sales in the near-term. In February 2022, we appointed Kevin Danahy as Chief Commercial Officer. Mr. Danahy has a proven track record of building exceptional commercial teams and implementing strategies to drive market penetration and significant growth with disruptive medical technologies across a variety of medical disciplines. Under Mr. Danahy's leadership, the near-term focus of our commercial team's efforts will be to increase utilization at our commercial clinics.

Potential of Nano-Pulse Stimulation Technology Beyond Dermatology

We continue to invest in and investigate potential uses for our NPS technology outside of dermatology, and one of our directors, Mitch Levinson, joined the Company as our Chief Strategy Officer in August 2021 to lead these efforts. Mr. Levinson has over 30 years of experience developing and launching novel medical device technologies across multiple medical disciplines, including dermatology, wound care, surgery, diagnostics, patient monitoring, and digital health.

Some early research initiatives outside of dermatology have been encouraging. For example, preclinical data was recently presented on the use of NPS technology in the field of gastroenterology by Dr. Robert Ganz at the Annual Meeting of the American Foregut Society. Dr. Ganz is a key opinion leader in this field and one of the foremost experts on the treatment of Barrett's esophagus using ablative technologies. Dr. Ganz's presentation, entitled "Nano-Pulse Stimulation Technology is a Promising New Energy Modality for Barrett's Esophagus," showed the successful use of NPS technology in an animal model of Barrett's Esophagus.

Barrett's esophagus is a complication of gastroesophageal reflux disease, or GERD, faced by approximately 10% of people with chronic GERD symptoms, in which the tissue lining the esophagus becomes dysplastic or precancerous as a result of the damage caused by the chronic acid reflux. The dysplastic cells are associated with an increased risk of esophageal cancer, and for this reason they are typically removed or destroyed using thermal energy modalities. The porcine study presented by Dr. Ganz demonstrated that the CellFX System using our novel and proprietary esophageal applicator can remove the esophageal epithelium and submucosal glands without causing significant fibrosis or evidence of stricture, which suggests that NPS technology may provide unique safety and efficacy benefits for the treatment of Barrett's esophagus over currently used thermal ablative technologies that can sometimes lead to adverse outcomes such as esophageal stricture, scarring, pain, and retreatment. Importantly, this evidence also demonstrates that the proven mechanism of action of NPS in skin can be applicable to other tissues of similar architecture, such as in the esophagus.

This early preclinical work represents one of several potential new application areas for the CellFX platform and NPS technology outside of dermatology. However, while we believe there are exciting potential applications across many medical specialties for our NPS platform technology, we remain committed and focused on execution of our commercial launch in dermatology.

Intellectual Property

We maintain a portfolio of intellectual property surrounding our CellFX System and our NPS technology platform. As a medical technology company our current patents and ongoing intellectual property development are, and will continue to be, a priority for our business. We believe our intellectual property is an important competitive advantage for us. We also rely on trade secrets, know-how, continuing technological innovations, and licensing opportunities to further develop, maintain, and strengthen our competitive position. We actively protect our intellectual property through a combination of patent registrations, trademarks, and copyright protections; confidentiality agreements with our employees, consultants, and other parties; and access control to sensitive information.

We own or have a license to 123 issued patents worldwide and have 105 patent applications pending worldwide, with the earliest expiration of a U.S.-issued licensed patent in 2024 and the latest in 2039. As in the past, we plan to continue to file new patent applications to protect our systems, algorithms, applicators, methods, and designs of our technologies and products as they evolve. Medical technologies such as ours may be utilized in many different applications and incorporate several patentable features, and our strategy will be to always strive to protect our products and technologies with multiple patents directed to the variety of features and applications, in order to establish a strong defense against competitors and such that an expiration of a single patent does not lessen our overall comprehensive coverage. We believe our NPS platform and current CellFX System are protected by several issued patents, as well as pending applications.

Research and Development

Since inception, the majority of our business has focused on the development of the CellFX System and earlier clinical versions of the system, conducting clinical studies, including dermatology studies in SK, SH, warts, acne, moles (nevi), syringoma, and BCC, and pre-clinical and basic research into the unique mechanism of action of our NPS technology platform.

In 2022, we have the following planned clinical studies:

- US: dermatofibroma and BCC
- Europe: dermatofibroma, moles (nevi), actinic keratosis, and BCC
- Canada: plantar warts

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

Competition

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

Government Regulation

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

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

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

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

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

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

Regulatory System for Medical Devices in Europe

The European Union (the “EU”) consists of 27-member states and has a coordinated system for the authorization of medical devices. Marketing medical devices in the EU is subject to compliance with the Medical Devices Directive 93/92/EEC (MDD) and the European Union Medical Device Regulation (2017/745 or EU MDR) following its entry into application on May 26, 2020. A medical device may be placed on the market within the EU only if it conforms to certain “essential requirements” and bears the CE Mark. The most fundamental and essential requirement is that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the essential performance(s) intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner.

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

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 May 27, 2024 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.

Health Insurance Portability and Accountability Act

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

The HIPAA Rules apply to "covered entities", which includes healthcare providers who conduct certain transactions electronically, including but not limited to the electronic submission of health care claims to an insurance carrier.

On February 17, 2009, Congress enacted Subtitle D of the Health Information Technology for Economic and Clinical Health Act ("HITECH") provisions of the American Recovery and Reinvestment Act of 2009. This law includes strengthened federal privacy and security provisions to protect PHI, such as the notification requirements set forth in the Breach Notification Rule. On January 25, 2013, the Office for Civil Rights of the HHS published its final rule to modify the HIPAA Privacy, Security, Breach and Enforcement Rules, including most revisions/additions made by the HITECH. The rule became effective on March 23, 2013, and entities and business associates covered by the rule were required to comply with most of the applicable requirements by September 23, 2013. HITECH increased the civil and criminal penalties that may be imposed against Covered Entities, their Business Associates, and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

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

If we or our operations are found to be in violation of HIPAA, HITECH, or their implementing regulations, we may be subject to penalties, including civil and criminal penalties, fines, and exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations.

Federal, State and Foreign Fraud and Abuse Laws

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

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

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

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

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

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

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

When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between $11,463 and $22,927 for each separate instance of false claim, subject to adjustment for inflation. As part of any settlement, the government may ask the entity to enter into a corporate integrity agreement, which imposes certain compliance, certification, and reporting obligations. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The federal government has used the False Claims Act to assert liability on the basis of inadequate care, non-compliance with medical necessity criteria, kickbacks and other improper referrals, and improper use of Medicare numbers when detailing the provider of services, in addition to the more predictable allegations as to misrepresentations with respect to the services rendered. In addition, the federal government has prosecuted companies under the False Claims Act in connection with off-label promotion of products. Our future activities relating to the reporting of wholesale or estimated retail prices of our products, the reporting of discount and rebate information, and other information affecting federal, state, and third-party reimbursement of our products and the sale and marketing of our products may be subject to scrutiny under these laws.

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

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

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

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

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

U.S. Healthcare Reform

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

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

Environmental

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

Insurance

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

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

Employees and Human Capital

As of December 31, 2021, we had 142 employees, of which substantially all are located at our headquarters in Hayward, California. Of these employees, 81 were engaged in research and development activities, and 61 were engaged in sales, marketing and general and administrative activities.

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

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

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

Wellness and Safety. The health and safety of our employees is of utmost importance to us. In response to the COVID-19 pandemic, we are requiring all of our employees to work remotely unless they cannot perform their essential functions remotely and have also suspended all non-essential travel for our employees. For the employees who are unable to perform their essential functions remotely, we have established extensive policies and guidelines which are designed to protect those individuals while they are physically in our offices.

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, the impact of COVID-19 and 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;
- Substantial doubt about our ability to continue as a going concern;
- Competition within our industry;
- Health epidemics, including the coronavirus pandemic;
- Our reliance on certain third parties such as key suppliers;
- Potential loss of key management personnel;
- 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 trial results and unfavorable long-term trial data;
- 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;
- 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 Board Chairman, Robert W. Duggan;
- Unfavorable global economic or political conditions; and
- Potential material weaknesses and uncertainties concerning our ability to maintain an effective system of internal control over financial reporting.

Risks Relating to Our Business, Industry and Financial Condition

Because we have a limited operating history and have recently commenced revenue producing operations, it is difficult to evaluate the future of our business.

We are a bioelectric medicine technology company and have recently commenced 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 currently have very limited product revenue and we may never become profitable.

To date, we have not generated significant revenue and we have historically relied on financing from the sale of equity securities 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 the CellFX System or other products based on 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, marketing and promotion, capital expenditures, working capital, general and administrative expenses, and fees and expenses associated with our capital raising efforts. We expect to incur costs and expenses related to consulting costs, laboratory development costs, hiring of scientists, engineers, sales representatives, and other operational personnel, and the continued development of relationships with potential partners. 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. Investors should evaluate an investment in us in light of the uncertainties typically encountered by developing medical technology companies in a competitive environment. There can be no assurance that our efforts will be successful or that we will ultimately be able to achieve profitability. Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could adversely affect the market price of our common stock and could significantly impair our ability to raise capital, expand our business, or continue to implement our business plan.

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

To date, we have generated limited revenue from product sales and have incurred significant operating losses in each year since our inception and we anticipate that losses may continue for the next several years or until such time as we can generate substantial product revenue and achieve profitability. In connection with the preparation of this Annual Report for the twelve months ended December 31, 2021, our management has concluded that there is substantial doubt as to whether we can continue as a going concern for the twelve months following the issuance of this Annual Report. We plan to raise additional capital to fund our operations through public or private equity offerings, debt financings, our at-the-market equity offering program, and/or potential new collaborations. There is no assurance, however, that any additional financing or any revenue-generating collaboration will be available when needed or that management of the Company will be able to obtain financing or enter into a collaboration on terms acceptable to the Company.

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. Accordingly, there is no assurance that cash flows from operations and other internal and external sources of liquidity will at all times be sufficient for our cash requirements. If necessary, we may need to consider actions and steps to improve our cash position and mitigate any potential liquidity shortfall, such as modifying our business plans, pursuing additional financing to the extent available, reducing capital expenditures, suspending certain activities or programs, pursuing and evaluating other alternatives and opportunities to obtain additional sources of liquidity, and other potential actions to reduce costs. There can be no assurance that any of these actions would be successful, sufficient or available on favorable terms. Any inability to generate or obtain sufficient levels of liquidity to meet our cash requirements at the level and times needed could have a material adverse impact on our business and financial position.

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

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

We will need to raise additional capital in order to continue to execute our business plan. If we are unable to raise sufficient additional funds, we will have to scale back our operations. Also, the ongoing hostilities between Russia and Ukraine and the ongoing COVID-19 pandemic and resulting negative impact on the global macroeconomic environment and capital markets may make it more difficult for us to raise additional funds. We may be required to incur 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 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. If any of these things were to occur, our ability to grow and support our business and to respond to market challenges could be significantly limited or we may be unable to continue operations, in which case you could lose your entire investment.

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

If we decide to 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. For example, 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, 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 and could also harm our existing and planned commercial activities in dermatology.

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

Our revenue is generated entirely from the CellFX System, which consists of a console, handpieces and tips, and both these products and all our potential products under development are based upon the same patented platform technology, Nano-pulse Stimulation (“NPS”). Our revenue is therefore dependent on the success of these products and platform technology, and if these products are not widely adopted by dermatologists or if we suffer any disruptions in our ability to sell these products, our business will suffer. 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 products and platform technology.

We market the CellFX System primarily to aesthetic and medical dermatologists 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, among others:

- 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.

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, such as laser ablation 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; 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 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 aesthetic device market, 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 in the United States or internationally;
- 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 product, 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 a highly competitive market, we can expect to face competition from large, well-established manufacturers of medical technologies, devices and similar products; we may not be able to compete effectively against companies with significantly more resources.

The medical technology, medical device, biotechnology, and pharmaceutical industries are characterized by intense and dynamic competition to develop new technologies and proprietary therapies. We face competition from a number of sources, such as pharmaceutical companies, medical device companies, generic drug companies, biotechnology companies, and academic and research institutions. We may find ourselves in competition with companies that 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. While we will seek to expand our technological capabilities to remain competitive, research and development by others may render our technology or product candidates obsolete or noncompetitive or result in treatments or cures superior to any therapy developed by us. In addition, certain of our product candidates may compete with other dermatological products, including over the counter (“OTC”) treatments, for a share of some patients’ discretionary budgets and for physicians’ attention within their clinical practices. Even if a generic product or an OTC product is less effective than our product candidates, a less effective generic or OTC product may be more quickly adopted by physicians and patients than our competing product candidates based upon cost or convenience. As a result, we may not be able to compete effectively against current and potential future competitors or their devices and products.

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. These third parties may also be adversely impacted by COVID-19 which could affect their ability to perform satisfactorily. Any failure of these third parties to perform satisfactorily and in compliance with relevant laws and regulations could lead to delays in the development of our 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; however, we may be unsuccessful in earning significant revenues. We 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, Darrin Uecker, and members of our finance, sales, marketing, scientific, and engineering teams. These persons have significant experience and knowledge with sub-microsecond pulsed electric fields and more broadly in aesthetics, dermatology, life sciences, and medical technologies. The loss of any team member could impair our ability to design, identify, and develop new intellectual property and new scientific or product ideas. The loss of a key employee, the failure of a key employee to perform in his or her current position, or our inability to attract and retain skilled employees could result in our inability to continue to grow our business or to implement our business strategy. We compete for qualified management and scientific personnel with other life science companies, academic institutions, and research institutions. Our employees could leave our Company with little or no prior notice. 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. As of December 31, 2021, our U.S. sales force consisted of 7 sales managers and directors and 3 clinical support specialists directly employed by us. As of December 31, 2021, our international sales force consisted of 3 sales managers and directors and 7 clinical support specialists, all of whom are employed by Globalization Partners, a third-party employer of record engaged by us. We therefore have limited experience marketing and selling the CellFX System and our revenues and cash flows have been volatile and difficult to predict.

We hire and train sales representatives and clinical specialists with backgrounds and experience in the aesthetic dermatology market, 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 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;
- our ability to obtain, maintain, and enforce our intellectual property rights in and to our CellFX System;
- our ability to raise additional capital on acceptable terms, or at all, if needed to support the commercialization of our products; and
- our ability to achieve and maintain compliance with all regulatory requirements applicable to our products.

Our intention is for our direct sales representatives to develop long-lasting relationships with the dermatologists 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 dermatology 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 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 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 our products, and we may not generate sufficient revenue to become profitable. If we are unable to expand our sales and marketing 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 of technological and scientific advances. These new market opportunities may be outside the scope of our proven expertise or in areas which have unproven market demand. Any new products developed by us may not be accepted in the intended markets. Our inability to gain market acceptance of new products could harm our future operating results.

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

We have experienced rapid growth in our business. Recent and future growth imposes significant added responsibilities on management, including the need to identify, recruit, train, and integrate additional employees. Rapid expansion in personnel could mean that fewer experienced people carry out our research and development activities, manufacture, market, and sell CellFX Systems and NPS therapies and procedures, which could result in inefficiencies and unanticipated costs, reduced quality, and disruptions to our operations. In addition, rapid and significant growth may strain our administrative and operational infrastructure, and the failure to continue to upgrade our technical, administrative, operating, and financial control systems, or the occurrence of other unexpected expansion difficulties, could have a material adverse effect on our business, financial condition and results of operations, and our ability to timely execute our business plan. We may be unable to maintain the quality of, or delivery timelines of, our products or satisfy worldwide 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 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 dermatologists and their staff on the proper use of the CellFX System.

Although most dermatologists 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 dermatologists in the use of our products. Convincing dermatologists 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 dermatologists 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 dermatologists 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 significant adverse effect on our business, financial condition and results of 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 establishing these systems as a standard of care, our ability to achieve market acceptance of the products we introduce could be significantly limited.

Although we believe our training methods for dermatologists are conducted in compliance with FDA and other applicable regulations developed both nationally and in other countries, if the FDA or other regulatory agency determines that our training constitutes promotion of an unapproved use or promotion of an intended purpose not covered by the CE mark affixed to our products or FDA approved labeling, they could request that we modify our training or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine, or criminal penalty.

Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.

To ensure adequate inventory supply, we must forecast inventory needs and place orders with suppliers based on our estimates of future demand for our products. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including our failure to adequately manage our expansion efforts, product introductions by competitors, an increase or decrease in customer demand for our products or for products of our competitors, our failure to accurately forecast customer acceptance of new product enhancements, unanticipated changes in general market conditions or regulatory matters, and weakening of economic conditions or consumer confidence in future economic conditions.

Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Similarly, a portion of our inventory could become obsolete or expire, which could have a material and adverse effect on our earnings and cash flows due to the resulting costs associated with inventory impairment charges and costs required to replace obsolete inventory. Any of these occurrences could negatively impact our financial performance.

Conversely, if we underestimate customer demand for our products, we may not be able to deliver sufficient products to meet our customers' requirements, which could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers or our third-party manufacturers may not be able to allocate sufficient resources to meet our increased requirements, which could have an adverse effect on our ability to meet customer demand for our products and our results of operations.

We have limited experience in manufacturing our products in large-scale commercial quantities and we may face manufacturing risks that may adversely affect our ability to manufacture products and could reduce our gross margins and negatively affect our business and operating results.

Our success depends, in part, on our ability to manufacture our current and future products in sufficient quantities and on a timely basis to meet demand, while adhering to product quality standards, complying with regulatory quality system requirements, and managing manufacturing costs. We have a manufacturing facility located in Hayward, California where we produce, package and warehouse the CellFX System. We also rely on third-party manufacturers for production of some of the components used in the CellFX System. If our facility, or the facilities of our third-party contract manufacturers, suffer damage, or a force majeure event, this could materially impact our ability to operate.

We are also subject to other risks relating to our manufacturing capabilities, including:

- quality and reliability of components, sub-assemblies and materials that we source from third-party suppliers, who are required to meet our quality specifications, some of whom are our single-source suppliers for the products they supply;
- failure to secure raw materials, components and materials in a timely manner, in sufficient quantities or on commercially reasonable terms;
- inability to secure raw materials, components and materials of sufficient quality to meet the exacting needs of medical device manufacturing;
- failure to maintain compliance with quality system requirements or pass regulatory quality inspections;
- inability to increase production capacity or volumes to meet demand; and
- inability to design or modify production processes to enable us to produce future products efficiently or implement changes in current products in response to design or regulatory requirements.

Certain parts used in the manufacturing of our equipment may experience shortages in global supply which could impact our ability to manufacture our device for customers or maintain research and development timelines.

There are several component parts used in the manufacture of our device that are used by many manufacturers in a variety of products. We will compete with other manufacturers for the supply of these components. Additionally, certain parts that are currently in our design may be discontinued by our suppliers requiring us to find alternative parts. This issue may require us to change the design of our device or purchase significant inventories of these parts in order to protect against manufacturing delays. We may not be able to procure alternative components or adequate raw material inventories which would result in an inability to produce our device.

As our international sales and operations grow, we could become increasingly subject to additional economic, political, and other risks that could harm our business.

We have sales and operations both inside and outside the United States, including a limited sales and marketing organization outside the United States. Our short-term international sales strategy is to increase our presence in Europe and Canada. To successfully market and sell our products in markets outside of the United States, we must address many international business risks with which we have limited experience, and failure to manage these risks may adversely affect our operating results and financial condition. These risks include:

- the impact of recessions and other economic conditions in economies, including impact of COVID-19 pandemic, outside the United States;

- instability of foreign economic, political and labor conditions;
- unfavorable labor regulations applicable to our European operations, such as severance and the unenforceability of non-competition agreements in the European Union;
- difficulties in complying with restrictions imposed by regulatory or market requirements, tariffs, or other trade barriers or by U.S. export laws;
- potentially adverse tax consequences, including, if required or applicable, difficulties transferring funds generated in non-U.S. jurisdictions to the United States in a tax efficient manner;
- difficulties in protecting intellectual property, especially in international jurisdictions;
- foreign certification and regulatory clearance or approval requirements;
- difficulties in developing effective marketing campaigns in unfamiliar foreign countries;
- customs clearance and shipping delays;
- difficulties in managing international operations; and
- burdens of complying with a wide variety of foreign laws.

Our success depends, in part, on our ability to anticipate and address these and any new risks. We cannot guarantee that these or other factors will not adversely affect our business or operating results.

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.

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 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.

Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, or those of our vendors, may be vulnerable to attacks by hackers or viruses or otherwise breached due to employee error, malfeasance or other activities. While we believe we have not experienced any such attack or breach, both we and our vendors may be unable to anticipate attacks, to implement adequate preventative or mitigation measures, to identify any attacks or incidents on a timely basis, or to remediate or otherwise address any attacks or incidents in a timely manner. If any such attack or other incident were to occur, our systems and networks would be compromised and the information we store on those systems and networks could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Any such access, disclosure or other loss of information could result in a loss of intellectual property protection, legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and the California Consumer Privacy Act of 2018 ("CCPA"), or regulatory penalties, and could require substantial efforts to remediate and otherwise respond to the incident. The CCPA requires covered companies to, among other things, make certain enhanced disclosures related to California residents regarding our use or disclosure of their personal information, allow California residents to opt out of certain uses and disclosures of their personal information without penalty, provide Californians with other choices related to personal data in our possession, and obtain opt-in consent before engaging in certain uses of personal information relating to Californians under the age of 16. The California Attorney General may seek substantial monetary penalties and injunctive relief in the event of our noncompliance with the CCPA. The CCPA also allows for private lawsuits from Californians in the event of certain data breaches. Certain aspects of the CCPA and its interpretation remain uncertain, and we may need to modify our policies or practices in an effort to comply with it. Moreover, in November 2020, California voters approved a new privacy law, the California Privacy Rights Act ("CPRA"), which significantly modifies the CCPA, resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. Most of the substantive provisions of the CPRA will not take effect until January 2023, however.

Unauthorized access, loss or dissemination of data could also disrupt our operations, including our ability to process tests, provide test results, provide services, conduct research and development activities, collect, process and prepare company financial information, provide information about our product candidates and manage the administrative aspects of our business and could damage our reputation, any of which could adversely affect our business. We cannot be certain that our insurance coverage will be adequate for data handling or data security liabilities actually incurred, that insurance will continue to be available to us on economically reasonable terms, or at all, or that any future claim will not be excluded or otherwise be denied coverage by any insurer. The successful assertion of one or more claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, including our financial condition, operating results and reputation.

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

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

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

We may fail to meet expectations relating to environmental, social and governance factors.

Market participants, including investors, analysts, customers, and other key stakeholders are increasingly focused on environmental, social and governance ("ESG") factors. We have never had a comprehensive ESG initiative at the Company. Moreover, the ESG factors by which companies' corporate responsibility practices are assessed differ among market participants, are constantly evolving and could result in greater expectations of us and/or cause us to undertake costly initiatives to satisfy such new criteria. We risk damage to our brand and reputation if our corporate responsibility procedures or standards do not meet the standards expected by us. Furthermore, we could fail, or be perceived to fail, in our achievement of any ESG initiatives or goals we may establish in the future and we could also be criticized for the scope of such initiatives or goals. If we fail to satisfy the expectations of investors and other key stakeholders or our initiatives are not executed as planned, our reputation and financial results could be materially and adversely affected.

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; and
- the inability to commercialize any future products that we may develop.

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

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

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

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

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

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

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

Risks Related to Product Development

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

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

Our long-term growth depends on our ability to commercialize our products in development and to develop and commercialize additional products through our research and development efforts, and if we fail to do so we may be unable to compete effectively.

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 and commercialize new products and applications for our NPS technology, including in new markets that develop as a result of technological and scientific advances, while improving the performance and cost-effectiveness of our products in the dermatology market. 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. Additionally, these products and any future products might not be accepted by dermatologists 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.

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

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

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

In February 2021, we received a 510(k) clearance from the FDA for the CellFX System for dermatologic procedures requiring ablation and resurfacing of the skin. We plan to pursue specific indications for the CellFX System, starting with an indication for the treatment of SH lesions, requiring additional 510(k) submissions for each indication, and will likely be based on comparative clinical data. In February 2022, we received an Additional Information ("AI") letter from the FDA in response to a 510(k) submission to the FDA to add the specific indication for the treatment of sebaceous hyperplasia to expand the CellFX System's current labeling. In the AI letter, the FDA stated it did not believe the Company provided sufficient clinical evidence at this time to support the expanded indication for use, and that the Company had not met the primary endpoints of the sebaceous hyperplasia FDA-approved IDE study. The Company anticipates meeting with the FDA to discuss the contents of the AI letter and potential next steps, which may require additional clinical data and potentially a new 510(k) submission.

Any failure to obtain further 510(k) clearances may add significant time and expense to our regulatory clearance process, may delay our ability to generate revenue, and may have a negative impact on our stock price. We may not be able to obtain the necessary clearances or approvals necessary to market the CellFX System for specific indications or such approvals or clearances may be unduly delayed, which could harm our business. If the FDA rejects our 510(k) submissions for specific indications, we may be required to obtain FDA approval through the de novo pathway, which will require additional time and resources, including the need to conduct more clinical studies to demonstrate safety and effectiveness of our candidate device.

The FDA may not approve or clear our 510(k), de novo, or PMA applications on a timely basis or at all. Such delays or refusals could have a material adverse effect on our business operations and financial condition. The FDA may also change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other 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 the 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 product 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, and we have only completed a limited number of feasibility studies in humans. Undesirable side effects caused by the CellFX System, NPS pulses, or any of our planned future products could cause us or regulatory authorities to interrupt, delay or halt clinical trials or to revoke previously granted regulatory approvals. Undesirable side effects could also result in more restrictive labeling requirements or the delay or denial of regulatory approval of planned future products by the FDA or other comparable foreign regulatory authority.

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

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

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

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

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

We may find it difficult to enroll patients in our clinical trials. If we cannot enroll a sufficient number of eligible patients to participate in 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, CellFX procedures will be administered by healthcare professionals and will require a degree of training and practice to administer correctly. Treatment results achieved in the laboratory or in clinical trials conducted by us or by other investigators may not be representative of the results actually encountered during commercial use of our products due to variability in administration technique. The training and skills of investigators in our clinical trials may not be representative of the training and skills of future product users, which could negatively affect treatment results and the reputation of the Company or its products. In addition, there may be a selection bias in the patients and/or sites of administration chosen for any clinical trials that would positively affect treatment results that may not be representative or predictive of real-world experience with our products, including the CellFX System.

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

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

We may encounter manufacturing problems or delays that could result in lost revenue. 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 are in the process of commencing commercial-scale manufacturing of our product, and we currently rely upon third-party suppliers to manufacture and supply components for the CellFX System. We perform final assembly of our devices at our facility in California. We believe we have an adequate inventory of materials and manufacturing capacity to support all our anticipated commercial launch activities. However, if demand for our product increases significantly, we will need to either expand our manufacturing capabilities or outsource to other manufacturers. 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 product in a manner that conforms to our specifications and these strict regulatory requirements, we may not be able to rely on their manufacturing facilities for the manufacture of our product. 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 the CellFX System under purchase orders and do not have long-term contracts with most of the suppliers of these materials. If suppliers were to delay or stop producing our components, or if the prices they charge us were to increase significantly, or if they elected not to sell to us, we would need to identify other suppliers and we may not be able to secure alternative suppliers on favorable terms, or at all. Also, any number of our suppliers may be adversely impacted by COVID-19 which could affect their ability to perform satisfactorily. Any failure of these suppliers to perform satisfactorily could adversely impact our business and results of operations and we may experience delays in manufacturing of our devices while finding another acceptable supplier.

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

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

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

Medicare reimburses for medical technologies and products in a variety of ways, depending on where and how the item is used. However, Medicare only provides reimbursement if CMS determines that the item should be covered and that the use of the device or product is consistent with the coverage criteria. A coverage determination can be made at the local level by the Medicare administrative contractor, a private contractor that processes and pays claims on behalf of CMS for the geographic area where the services were rendered, or at the national level by CMS through a national coverage determination. There are statutory provisions intended to facilitate coverage determinations for new technologies, but it is unclear how these new provisions will be implemented, and it is not possible to indicate how they might apply to the CellFX System or to any of our proposed devices and products, as they are still in the development stages. Coverage presupposes that the technology, device, or product has been cleared or approved by the FDA and further, that the coverage will be consistent with the approved intended uses of the device or product as approved or cleared by the FDA, but coverage can be narrower. A coverage determination may be so limited that relatively few patients will qualify for a covered use of a device or product.

Obtaining a coverage determination, whether local or national, is a time-consuming, expensive and highly uncertain proposition, especially for a new technology, and inconsistent local determinations are possible. On average, Medicare coverage determinations for medical devices and products lag behind FDA approval or clearance. The Medicare statutory framework is also subject to administrative rulings, interpretations and discretion that affect the amount and timing of reimbursement made under Medicare. Medicaid coverage determinations and reimbursement levels are determined on a state-by-state basis, because Medicaid, unlike Medicare, is administered by the states under a state plan filed with the Secretary of the U.S. Department of Health and Human Services ("HHS"). Medicaid generally reimburses at lower levels than Medicare. Moreover, Medicaid programs and private insurers are frequently influenced by Medicare coverage determinations.

We work with outside scientists and their institutions in developing our product and product candidates. These scientists may have other commitments or conflicts of interest, which could limit our access to their expertise, harm our ability to leverage our discovery platforms, or negatively impact our clinical trials.

We work with scientific advisors and collaborators at academic research institutions in connection with our product development efforts. These scientists and collaborators are not our employees, but they serve as either independent contractors or researchers under research agreements that we have with their sponsoring clinic, academic institution or research institution. These scientists and collaborators may have other commitments limiting their availability to us. Although our scientific advisors generally agree not to do competing work, if an actual or potential conflict of interest between their work for us and their work for another entity arises, we may lose their services. It is also possible that some of our valuable proprietary knowledge may become publicly known through these scientific advisors if they breach their confidentiality agreements with us, which could cause competitive harm to our business. To the extent these scientists and collaborators, including those assisting us with our clinical trials, may receive cash or equity compensation in connection with such services from time to time, these relationships and any related compensation may result in perceived or actual conflicts of interest, or cause a regulatory authority to conclude that the financial relationship may have affected the interpretation of the trial, such that the integrity of the data generated by them or by their institutions may be questioned and the utility of the data itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit.

Risks Related to Intellectual Property

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

Patents and other proprietary rights are essential to our business and our ability to compete effectively with other companies is dependent upon the proprietary nature of our technologies. 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 to maintain our competitive advantage. The following examples are illustrative:

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

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

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

In addition to patented technology, we rely upon, among other things, unpatented proprietary technology, processes, trade secrets, and know-how. Any involuntary disclosure to, or misappropriation by, third parties of our confidential or proprietary information could enable competitors to duplicate or surpass our technological achievements, potentially eroding our competitive position in our market. We seek to protect confidential 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.

We have not yet registered some of our trademarks in all of our potential markets, and failure to secure those registrations could adversely affect our business. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic, or conflict with third-party rights. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. Additionally, even if we apply to register our trademarks in all of our potential markets, our applications may not be allowed for registration, and our registered trademarks may not be maintained or enforced. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. If we are unable to establish name recognition based on our trademarks and trade names, then our marketing abilities may be impacted.

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.

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

The development, marketing, and sale of the CellFX System, and 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. 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;

- 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 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. In addition, we are subject to the risk that a person or government could allege violations of such laws, regulations and other obligations, or allege that fraud or other misconduct has taken place, even if no misconduct has occurred. If any such actions are instituted against us, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations if we are not successful in defending ourselves or asserting our rights. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the above occur, it could have a material adverse effect on our liquidity and financial condition.

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

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

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

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

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

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

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

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

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

Because we and one of our licensors have used federal funding in the development of certain aspects of our technology, the federal government retains 'march-in' rights in connection with results derived from these grants.

March-in rights give the federal government the right to grant to other entities, which may include competitors, licenses or to take a license for itself if the government funded the development of a patent. The march-in right applies to patents that have been issued. The march-in right is intended to be used only if there is a threat to public health and safety that the owner of the patent is not equipped to handle. The march-in right may also be used to remove the exclusive rights belonging to a patent holder if the patent for which the government provided funding is not suitable for public use. If march-in rights are used by the government, the entities using the patent are required to pay royalties to the patent holder, which amount would be subject to negotiation. Because federal funding was used for some aspects of the Company's technology that will be the subject of some of our patents, the Company could be subject to the march-in right and lose its exclusivity of those patents, and may suffer direct competition if any license is granted by the government under the march-in right to a competitor.

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

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

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

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

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

Risks Related to Owning Our Common Stock

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

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

- results of clinical trials of our planned products or those of our competitors;
- actions by regulatory bodies, such as the FDA, that affect our business or have the effect of delaying or rejecting approval or clearance of our planned products;
- actual or anticipated fluctuations in our financial condition and operating results;
- announcements by our customers, partners or suppliers relating directly or indirectly to our products, services or technologies;
- announcements of technological innovations by us or our competitors;
- changes in laws or regulations applicable to the CellFX System or to our planned products;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, capital commitments, or achievement of significant milestones;
- additions or departures of key personnel;
- competition from existing products or new products that may emerge;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- disputes or other developments related to proprietary rights, including patents, litigation matters or our ability to obtain intellectual property protection for our technologies;
- actual or alleged security breaches;

- announcements or expectations of additional financing efforts;
- sales of our common stock by us or our stockholders;
- stock price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- reports, guidance and ratings issued by securities or industry analysts;
- overall conditions in our industry and market including the negative impact of COVID-19 on the global economy and markets; and
- general economic and market conditions.

Any of the above may cause our stock price or trading volume to decline. Stock markets in general, and the market for companies in our industry in particular, have experienced price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies, including ours. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively impact the market price of our common stock. Investors may not realize any return on their investment in us and may lose some or all of their investment. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. The high volatility of our stock price, the composition of our Board and governance practices, including our 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 Board 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 may issue shares of common stock or securities convertible into, exchangeable or exercisable for our common stock from time to time in connection with financings, acquisitions, investments, or otherwise. Any such issuances would result in dilution to some or all of our existing stockholders and could cause our stock price to fall. We may also sell shares or other securities at a price per share that is less than the price per share paid by existing investors, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders.

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

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

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

A majority percentage of our outstanding stock is held by Robert W. Duggan, Chairman of our Board, who beneficially owns approximately 51% of our common stock outstanding as of the date of this Annual Report. As a result, Mr. Duggan has control over corporate actions requiring stockholder approval, including the following actions:

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

Mr. Duggan's controlling interest in the Company also creates the potential for conflicts of interest which be viewed unfavorably by minority stockholders, thereby hurting our stock price. For example, in November 2021, we engaged outside legal counsel to represent the Company even though the same legal counsel currently represents Mr. Duggan personally in other matters. This legal counsel represented Mr. Duggan in certain related party transactions described herein and could represent both the Company and Mr. Duggan in future related party transactions. Three of our directors, including Mr. Duggan, are executives at Summit Therapeutics Inc., another company in which Mr. Duggan holds a controlling equity interest.

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 Board Chairman, and beneficially owns approximately 51% 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 Robert W. Duggan's controlling ownership and position as Board Chairman, others may be less inclined to pursue an acquisition of us and therefore we may not have the opportunity to be acquired in a transaction that stockholders might otherwise deem favorable, including transactions in which our stockholders might realize a substantial premium for their shares. In addition, public speculation regarding Mr. Duggan, as well as our relationship with Mr. Duggan, could cause our stock price to fluctuate.

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

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

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

Furthermore, these and future rules and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. 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. We are no longer an emerging growth company, however, we still qualify as a "smaller reporting company," as defined in the Exchange Act, and so long as we remain a smaller reporting company, we benefit from and may take advantage of scaled disclosure requirements. We cannot know if investors find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our reporting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected.

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

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

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

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

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

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

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

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

General Risk Factors

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including the negative impact of COVID-19 on the global economy and markets. Furthermore, the market for aesthetic medical treatments may be particularly vulnerable to unfavorable economic conditions. A global financial crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets, as has recently been the case due to COVID-19. A severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including weakened demand for our lead product, the CellFX System, or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our products. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

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

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

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

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

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

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

The COVID-19 pandemic has resulted in government authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns.

For most of 2020 and much of 2021, we required, in accordance with local and state guidelines regarding the COVID-19 pandemic, all of our employees to work remotely unless they could not perform their essential functions remotely. We also suspended all non-essential travel for our employees. While many of our employees are accustomed to working remotely or working with other remote employees, much of our workforce has not historically been remote. We continue to monitor the situation and may adjust our current policies as more information and public health guidance becomes available. Operational restrictions as a result of the COVD-19 pandemic could harm our business, financial condition and results of operations.

In addition, our clinical trials may be affected by the continuing COVID-19 pandemic. Site initiation and patient enrollment may be delayed, for example, due to prioritization of hospital resources toward the COVID-19 pandemic, travel restrictions imposed by governments, and the inability to access sites for initiation and monitoring. Some of our suppliers of certain materials used in the production of the CellFX System are located in areas heavily impacted by COVID-19 which could limit our ability to obtain sufficient materials. COVID-19 has and will continue to adversely affect global economies and financial markets of many countries, resulting in an economic downturn that could affect demand for the CellFX System and other product candidates, if approved, and impact our operating results. Even after the COVID-19 pandemic has subsided, we may continue to experience an adverse impact to our business as a result of the continued global economic impact of the pandemic. Although we are continuing to monitor and assess the effects of the COVID-19 pandemic on our business, the ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change.

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We currently lease approximately 50,300 square feet of premises located in Hayward, California, which is used for our corporate headquarters and principal operating facility. The term of the original lease included approximately 15,700 square feet for 62 months and commenced on July 1, 2017. In May 2019, we entered into an amendment which enabled us to expand the lease by approximately 34,600 additional square feet, for a total of approximately 50,300 square feet. The amendment also included an option to extend the term of the lease. Approximately 13,300 square feet of the additional space was occupied in November 2019 as part of the first phase, and the remaining approximately 21,300 square feet was occupied in May 2020 as part of the second phase. The term of the total lease was extended through October 2029.

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

Item 3. Legal Proceedings.

From time to time, we may be involved in a variety of claims, lawsuits, investigations and proceedings relating to securities laws, product liability, patent infringement, contract disputes and other matters relating to various claims that arise in the normal course of our business in addition to governmental and other regulatory investigations and proceedings. In addition, third parties may, from time to time, assert claims against us in the form of letters and other communications.

In February 2022, a civil securities lawsuit was filed in the U.S. District Court for the Northern District of California against the Company and certain of its executive officers, following the Company's announcement on February 8, 2022 that it had received an Additional Information letter from the FDA indicating that the FDA did not believe the Company provided sufficient clinical evidence to support its 510(k) submission to add the treatment of sebaceous hyperplasia to the CellFX System's current U.S. labeling, and the subsequent decline of the market price of the Company's common stock. The Company is currently evaluating the case and its allegations. The lawsuit seeks class certification, unspecified damages, fees, costs, and expenses. The Company expects to file a motion to dismiss the case later this year, and an estimate of possible loss or range of loss, if any, cannot be made.

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

Item 4. Mine Safety Disclosures

Not applicable.

Part II

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

Market Information

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

Holders of Record

As of March 25, 2022, there were approximately 12 stockholders of record of our common stock. We believe the actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in "street" name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

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

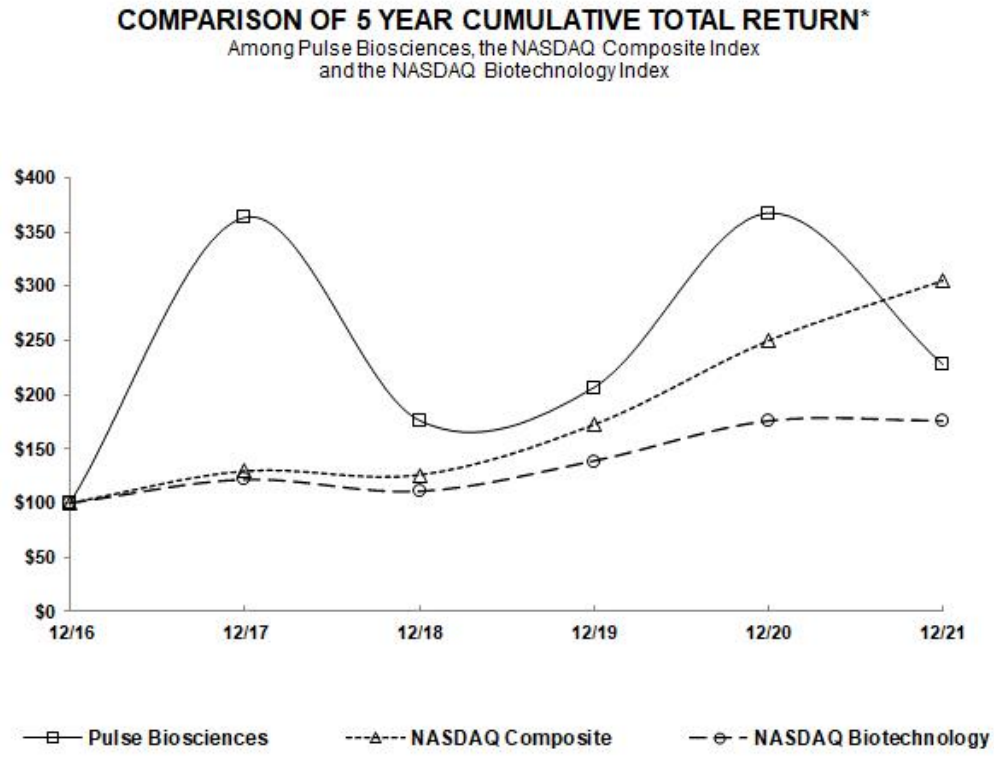
Sales of Unregistered Securities

None.

Performance Graph

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

The following graph matches our cumulative 5-year total shareholder return on common stock with the cumulative total returns of the Nasdaq Composite Index and the Nasdaq Biotechnology Index. The graph tracks the performance of a $100 investment in our common stock and in each index (with the reinvestment of all dividends) from December 31, 2016, to December 31, 2021. Such returns are based on historical results and are not intended to suggest future performance.



Item 6. Selected Financial Data

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

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes thereto included in Item 8 under the heading "Financial Statements and Supplementary Data". Some of the information contained in this discussion and analysis or set forth elsewhere in this Form 10-K contains forward-looking statements that involve risks and uncertainties, including statements regarding our expected financial results in future periods. The words "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "might," "plans," "projects," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. You should read the "Risk Factors" section of this Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. We do not assume any obligation to update any forward-looking statements.

Overview

We are a novel bioelectric medicine company committed to health innovation using an entirely new and proprietary energy modality. The CellFX System is the first commercial product to harness the distinctive advantages of our proprietary Nano-Pulse Stimulation technology. The CellFX System delivers nano second duration pulses of electrical energy, each less than a millionth of a second long, to non-thermally clear targeted cells while sparing adjacent non-cellular tissue, to treat a variety of medical conditions for which an optimal solution remains unfulfilled.

In January 2021, we received CE marking approval for the CellFX System, which allows us to market the system in the European Union and, in June 2021, we received Health Canada approval for the CellFX System, which allows for marketing of the system in Canada. The CE mark and Health Canada approvals allow us to market the CellFX System for use in dermatological procedures requiring ablation and resurfacing of the skin for the reduction, removal, and/or clearance of cellular-based benign lesions, including SH, SK, and cutaneous non-genital warts. In February 2021, we received 510(k) clearance from the FDA for the CellFX System for dermatologic procedures requiring ablation and resurfacing of the skin.

In February 2021, we initiated controlled launch programs in the United States and the European Union and in June 2021 we initiated a controlled launch program in Canada (collectively, our "Controlled Launch"). Under the Controlled Launch program, the physicians and their patients complete evaluation surveys about their experiences with the CellFX System and provide other information helpful to defining best practices for the introduction of the CellFX System into the clinic practice. As of December 31, 2021, we onboarded a total of seventy CellFX Controlled Launch Program participants across the United States, Europe, and Canada, completing program enrollment. In August 2021, we began to convert Controlled Launch Program participants into sales agreements, triggering revenue recognition. As of December 31, 2021, twenty-nine Controlled Launch Program participants opted to purchase their CellFX System and six clinics opted out of the program. An objective of the Controlled Launch program is to turn participating clinics into high utilization commercial customers that will serve as important reference clinics for future commercial customers.

We initially expected clinics to complete the program requirements within three to five months. However, the average time for clinics that have completed the Controlled Launch program has been seven months. We continue to gain valuable information from the Controlled Launch process. While the real-world delivery of NPS technology through the CellFX System has proven to clear benign lesions in clinical studies, we have learned that the market development for benign lesions and the integration of this procedure into the practice workflow will require a higher touch model to generate the system utilization we are expecting. We now expect clinics to continue to move through the program throughout 2022, as they complete the program requirements.

Controlled Launch participants that have opted to purchase the CellFX System for commercial use have performed CellFX procedures since becoming commercial users and, in the aggregate, have increased the number of treatment sessions per month. Currently, our commercial clinics are averaging ten patient treatment sessions per month wither their CellFX System. Our goal for the end of 2022 is to increase utilization to forty patient treatment sessions per month at our current commercial clinics. To drive this increased utilization and emphasis on education, training and marketing at our current accounts, we have implemented changes to our commercial leadership, restructured our commercial field organization and modified our strategy in support of our utilization focus and reduced emphasis on new system sales in the near-term. In February 2022, we appointed Kevin Danahy as Chief Commercial Officer. Mr. Danahy has a proven track record of building exceptional commercial teams and implementing strategies to drive market penetration and significant growth with disruptive medical technologies across a variety of medical disciplines. Under Mr. Danahy's leadership, the near-term focus of our commercial team's efforts will be to increase utilization at our commercial clinics.

We completed the first two commercial sales of CellFX Systems in the fourth quarter of 2021. The majority of our revenue for the year ended December 31, 2021 was recognized on a non-cash basis when Controlled Launch Program participants applied their earned credits towards the purchase of a CellFX System. See Note 8 for additional details of the Controlled Launch Program and Note 9 for additional details of the revenue transactions.

We are pursuing specific indications for the CellFX System in the United States similar to the regulatory clearances we have received in Europe and Canada, requiring additional 510(k) submissions, and likely based on comparative clinical data. In December 2021, we submitted a 510(k) to add the treatment of SH to the CellFX System's indications for use in the United States. In February 2022 we received an AI letter from the FDA in response to the 510(k) submitted. In the AI letter, the FDA stated it did not believe the Company provided sufficient clinical evidence at this time to support the expanded indication for use, and that the Company had not met the primary endpoints of the SH FDA-approved IDE study. The Company anticipates meeting with the FDA to discuss the contents of the AI letter and potential next steps, which may require additional clinical data and potentially a new 510(k) submission.

We have incurred substantial operating losses and have used cash in our operating activities since inception. Based on our current operating plan, we believe we do not have sufficient cash and cash equivalents on hand to support current operations for the twelve months following the filing of this Annual Report. Therefore, to finance our ongoing operations, we will need to raise additional capital or enter into a revenue-generating collaboration, which cannot be assured. We plan to seek to raise capital from time to time through public or private equity offerings, debt financings, our at-the-market equity offering program, or to enter into collaborations with third parties, to fund our future operations. Meanwhile, over the past few years, Mr. Duggan, our majority stockholder, has made significant investments in our Company to fund its operations. Mr. Duggan may 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 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 CellFX commercial program, as well as future clinical and regulatory developments concerning the CellFX System and our other NPS-based technologies. Funding may not be available when needed, at all or on terms acceptable to us. Lack of necessary funds may require us to, among other things, delay, scale back or eliminate some or all of our commercial activities, reduce headcount, trim research and product development programs, discontinue clinical trials, stop all or some of our manufacturing operations, defer capital expenditures, deregister from being a publicly traded company and delist from Nasdaq, or license our potential products or technologies to third parties, possibly on terms that cannot sustain our current business. In addition, the recent decline in economic activity caused by the armed conflict between Russia and Ukraine and by the COVID pandemic, together with the deterioration of the credit and capital markets, could have an adverse impact on potential sources of future financing.

Plan of Operation

We plan to establish ourselves as a medical therapy company with a local, nonthermal, and drug-free treatment platform that initiates cell death in targeted tissue by a process of cell signaling. In order to accomplish this, we plan to:

- Improve our technology by continuing our research and product development efforts. We expect to develop interchangeable tissue applicators to target different tissue types that will leverage the novel characteristics of our NPS technology platform.

- Further explore and understand the benefits of our NPS technology platform with the objectives of broadening the currently planned cosmetic and therapeutic applications, while also identifying new applications. We anticipate that results of our clinical studies will enable us to recognize certain unmet medical needs that may be addressed by our technology.

- Continue to protect and expand our intellectual property portfolio with respect to NPS technology, which we expect will increase our ability to deter competitors and position our Company for favorable licensing and partnering opportunities.

- Partner with medical or biomedical device companies for certain applications which we anticipate may accelerate product development and acceptance into target market areas and allow us to gain the sales and marketing advantages of one or more established distribution infrastructures.

COVID-19 Pandemic

Our clinical trials may be affected by the COVID-19 pandemic. Site initiation and patient enrollment may be delayed, for example, due to prioritization of hospital resources toward the COVID-19 pandemic, travel restrictions imposed by governments, and the inability to access sites for initiation and monitoring. Also, it is possible that delivery from some of our suppliers of certain materials used in the production of our product candidates could be delayed due to COVID-19 which could affect our ability to obtain sufficient materials for our product candidates. COVID-19 has adversely affected global economies and financial markets and will likely continue to do so, resulting in an economic downturn that could affect demand for our product candidates and impact our operating results. Even after the COVID-19 pandemic has subsided, we may continue to experience an adverse impact to our business as a result of the continued global economic impact of the pandemic. We cannot anticipate all of the ways in which health epidemics such as COVID-19 could adversely impact our business. Although we are continuing to monitor and assess the effects of the COVID-19 pandemic on our business, the ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. See the Risk Factors section for further discussion of the possible impact of the COVID-19 pandemic on our business.

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. During the year ended December 31, 2021, the Company received 510(k) clearance, CE marking approval, and Health Canada clearance for the CellFX System and began to capitalize inventory in preparation of commercialization. Additionally, during the year ended December 31, 2021, the Company entered into sales contracts with customers and began to recognize revenue.

Valuation of Inventory

Inventory is stated at lower of cost or net realizable value. We established 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 our business, less reasonably predictable costs of completion, disposal, and transportation. The cost basis of our 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, 2021, there is no reduction to the balance of inventory for excessive and obsolete inventory.

Revenue from Contracts with Customers

We recognize revenue at a point in time as we satisfy performance obligations by transferring control of promised goods to our customers. The amount of revenue recognized is equal to the consideration which we are entitled to in exchange for the promised goods, excluding any amounts assessed by government authorities for taxes which might be collected from a customer. Sales contracts often involve the sale and delivery of multiple products, each of which typically represent a separate performance obligation in the contract. While we sell these products on a stand-alone basis at a particular stand-alone selling price ("SSP"), initial customer contracts will likely involve the bundling of products which will be delivered concurrently to the customer and have the same pattern of transfer. In such instances, the full consideration of the contract will be recognized upon delivery of the products. We include a standard warranty on our products which provides assurances that the products comply with agreed-upon specifications.

Product Warranty

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

Stock-Based Compensation

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

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

Income Taxes

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

We provide a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realized. If we determine that we would be able to realize deferred tax assets in the future in excess of the recorded amount, an adjustment to the deferred tax assets would be credited to operations in the period such determination was made. Likewise, should we determine that we would not be able to realize all or part of its deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to operations in the period such determination was made.

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

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

Results of Operations

Comparison of the Years ended December 31, 2021 and 2020

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

(in thousands)	Year Ended December 31, 2021	2020*	$ Change
Revenues:			
Product revenues	$ 1,418	$ —	$ 1,418
Total revenues	1,418	—	1,418
Cost and expenses:			
Cost of revenues	1,968	—	1,968
Research and development	28,640	26,444	2,196
Sales and marketing	14,751	7,256	7,495
General and administrative	19,073	16,265	2,808
Total cost and expenses	64,432	49,965	14,467
Loss from operations	(63,014)	(49,965)	(13,049)
Other income (expense):			
Interest income (expense), net	(646)	114	(760)
Total other income (expense)	(646)	114	(760)
Loss from operations, before income taxes	(63,660)	(49,851)	(13,809)
Income tax benefit	—	—	—
Net loss	$ (63,660)	$ (49,851)	$ (13,809)

* Certain 2020 amounts have been reclassified to conform to the current period presentation. Sales and marketing expenses have been reclassified out of general and administrative and presented as a separate line item. Amortization of intangible assets have been reclassified to general and administrative expenses.

Revenues

Revenues increased by $1.4 million to $1.4 million for the year ended December 31, 2021, from zero during the same period in 2020. We commenced sales agreement activity in August 2021, triggering the recognition of revenue.

Cost of Revenues

Cost of revenues increased by $2.0 million to $2.0 million for the year ended December 31, 2021, from zero during the same period in 2020. Prior to commercialization in August 2021, all uncapitalized manufacturing related overhead costs were recorded as research and development expenses. Upon commercialization, these costs are recorded as cost of revenues.

Research and Development

Research and development expenses consist of salaries and related expenses for research and development personnel, clinical trials, professional fees and consulting costs related to the design, development and enhancement of our current and potential future products, engineering prototypes and pre-commercial manufacturing supplies. Research and development expenses increased by $2.2 million to $28.6 million in 2021 from $26.4 million in 2020 due to $1.4 million of increased clinical trial and other outside research costs, $1.2 million of increased stock-based compensation, and $1.0 million of increased compensation and other employee related expenses. These increases were partially offset by decreases of $1.0 million in expensed equipment and supplies and $0.7 million of manufacturing absorption related to inventory production previously expensed to research and development prior to commercialization. Compensation costs increased primarily due to headcount growth, while consulting and outside services increased primarily due to new application development, medical research and studies.

Sales and Marketing

Sales and marketing expenses consist of compensation and other related employee expenses for sales and marketing personnel, expenses associated with advertising and training, and marketing studies including our Controlled Launch program. Sales and marketing expenses increased by $7.5 million to $14.8 million in 2021 from $7.3 million in 2020 due to $3.0 million of increased compensation and other employee related expenses as a result of increased headcount, $1.6 million increased stock-based compensation, $1.8 million of non-cash Controlled Launch expenses, and $0.5 million of increased paid services. The increases in sales and marketing expenses are attributable to commercialization activities of the CellFX System subsequent to receiving FDA clearance, CE marking approval, and Health Canada clearance.

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, public company costs, and other general corporate expenses. General and administrative expenses increased by $2.8 million to $19.1 million in 2021 from $16.3 million in 2020 due to $1.2 million of increased compensation and other employee related expenses and $1.6 million of increased stock-based compensation, both primarily related to headcount growth.

Other Income (Expense)

Interest expense increased by $0.7 million to $0.7 million for the year ended December 31, 2021, from zero during the same period in 2020 due to the Loan Agreement entered into in March 2021 and Insurance Loan Agreement entered into in May 2021. Interest income decreased by $0.1 million primarily due to decreased investment activity.

Comparison of the Years ended December 31, 2020, and 2019

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, 2020, filed on March 12, 2021, for the discussion of the comparison of the fiscal year ended December 31, 2020, to the fiscal year ended December 31, 2019, the earliest of the three fiscal years presented in the consolidated financial statements.

Liquidity and Capital Resources

To date, we have not generated significant revenues from product sales. Since inception, we have funded our business primarily through the issuance of equity securities and debt. Over the next few years, we intend to invest in research and development to develop new applications for existing products and additional commercially viable products and to assess the feasibility of potential future products. Additionally, we expect that our general and administrative expenses will increase as we continue to incur incremental costs associated with being a public company and our sales and marketing expenses will increase as we continue to commercialize the CellFX System.

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, 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 Board 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.

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

	Year Ended December 31,		
(in thousands)	2021	2020	2019
Net cash used in operating activities	$ (54,097)	$ (35,365)	$ (34,185)
Net cash provided by (used in) investing activities	$ 7,563	$ 10,044	$ (10,101)
Net cash provided by financing activities	$ 62,685	$ 30,885	$ 82
Net increase (decrease) in cash and cash equivalents	$ 16,151	$ 5,564	$ (44,204)

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, 2021, the Company had an accumulated deficit of $236.2 million, cash outflows from operations of $54.1 million for the year then ended, cash and cash equivalents of $28.6 million and a net loss of $63.7 million. These factors, combined with the Company's forecast of cash required to fund operations for a period of at least twelve months from the date of issuance of the accompanying consolidated financial statements, raise substantial doubt under ASC 205-40, *Presentation of Financial Statements – Going Concern* about the Company's ability to continue as a going concern within one year after the issuance of these consolidated financial statements. We plan to raise additional capital in the future to fund our operations through public or private equity offerings, debt financings, or our at-the-market equity offering program, or by entering into revenue-generating collaborations. Mr. Duggan, our majority stockholder, may elect to participate in any number of our future financings, or alternatively he may offer to provide debt financing as may be needed in order to maintain the Company as a going concern. 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 will be diluted, and the holders of new equity securities may have priority rights over our existing stockholders. If adequate funds are not available, we may be required to curtail operations significantly or 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, delay, scale back or eliminate some or all of our commercial activities, reduce headcount, trim research and product development programs, discontinue clinical trials, stop all or some of our manufacturing operations, defer capital expenditures, deregister from being a publicly traded company and delist from Nasdaq, or license our potential products or technologies to third parties, possibly on terms that cannot sustain our current business. In addition, the recent decline in economic activity caused by the armed conflict between Russia and Ukraine and by the COVID pandemic, together with the deterioration of the credit and capital markets, could have an adverse impact on potential sources of future financing.

Operating Activities

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.

During 2020, we used cash of $35.4 million in operating activities. The difference between cash used in operating activities and net loss consisted primarily of stock-based compensation, accrued expenses, depreciation and amortization, and right-of-use assets, partially offset by decreases in prepaid expenses and other current assets.

Investing Activities

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

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

During 2020, cash provided from investing activities was $10.0 million, of which $39.5 million was provided from the maturities and sales of investments, offset by $29.5 million for the purchase of investments and property and equipment.

Financing Activities

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.

During 2020, cash provided from financing activities was $30.9 million, of which $29.4 million was received from the rights offering, $1.0 million received from the exercise of stock options and warrants, and $0.5 million received from the sale of our stock under our employee stock purchase plan.

Comparison of the Years ended December 31, 2020, and 2019

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, 2020, filed on March 12, 2021, for the discussion of the comparison of the fiscal year ended December 31, 2020, to the fiscal year ended December 31, 2019, 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 August 2018, we agreed to sponsor a task order for research in the amount of $0.8 million and in September 2019, we agreed to sponsor an additional task order for research in the amount of $0.8 million each to be performed during their respective subsequent 12-month periods. In March 2021, we agreed to sponsor a task order for research in the amount of $0.3 million and in May 2021 we sponsored an additional task order for $0.3 million each to be performed during their respective subsequent 12-month periods. These sponsored researches are funded through monthly payments made upon ODURF certifying, to our reasonable satisfaction, that ODURF has met its obligations pursuant to the specified task order and statement of work. The principal investigator may transfer funds within the budget as needed with our approval so long as the obligations of ODURF under the task order and statement of work remain unchanged and unimpaired. During the years ended December 31, 2021, 2020, and 2019, we incurred costs relating to the SRA equal to $0.3 million, $0.6 million and $0.9 million, respectively. As of December 31, 2021, there is a $0.3 million balance payable under this research agreement.

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.

Under the original lease agreement, the landlord provided a $2.1 million allowance for tenant improvements, which was recorded as deferred rent at the inception of the lease term. Future minimum lease payments are net of amortization of tenant improvement allowance. The following table summarizes our contractual obligations as of December 31, 2021 (in thousands):

	Payments Due by Period				
(in thousands)	Total	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 Years
Operating leases	$ 15,775	$ 1,806	$ 3,755	$ 4,023	$ 6,191

Off-Balance Sheet Arrangements

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

JOBS Act Accounting Election

Through the end of 2021, we were an emerging growth company as defined by the JOBS Act. Under the JOBS Act, we were given the option to delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we were subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Trends, Events and Uncertainties

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

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

See the section entitled “COVID-19 Pandemic” above and elsewhere in this Management’s Discussion and Analysis of Financial Condition and Results of Operations for a discussion of the current and potential future impact of COVID-19 on our business, financial condition and results of operation.

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, 2021, we did not have any investments.

Foreign Exchange Risk

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

Item 8. Financial Statements and Supplementary Data

PULSE BIOSCIENCES, INC.

Index to Consolidated Financial Statements

	Page Number
CONSOLIDATED FINANCIAL STATEMENTS	
Report of Independent Registered Public Accounting Firm (PCAOB ID No. 34)	65
Consolidated Balance Sheets	67
Consolidated Statements of Operations and Comprehensive Loss	68
Consolidated Statements of Stockholders' Equity	69
Consolidated Statements of Cash Flows	70
Notes to Consolidated Financial Statements	71

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, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

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

Basis for Opinion

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

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

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

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit 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.

Private Placement Securities Purchase Agreement and Termination of Loan Agreement — Refer to Notes 6, 12 and 13 to the consolidated financial statements

Critical Audit Matter Description

In March 2021, the Company and Robert W. Duggan, the Company's largest stockholder and Board Chairman, entered into a $41.0 million loan agreement. On June 30, 2021, the Company entered into a securities purchase agreement with Mr. Duggan in which the Company issued and sold approximately 3.0 million shares of common stock in a private placement. The shares were paid for through conversion of the $41.0 million aggregate principal amount of the loan, along with accrued interest and unpaid interest, and additional cash of approximately $8.4 million.

We identified the accounting for the conversion of the loan in connection with the private placement as a critical audit matter because of the complexity in applying the accounting framework for this related party transaction.

This required a high degree of auditor judgment and an increased extent of effort, including the use of professionals with specialized skill and knowledge, to evaluate the appropriateness of the accounting framework.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the accounting for the conversion of the loan included the following, among others:

- We read the Private Placement Securities Purchase Agreement and tested the accuracy and completeness of management's analysis of the transaction by agreeing the terms used in management's analysis to the Private Placement Securities Purchase Agreement.
- We read the Private Placement Securities Purchase Agreement and the Loan Agreement to evaluate management's conclusion that the Company was released from its obligations under the loan agreement as of June 30, 2021.
- We evaluated the accounting relative to the timing of cash received and shares issued, including its underlying supporting documents.
- With the assistance of professionals in our firm having expertise in accounting treatment for financial instruments, we evaluated management's conclusions regarding the accounting treatment applied to the accounting for the Private Placement Securities Purchase Agreement and Termination of Loan Agreement.
- We evaluated the Company's disclosures related to this related party transaction.

/s/ Deloitte & Touche LLP

San Jose, California
March 31, 2022

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

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

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 28,614	$ 12,463
Investments	—	8,012
Accounts receivable	61	—
Inventory	5,824	—
Prepaid expenses and other current assets	2,131	1,864
Total current assets	36,630	22,339
Property and equipment, net	2,462	2,478
Intangible assets, net	3,216	3,882
Goodwill	2,791	2,791
Right-of-use assets	8,785	9,438
Other assets	365	365
Total assets	$ 54,249	$ 41,293
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,904	$ 1,717
Accrued expenses	4,389	5,326
Deferred revenue	16	—
Lease liability, current	774	542
Note payable, current	436	—
Total current liabilities	8,519	7,585
Lease liability, less current portion	10,040	10,814
Total liabilities	18,559	18,399
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 – 29,716 shares and 25,550 shares at December 31, 2021 and 2020, respectively	29	25
Additional paid-in capital	271,861	195,410
Accumulated other comprehensive income (loss)	—	(1)
Accumulated deficit	(236,200)	(172,540)
Total stockholders' equity	35,690	22,894
Total liabilities and stockholders' equity	$ 54,249	$ 41,293

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,		
	2021	2020	2019
Revenues:			
Product revenues	$ 1,418	$ —	$ —
Total revenues	1,418	—	—
Cost and expenses:			
Cost of revenues	1,968	—	—
Research and development	28,640	26,444	24,961
Sales and marketing	14,751	7,256	5,857
General and administrative	19,073	16,265	17,136
Total cost and expenses	64,432	49,965	47,954
Loss from operations	(63,014)	(49,965)	(47,954)
Other income (expense):			
Interest income (expense), net	(646)	114	983
Total other income (expense)	(646)	114	983
Loss from operations, before income taxes	(63,660)	(49,851)	(46,971)
Income tax benefit	—	—	—
Net loss	(63,660)	(49,851)	(46,971)
Other comprehensive gain (loss):			
Unrealized gain (loss) on available-for-sale securities	1	(5)	5
Comprehensive loss	$ (63,659)	$ (49,856)	$ (46,966)
Net loss per share:			
Basic and diluted net loss per share	$ (2.28)	$ (2.14)	$ (2.26)
Weighted average shares used to compute net loss per common share — basic and diluted	27,964	23,248	20,746

See accompanying notes to the consolidated financial statements.

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2018	20,593	$ 21	$ 142,032	$ (1)	$ (75,718)	$ 66,334
Issuance of shares upon exercise of warrants	37	—	—	—	—	—
Issuance of shares upon exercise of stock options	99	—	272	—	—	272
Issuance of shares under employee stock purchase plan	38	—	423	—	—	423
Issuance of shares on vesting of restricted stock units	58	—	—	—	—	—
Stock-based compensation expense	—	—	11,287	—	—	11,287
Tax payments related to shares withheld for vested restricted stock units	—	—	(613)	—	—	(613)
Unrealized gain on available-for-sale securities	—	—	—	5	—	5
Net loss	—	—	—	—	(46,971)	(46,971)
Balance, December 31, 2019	20,825	21	153,401	4	(122,689)	30,737
Issuance of common stock upon exercise of stock options	175	—	887	—	—	887
Issuance of shares under employee stock purchase plan	83	—	490	—	—	490
Issuance of shares upon exercise of warrants	187	—	1,127	—	—	1,127
Issuance of common stock and warrants in connection with rights offering at $7.01 per unit, net of issuance cost of $565	4,280	4	29,430	—	—	29,434
Stock-based compensation expense	—	—	10,075	—	—	10,075
Unrealized loss on marketable investments, net of tax	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	(49,851)	(49,851)
Balance, December 31, 2020	25,550	25	195,410	(1)	(172,540)	22,894
Issuance of common stock as part of debt extinguishment and private investment, net of issuance cost of $106	3,049	3	49,891	—	—	49,894
Issuance of shares upon exercise of warrants	585	1	3,333	—	—	3,334
Issuance of common stock as part of ATM offering, net of issuance cost of $568	288	—	7,432	—	—	7,432
Issuance of common stock upon vesting of restricted stock units, net of shares withheld for employee taxes	99	—	(232)	—	—	(232)
Issuance of shares under employee stock purchase plan	91	—	810	—	—	810
Issuance of common stock upon exercise of stock options	54	—	616	—	—	616
Stock-based compensation expense	—	—	14,601	—	—	14,601
Unrealized gain on available-for-sale securities	—	—	—	1	—	1
Net loss	—	—	—	—	(63,660)	(63,660)
Balance, December 31, 2021	29,716	$ 29	$ 271,861	$ —	$ (236,200)	$ 35,690

See accompanying notes to the consolidated financial statements.

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

	Year Ended December 31,		
	2021	**2020**	**2019**
Cash flows from operating activities:			
Net loss	$ (63,660)	$ (49,851)	$ (46,971)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	480	430	494
Amortization of intangible assets	666	665	666
Stock-based compensation	14,601	10,075	11,287
Net premium amortization and discount on available-for-sale securities	13	5	(521)
Loss on disposal of fixed assets	—	119	—
Gain on U.S. Treasury securities	—	(8)	—
Changes in operating assets and liabilities:			
Accounts receivable	(61)	—	—
Inventory	(5,824)	—	—
Prepaid expenses and other current assets	(1,374)	194	(226)
Other receivables	54	—	—
Right-of-use assets	653	509	68
Other long-term assets	—	129	(393)
Accounts payable	1,160	(266)	646
Accrued expenses	(937)	2,830	841
Deferred revenue	16	—	—
Lease liabilities	(542)	(196)	(76)
Accrued interest on note payable	658	—	
Net cash used in operating activities	(54,097)	(35,365)	(34,185)
Cash flows from investing activities:			
Purchases of property and equipment	(437)	(441)	(608)
Purchases of investments	—	(29,025)	(77,993)
Maturities of investments	8,000	35,000	68,500
Sales of investments	—	4,510	—
Net cash provided by (used in) investing activities	7,563	10,044	(10,101)
Cash flows from financing activities:			
Proceeds from issuance of common stock under employee stock purchase plan	810	490	423
Proceeds from exercises of warrants	4,217	244	—
Proceeds from exercises of stock options	786	717	272
Proceeds from issuance of common stock	56,697	29,434	—
Proceeds from insurance loan agreement	1,939	—	—
Payments made on insurance loan agreement	(1,532)	—	—
Tax payments related to shares withheld for vested restricted stock units	(232)	—	(613)
Net cash provided by financing activities	62,685	30,885	82
Net increase (decrease) in cash and cash equivalents	16,151	5,564	(44,204)
Cash and cash equivalents at beginning of period	12,463	6,899	51,103
Cash and cash equivalents at end of period	$ 28,614	$ 12,463	$ 6,899
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)	5
Equipment purchases included in accounts payable and accrued expenses	27	20	279
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 an entirely new and proprietary energy modality. The Company's CellFX System is the first commercial product to harness the distinctive advantages of the Company's proprietary NPS technology. The CellFX System 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 non-cellular tissue, to treat a variety of medical conditions for which an optimal solution remains unfulfilled.

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 CE marking approval for the CellFX System, which allows for marketing of the system in the EU and, in June 2021, the Company received Health Canada approval for the CellFX System, which allows for marketing of the system in Canada. The CE mark and Health Canada approvals allow for use of the CellFX System in dermatological procedures requiring ablation and resurfacing of the skin for the reduction, removal, and/or clearance of cellular-based benign lesions, including SH, SK, and cutaneous non-genital warts. The Company will continue to pursue specific indications for the CellFX System in the United States similar to the regulatory clearances already received in Europe and Canada. This will require additional 510(k) submissions for each subsequent indication, and will likely be based on comparative clinical data. In December 2021, the Company submitted a 510(k) to add the treatment of SH to the CellFX System's indications for use in the United States. In February 2022 the Company received an AI letter from the FDA in response to the 510(k) submitted. In the AI letter, the FDA stated it did not believe the Company provided sufficient clinical evidence at this time to support the expanded indication for use, and that the Company had not met the primary endpoints of the SH FDA-approved IDE study. The Company anticipates meeting with the FDA to discuss the contents of the AI letter and potential next steps, which may require additional clinical data and potentially a new 510(k) submission.

In February 2021, the Company initiated controlled launch programs (Note 8) in the United States and the European Union and in June 2021 the Company initiated a controlled launch program in Canada (collectively, our "Controlled Launch"). In August 2021, the Company began to convert Controlled Launch Program participants into sales agreements, thereby triggering revenue recognition.

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 cash flows from operations. It has recently commenced revenue-generating operations and will need to raise additional capital to finance its operations. However, there can be no assurances that the Company will be able to obtain additional financing on acceptable terms and in the amounts necessary to fully fund its operating requirements.

2. Summary of Significant Accounting Policies

Going Concern

As of December 31, 2021, the Company had an accumulated deficit of $236.2 million, cash outflows from operations of $54.1 million for the year then ended, cash and cash equivalents of $28.6 million, and a net loss of $63.7 million. The Company has recently begun to generate revenue from product sales, but anticipates net losses for the next several years or until it can generate substantial product revenue and achieve profitability. Based on the Company's current operating plan, the Company has determined that, with its current financial resources, the Company would be able to operate into the second quarter of 2022. As the Company's operating plan does not allow the Company to operate for a period of twelve months from the date the consolidated financial statements are issued without additional financing, based on the ASC 205-40, *Presentation of Financial Statements – Going Concern*, the Company is required to disclose that substantial doubt regarding the Company's ability to continue as a going concern exists. This evaluation initially cannot take into consideration the potential mitigating effects of plans that have not been fully implemented as of the date the financial statements are issued. To continue to fund the operations of the Company beyond this time period, management has developed plans, which primarily consist of raising additional capital through some combination of public or private equity offerings, debt financings, the Company's at-the-market equity offering program, and/or potential new collaborations. There is no assurance, however, that any additional financing or any revenue-generating collaboration will be available when needed or that management of the Company will be able to obtain financing or enter into a collaboration on terms acceptable to the Company. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

Basis of Presentation

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

Principles of Consolidation

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

Use of Estimates

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

Concentration of Credit Risk

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

Fair Value of Financial Instruments

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

Cash, Cash Equivalents and Investments

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

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

Property and Equipment

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

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, 2021, there is no reduction to the balance of inventory for excessive and obsolete inventory.

Intangible Assets

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

Long-Lived Assets

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

Goodwill

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

Revenue from Contracts with Customers

The Company recognizes revenue at a point in time when it satisfies performance obligations by transferring control of promised goods to its customers. The amount of revenue recognized is equal to the consideration which the Company is entitled to in exchange for the promised goods, excluding any amounts assessed by government authorities for taxes which might be collected from a customer. Sales contracts often involve the sale and delivery of multiple products, each of which typically represent a separate performance obligation in the contract. While the Company sells these products on a stand-alone basis at their respective SSP, initial customer contracts will likely involve the bundling of products which will be delivered concurrently to the customer. In such instances, the full consideration of the contract will be recognized upon shipment of the products. The Company generally requires receipt of full payment prior to shipment, however, from time to time, payment terms may be extended to customers upon which the Company will perform a necessary credit evaluation to ensure future collectability of the outstanding balance. The Company does not believe any portion of the outstanding accounts receivable balance to be uncollectible, and 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 a warranty reserve for products sold based upon the best estimate of the nature, frequency, and costs of future claims. These estimates are inherently uncertain given the short history of sales, and changes to the historical or projected warranty experience may cause material changes to the warranty reserve in the future. The warranty reserve is included within Accrued expenses on the consolidated balance sheets. Warranty expense is recorded as a component of Cost of Revenues in the consolidated statements of operations and comprehensive loss.

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

	Year Ended December 31,	
	2021	2020
Beginning balance	$ —	$ —
Add: Accruals for warranties issued during the period	80	—
Less: Settlements made during the period	—	—
Ending balance	$ 80	$ —

Stock-Based Compensation

The Company recognizes the cost of stock-based compensation in the financial statements based upon fair value. The fair value of stock options is determined as of the grant date using the Black-Scholes option pricing model. The fair value of Restricted Stock Units (“RSU”) awards is determined based on the number of units granted and the closing price of the Company’s common stock on the grant date. The fair value of each purchase under the employee stock purchase plan (“ESPP”) is estimated at the beginning of the offering period using the Black-Scholes option pricing model. The Company’s determination of the fair value of equity-settled awards is impacted by the price of the Company’s common stock as well as changes in assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, the expected term that awards will remain outstanding, expected common stock price volatility over the term of the awards, risk-free interest rates and expected dividends. The fair value of an award is recognized over the period during which service is required to be performed in exchange for the award, the requisite service period (usually the vesting period) on a straight-line basis. The Company accounts for all equity instruments awarded to non-employees at the fair value of the award issued on the day of the grant. The fair value of these equity instruments are expensed over the requisite service period. Certain stock options awarded to the Company’s executives and other key employees contain performance conditions related to certain financial measures and achievements of strategic/operational milestones (“performance options”). These performance options can contain both service and performance-based vesting conditions. The fair value of these performance options is recognized using the graded vesting method over the requisite service period beginning in the period in which the awards are deemed probable to vest, to the extent such awards are probable to vest.

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

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

Research and Development Costs

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

Patent Costs

The Company is the owner of numerous domestic and foreign patents. Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company's research efforts and any related patent applications, patent costs not related to acquired patents, including patent-related legal fees, filing fees and other costs, including internally generated costs, are expensed as incurred. During the years ended December 31, 2021, 2020 and 2019, patent costs totaled $0.6 million, $0.5 million and $0.6 million, respectively. Patent costs are included in general and administrative costs in the consolidated statements of operations and comprehensive loss.

Income Taxes

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

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

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

The Company accounts for uncertainties in income tax law under a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns as prescribed by U.S. GAAP. The tax effects of a position are recognized only if it is more-likely-than-not to be sustained by the taxing authority as of the reporting date. If the tax position is not considered more-likely-than-not to be sustained, then no benefits of the position are recognized. At December 31, 2021 and 2020, the Company had not recorded any liability for uncertain tax positions. The Company includes interest and penalties related to uncertain tax positions as a component of income tax expense.

Comprehensive Loss

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

Net Loss per Share

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

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

	Year Ended December 31,		
	2021	2020	2019
Common stock warrants	—	612,310	167,847
Common stock options	5,996,813	5,039,194	3,749,186
Restricted stock units	—	111,305	222,606
Total	5,996,813	5,762,809	4,139,639

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. As of December 31, 2021 and 2020, 100% of long-lived assets were in the United States. Revenue is attributed to a geographic region based on the location of the end customer.

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

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers*, requiring an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. This updated standard became effective for the Company in the first quarter of fiscal year 2018. The Company began to recognize revenue in 2021 using this updated standard. See Note 9 for additional details of the revenue recognition approach.

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

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which eliminates certain exceptions related to the general principles in ASC 740 and makes amendments to other areas with the intention of simplifying various aspects related to accounting for income taxes. The new standard is effective for fiscal years beginning after December 15, 2020, including interim periods therein; with early adoption permitted. The Company adopted the Topic 740 effective January 1, 2021. The adoption did not have a material impact on the Company's financial statements.

3. Investments and Fair Value of Financial Instruments

Investments

The Company's investments have been classified and accounted for as available-for-sale. At December 31, 2021 the Company had no investments outstanding. The Company's investments consisted of the following at December 31, 2020 (in thousands):

	December 31, 2020			
	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities	$ 8,013	$ —	$ (1)	$ 8,012
Total assets measured at fair value	$ 8,013	$ —	$ —	$ 8,012

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

	December 31,	
	2021	2020
Due in one year	$ —	$ 8,012
Due in one to two years	—	—
Total	$ —	$ 8,012

Fair Value of Financial Instruments

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

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

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

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

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

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

		December 31, 2020			
Assets	Classification	Level 1	Level 2	Level 3	Total
Money market funds	Cash and cash equivalents	$ 7,176	$ —	$ —	$ 7,176
U.S. Treasury securities	Cash and cash equivalents	—	2,004	—	2,004
U.S. Treasury securities	Investments	—	8,012	—	8,012
Total assets measured at fair value		$ 7,176	$ 10,016	$ —	$ 17,192

During year ended December 31, 2021 and 2020, the Company did not record impairment charges related to its marketable investments. During the years ended December 31, 2021 and 2020, 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, 2021 or 2020.

4. Balance Sheet Components

Inventory

Inventory consisted of the following (in thousands):

	Year Ended December 31, 2021	2020
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, 2021	2020
Leasehold improvements	$ 2,519	$ 2,805
Laboratory equipment	1,019	878
Furniture, fixtures and equipment	932	517
Software	202	128
Construction in progress	186	66
	4,858	4,394
Less: Accumulated depreciation and amortization	(2,396)	(1,916)
	$ 2,462	$ 2,478

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

Depreciation expense for the years ended December 31, 2021, 2020, and 2019 was $0.5 million, $0.4 million, and $0.5 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, 2021	2020
Acquired patents and licenses	$ 7,985	$ 7,985
Less: Accumulated amortization	(4,769)	(4,103)
	$ 3,216	$ 3,882

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

Years ending December 31:	
2022	$ 665
2023	665
2024	665
2025	665
2026	556
	$ 3,216

Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2021	December 31, 2020
Compensation expense	$ 2,932	$ 3,324
Controlled launch (Note 8)	534	—
Director and officer liability insurance (Note 12)	—	1,563
Clinical trial fees and costs	245	188
Professional fees	85	87
Warranty	80	—
Other	513	164
	$ 4,389	$ 5,326

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, 2021, the Company determined that its goodwill was not impaired.

6. Stockholders' Equity and Stock-Based Compensation

Preferred Stock

The Company has authorized a total of 50,000,000 shares of preferred stock, par value $0.001 per share, none of which were outstanding at December 31, 2021 and 2020. 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 June 30, 2021, the Company entered into a Securities Purchase Agreement with Robert W. Duggan, the Company's largest stockholder and Board 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, 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.

Rights Offering

During June 2020, the Company completed a rights offering to purchase up to $30.0 million of units, each unit consisting of one share of the Company's common stock, par value $0.001 per share, and 0.15 warrants to purchase shares of common stock (the "Units") at a price of $7.01 per Unit (the "Rights Offering"). The common stock and warrants comprising the Units separated upon the closing of the Rights Offering and were issued separately.

A total of 4,279,600 shares of common stock and 641,571 warrants (the "Rights Offering Warrants") were issued and sold in the Rights Offering for net proceeds of approximately $29.4 million. Each warrant was exercisable for one share of the Company's common stock at an exercise price equal to $7.01, the subscription price for the Units. The 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 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 Rights Offering Warrants for 10 consecutive trading days.

Common Stock Warrants

In connection with a private placement offering of the Company's shares of common stock, par value $0.001 per share in 2014, the Company issued warrants as compensation to the placement agent to purchase a total of 299,625 shares of its common stock at a price of $2.67 per share (the "Private Placement Warrants"). The Private Placement Warrants were exercisable for a period of seven years. 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. As of December 31, 2021, there were no Private Placement Warrants outstanding.

In connection with the closing of the Company's initial public offering in 2016, the Company issued warrants as compensation to its underwriters, as representatives of the underwriters of its initial public offering to purchase a total of 574,985 shares of its common stock at a price of $5.00 per share (the "IPO Warrants"). The IPO Warrants were exercisable for a period of five years. 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. As of December 31, 2021, there were no IPO Warrants outstanding.

In connection with the Rights Offering, the Company issued warrants ("Rights Offering Warrants") to purchase a total of 641,571 shares of its common stock at an exercise price of $7.01. 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 Rights Offering 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, 2021, there were no Rights Offering Warrants outstanding.

A summary of total warrants activity for the year ended December 31, 2021 is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Warrants outstanding at December 31, 2020	612,310	$ 6.40	0.26
Issued	—	—	
Exercised	(585,069)	6.47	
Expired/Redeemed	(27,241)	3.56	
Warrants outstanding and exercisable at December 31, 2021	—	$ —	—

Equity Plans

2017 Equity Incentive Plan and 2017 Inducement Equity Incentive Plan

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

The 2017 Plan has a 10-year term, and provides for the grant of stock options, stock appreciation rights, restricted stock, RSUs, performance units, and performance shares to employees, directors and consultants of the Company and any parent or subsidiary of the Company, as the Compensation Committee of the Board may determine. Subject to an annual evergreen increase and adjustment in the case of certain capitalization events, the Company initially reserved 1,500,000 shares of the Company's common stock for issuance pursuant to awards under the 2017 Plan. In addition, shares remaining available under the Company's 2015 Equity Incentive Plan, as amended (the "2015 Plan"), and shares reserved but not issued pursuant to outstanding equity awards that expire or terminate without being exercised or that are forfeited or repurchased by the Company will be added to the shares of common stock available for issuance under the 2017 Plan. The 2017 Plan is administered by the Board's Compensation Committee. Effective January 1, 2021 and 2020, the number of shares of common stock available under the 2017 Plan increased by 1,022,002 and 833,018 shares, respectively, pursuant to the evergreen provision of the 2017 Plan. Under the evergreen provision of the 2017 Plan, the share increase is determined based on the least of (i) 1,200,000 shares, (ii) 4% of the Company's common stock outstanding at December 31 of the immediately preceding year, or (iii) such number of shares as determined by the Board. As of December 31, 2021, 443,196 shares of common stock remained available for issuance under the 2017 Plan.

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

The Inducement Plan has a 10-year term and provides for the grant of equity-based awards, including non-statutory stock options, RSUs, restricted stock, stock appreciation rights, performance shares and performance units, and its terms are substantially similar to the 2017 Plan, including with respect to treatment of equity awards in the event of a "merger" or "change in control" as defined under the Inducement Plan. Options issued under the Inducement Plan may have a term up to ten years and have variable vesting provisions. New hire grants generally vest 25% per year starting upon the first anniversary of the grant. Equity-based awards issued under the Inducement Plan are only issuable to individuals not previously engaged as employees or non-employee directors of the Company prior to the Inducement Plan's adoption date. In May 2021, the Board approved an amendment to the Inducement Plan to reserve an additional 1,000,000 shares of the Company's common stock for issuance pursuant to the Inducement Plan. As of December 31, 2021, 1,044,513 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, 2021 is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in Years)
Balances - December 31, 2020	5,039,194	$ 14.26	7.83
Options granted	1,239,588	22.10	
Options exercised	(53,731)	11.47	
Options canceled	(162,975)	16.94	
Options expired	(65,263)	19.92	
Balances - December 31, 2021	5,996,813	$ 15.77	7.33
Stock options exercisable at December 31, 2021	3,312,074	$ 15.96	6.23

Time-based Options

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

A summary of the time-based stock option activity under the 2015 Plan, 2017 Plan and Inducement Plan for the year ended December 31, 2021 is presented below:

	Stock Options Outstanding		
	Number of shares	Weighted average exercise price	Weighted average remaining life (in years)
Balances — December 31, 2020	4,055,352	$ 15.04	6.37
Options granted	1,023,333	22.04	
Options exercised	(53,731)	11.47	
Options canceled	(162,975)	16.94	
Options expired	(65,263)	19.92	
Balances — December 31, 2021	4,796,716	$ 16.44	7.05
Exercisable — December 31, 2021	3,018,902	$ 16.38	6.05

The intrinsic value of time-based options exercised during the year ended December 31, 2021, 2020 and 2019 was $0.8 million, $1.6 million, and $1.0 million, respectively.

The fair value of the time-based options granted to employees and directors during the years ended December 31, 2021, 2020 and 2019 was $15.1 million, $6.7 million, and $8.4 million, respectively.

Performance Options

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. 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, 2021 is presented below:

	Stock Options Outstanding		
	Number of shares	Weighted average exercise price	Weighted average remaining life (in years)
Balances — December 31, 2020	983,842	$ 11.06	8.25
Options granted	216,255	22.41	
Options exercised	—	—	
Options canceled	—	—	
Options expired	—	—	
Balances — December 31, 2021	1,200,097	$ 13.11	8.44
Exercisable — December 31, 2021	293,172	$ 11.64	8.08

The fair value of the performance options granted to employees during the years ended December 31, 2021, 2020 and 2019 was $2.5 million, $5.5 million, and $0.4 million, respectively.

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

	Year Ended December 31,		
	2021	2020	2019
Expected term in years	5.3 - 6.1	5.3 - 6.1	0.4 - 6.1
Expected volatility	78%	70%	70%
Risk-free interest rate	0.9 - 1.4%	0.3 - 0.5%	1.4 - 2.6%
Dividend yield	—	—	—

2017 Employee Stock Purchase Plan

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

The 2017 ESPP is a broad-based plan that provides employees of the Company and its designated affiliates with the opportunity to become stockholders through periodic payroll deductions that are applied towards the purchase of Company common shares at a discount from the then-current market price. Subject to adjustment in the case of certain capitalization events, a total of 250,000 common shares of the Company were available for purchase at adoption of the 2017 ESPP. Pursuant to the 2017 ESPP, the annual share increase pursuant to the evergreen provision is determined based on the least of (i) 450,000 shares, (ii) 1.5% of the Company's common stock outstanding at December 31 of the immediately preceding year, or (iii) such number of shares as determined by the Board. In 2020 the Board determined not to increase the number of shares of common stock available pursuant to the evergreen provision. Effective January 1, 2021, pursuant to the evergreen provision of the 2017 ESPP, the number of shares of common stock available under the 2017 ESPP was increased by 383,250 shares. During the years ended December 31, 2021 and 2020, the Company issued 91,378 and 82,971 shares of common stock under the 2017 ESPP, respectively. As of December 31, 2021, 649,096 shares of common stock remained available for issuance under the 2017 ESPP.

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

	Year Ended December 31,		
	2021	2020	2019
Expected term in years	0.5 - 1.0	0.5 - 1.0	0.5 - 1.0
Expected volatility	78%	70%	70%
Risk-free interest rate	0.06% - 0.1%	0.1% - 1.0%	1.7% - 2.6%
Dividend yield	—	—	—

Restricted Stock Units

The fair value of RSU awards is determined based on the number of units granted and the closing price of the Company's common stock as of the grant date. The estimated fair value of RSUs is recognized on a straight-line basis over the requisite service period.

During the year ended December 31, 2017, the Company granted 160,974 RSUs to the Chief Executive Officer, all of which vested in June 2018. These shares were partially released in 2019, resulting in a net issuance of shares. Additional paid in capital was reduced for tax payments related to shares withheld in connection with the release. The remaining shares under this grant were released in 2021, and at December 31, 2021 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, 2021, 2022 and 2019. As of December 31, 2021, 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, 2021, 2020, and 2019 related to these RSUs was approximately $0.1 million, $0.3 million, and $0.4 million, respectively. As of December 31, 2021, 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,		
	2021	2020	2019
Cost of revenues	$ 129	$ —	$ —
Research and development	5,211	4,013	3,821
Sales and marketing	2,749	1,187	883
General and administrative	6,512	4,875	6,583
Total stock-based compensation expense	$ 14,601	$ 10,075	$ 11,287

As of December 31, 2021, 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 type was as follows (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Time-based options	$ 9,235	$ 8,739	$ 10,895
Performance options	4,840	133	100
RSU	—	86	—
ESPP	526	1,117	292
Total stock-based compensation expense	$ 14,601	$ 10,075	$ 11,287

At December 31, 2021, there was $15.8 million of unrecognized compensation cost related to unvested stock-based compensation arrangements, which is expected to be recognized over a weighted average period of 2.7 years.

7. Research Grants and Agreements

Sponsored Research Agreement

The Company entered into a SRA with ODURF during 2014 pursuant to which the Company sponsors research activities performed by ODURF's Frank Reidy Center. ODURF is compensated by the Company for its conduct of each study in accordance with the budget and payment terms set forth in the applicable task order. In August 2018, we agreed to sponsor a task order for research in the amount of $0.8 million and in September 2019, we agreed to sponsor an additional task order for research in the amount of $0.8 million each to be performed during their respective subsequent 12-month periods. In March 2021, we agreed to sponsor a task order for research in the amount of $0.3 million and in May 2021 we sponsored an additional task order for $0.3 million each to be performed during their respective subsequent 12-month periods. These sponsored researches are funded through monthly payments made upon ODURF certifying, to our reasonable satisfaction, that ODURF has met its obligations pursuant to the specified task order and statement of work. The principal investigator may transfer funds within the budget as needed with our approval so long as the obligations of ODURF under the task order and statement of work remain unchanged and unimpaired. During the years ended December 31, 2021, 2020, and 2019, we incurred costs relating to the SRA equal to $0.3 million, $0.6 million and $0.9 million, respectively. As of December 31, 2021, there is a $0.3 million balance payable under this research agreement.

8. Controlled Launch

In February 2021, the Company received 510(k) clearance from the U.S. 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 a 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. According to the Controlled Launch program, the Company provides and sets up a CellFX System at each physician site and provides the physician with the necessary related products and components, free of charge, to complete the requirements of the Controlled Launch. Each CellFX System and any unused component products remain the property of the Company throughout the Controlled Launch. Each physician identifies and recruits 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. Under the Controlled Launch, the physician and their patients complete evaluation surveys about their experiences with the CellFX System and provide other information helpful to the Company. Upon completion of the procedures and the survey feedback, the physician earns either credits which can 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 are limited to a maximum amount dependent on the number of surveys received by the Company. Upon completion of the Controlled Launch, each physician may choose to either enter into a purchase agreement with the Company, under which the physician may use the credits earned (or other payments earned, as applicable) towards the purchase of the already-delivered CellFX System, or the physician must return the CellFX System to the Company.

As patient procedures and surveys are completed under the Controlled Launch, the Company accrues the value of the credits earned, which are recorded in accrued expenses on the balance sheet, with a corresponding charge to sales and marketing expense. During year ended December 31, 2021, the Company recorded $1.8 million of sales and marketing expense in relation to the Controlled Launch.

During the year ended December 31, 2021, 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 $1.1 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.

9. Revenue

The Company recognizes revenue at a point in time when it satisfies performance obligations by transferring control of promised goods to its customers. The amount of revenue recognized is equal to the consideration which the Company is entitled to in exchange for the promised goods, excluding any amounts assessed by government authorities for taxes which might be collected from a customer. This consideration may include non-cash services performed, as is the case with revenue recognized in connection with the Controlled Launch. Total revenue recognized for the year ended December 31, 2021 was $1.4 million, of which approximately $1.1 million was driven by the redemption of non-cash credits earned as part of the Controlled Launch, with the balance of approximately $0.3 million driven by cash purchases of cycle units ("CUs") and the first two CellFX commercial consoles sold.

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

Performance Obligations

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

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

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 are available for sale on a stand-alone basis and payment is generally due prior to shipment. Tips represent a distinct performance obligation which is satisfied either upon shipment, or upon delivery of the tips to the customer, depending on the specific contract.

CUs are credits that authorize the customer to perform a procedure, or cycle. Each procedure requires a specific number of CUs, dependent upon type of tip used and procedure level selected. As the procedure is performed, the applicable number of CUs are decremented. When the customer's balance of CUs on a specific system is depleted, the system will no longer function until the customer purchases additional CUs. Customers can purchase additional CUs via the Company's CellFX Marketplace which is an online marketplace accessible directly from the CellFX System. Payment for CUs is due upon order placement and the CUs are immediately available for download to the console via CellFX CloudConnect. CUs represent a distinct performance obligation which is satisfied upon delivery of the CUs to CellFX CloudConnect.

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

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, generally containing only one performance obligation each, therefore no price allocation is necessary in that scenario either.

The Company evaluates the possible impact of variable consideration in determining the transaction price, in particular the possibility of future returns or credits. Sales agreements allow for a right of return only if the product does not conform to the agreed upon quality standards or if the product was shipped due to Company error. The Company anticipates such returns will be minimal and has made no adjustments to the transaction price for any estimated returns.

The 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.

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

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

	Year Ended December 31,		
	2021	2020	2019
Systems	$ 1,189	$ —	$ —
Cycle units	229	—	—
Total consolidated revenue	$ 1,418	$ —	$ —

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

	Year Ended December 31,		
	2021	2020	2019
North America	$ 1,182	$ —	$ —
Rest of World	236	—	—
Total consolidated revenue	$ 1,418	$ —	$ —

11. Income Taxes

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

	Year Ended December 31,		
	2021	2020	2019
Domestic	$ (63,660)	$ (49,851)	$ (46,971)
Foreign	—	—	—
	$ (63,660)	$ (49,851)	$ (46,971)

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

	December 31,		
	2021	2020	2019
Current			
Federal	$ —	$ —	$ —
State	3	3	3
Foreign	—	—	—
Total current	3	3	3
Deferred			
Federal	—	—	—
State	—	—	—
Foreign	—	—	—
Total deferred	—	—	—
Total provision for income taxes	$ 3	$ 3	$ 3

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,		
	2021	2020	2019
Federal tax at statutory rate	21.0 %	21.0 %	21.0 %
State tax (benefit) at statutory rate	8.4	8.4	(5.0)
Research and development credits	1.9	2.1	2.0
Change in valuation allowance	(26.8)	(43.3)	(18.0)
Deferred adjustment	—	8.5	—
Change in tax rate	—	4.2	—
Uncertain Tax Position	(2.3)	—	—
Other	(2.2)	(0.8)	—
Provision for income taxes	— %	— %	— %

Note that for presentation purposes, the 2019 percentages have been changed to present the opposite value from what was previously disclosed to allow for proper comparability to current year percentages.

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, 2021 and 2020, are as follows (in thousands):

	December 31, 2021	December 31, 2020
Deferred tax assets		
Accruals	$ 1,034	$ 894
Net operating loss carryforwards	49,246	36,531
Tax credit carryforwards	6,611	5,431
Stock-based compensation	12,188	9,391
Lease liability under ASC 842	3,182	3,339
Gross deferred tax assets	72,261	55,586
Valuation allowance	(69,006)	(51,973)
Total deferred tax assets	3,255	3,613
Deferred tax liabilities		
Intangibles	(365)	(486)
ROU asset under ASC 842	(2,862)	(3,096)
Fixed assets	(28)	(31)
Total deferred tax liabilities	(3,255)	(3,613)
Net deferred tax assets/(liabilities)	$ —	$ —

The Company's unrecognized tax benefits as of December 31, 2021, 2020, and 2019 were $5.1 million, $2.5 million, and $1.5 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, 2021	December 31, 2020	December 31, 2019
Unrecognized tax benefits at beginning of year	$ 2,491	$ 1,470	$ 877
Increases related to current year tax positions	2,649	1,021	593
Unrecognized tax benefits at end of year	$ 5,140	$ 2,491	$ 1,470

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, 2021 and does not anticipate any significant change within twelve months of this reporting date.

The Company's valuation allowance increased by $17.0 million in the year ended December 31, 2021 and increased by $21.6 million in the year ended December 31, 2020.

As of December 31, 2021, the Company had federal and state net operating loss ("NOL") carryforwards of $173.7 million and $163.4 million, respectively, which begin to expire in 2034. Of the total federal NOL carryforward of $173.7 million, approximately $148.0 million is carried forward indefinitely but is limited to 80% of the taxable income.

As of December 31, 2021, the Company had approximately $5.3 million and $5.0 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, 2021, the Company was not under examination by the Internal Revenue Service or any state tax jurisdiction.

Internal Revenue Code Section 382 ownership change generally occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. The Company is not aware of any ownership changes in this financial period ending on December 31, 2021.

12. Related Party Transactions

Kenneth A. Clark, a director of the Company from November 2017 to October 2021, is a member of the law firm of Wilson Sonsini Goodrich and Rosati ("WSGR"), which also served as the outside corporate counsel to the Company until November 18, 2021. During the years ended December 31, 2021, 2020 and 2019, the Company incurred expenses reported in general and administrative expenses in the consolidated statement of operations for legal services rendered by WSGR totaling approximately $0.6 million, $0.8 million and $0.5 million, respectively. During the year ended December 31, 2021, the Company capitalized approximately $0.2 million for legal expenses incurred in connection with the Sales Agreement. During the year ended December 31, 2020, the Company capitalized approximately $0.4 million for legal expenses incurred in connection with the 2020 rights offering. In October 2021, Mr. Clark resigned from the Company's Board of Directors, and in November 2021, the Board terminated the engagement of WSGR and appointed Baker & Hostetler LLP as the Company's outside corporate counsel.

In May 2020, the Company determined not to renew its director and officer liability insurance policies due to disproportionately high premiums quoted by insurance companies. Instead, Robert W. Duggan, majority stockholder and Board Chairman, and the Company entered into a letter agreement, dated May 12, 2020 (the "Letter Agreement"), pursuant to which Mr. Duggan agreed with the Company to personally provide indemnity coverage on substantially the same terms as the Company's prior coverage program for a one-year period, and has deposited security for such obligations. On May 13, 2021, in accordance with terms of the Letter Agreement, the Company paid Mr. Duggan the amount of $2.5 million. The Company did not enter into a new Letter Agreement with Mr. Duggan for the subsequent policy period, and in May 2021 secured its director and officer liability insurance through third-party insurance carriers.

In June 2020, the Company completed the Rights Offering (Note 6). Mr. Duggan participated in the Rights Offering and purchased an aggregate of 2,561,873 Units.

On March 11, 2021, the Company and Mr. Duggan entered into a 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.

13. Commitments and Contingencies

Loan Agreement

On March 11, 2021, the Company and Robert W. Duggan, the Board 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.

Insurance Loan Agreement

On May 13, 2021, the Company secured its annual director and officer liability insurance policy. The total premiums for the policy are approximately $2.6 million, of which the Company made a down payment of $0.7 million and financed the balance of $1.9 million via an Insurance Loan Agreement. The Insurance Loan Agreement has an annual interest rate of 3.69% and requires monthly payments through February 2022, upon which the Insurance Loan Agreement will be paid in full. The outstanding principal portion of the Insurance Loan Agreement, together with any accrued and unpaid interest, is recorded as a note payable in the balance sheet.

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, 2021, total right-of-use assets and lease lability was approximately $8.8 million and $10.8 million, respectively.

During the years ended December 31, 2021, 2020 and 2019, rent expense, including common area maintenance charges, was $1.9 million, $1.7 million and $0.5 million, respectively.

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

Year ending December 31:		
2022	$	1,806
2023		1,845
2024		1,910
2025		1,977
2026		2,046
Thereafter		6,191
Total lease payments		15,775
Less imputed interest		(4,961)
Total lease liabilities	$	10,814
Other supplemental information:		
Cash paid for operating lease liabilities	$	1,643
Current operating lease liabilities		774
Non-current operating lease liabilities		10,040
Total lease liabilities	$	10,814
Weighted-average remaining lease term		7.83
Weighted-average discount rate		10%

Legal Proceedings

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

From time to time, the Company may be involved in a variety of claims, lawsuits, investigations, and proceedings relating to securities laws, corporate governance, product liability and promotion, patent infringement, contract disputes, employment disputes, and other matters relating to various claims that arise in the normal course of the Company's business, such as demands to inspect Company records and correspondence from the SEC and other government officials. The Company currently believes that these ordinary course matters are not material to the consolidated financial statements of the business; however, the results of litigation and claims are inherently unpredictable.

In February 2022, a civil securities lawsuit was filed in the U.S. District Court for the Northern District of California against the Company and certain of its executive officers, following the Company's announcement on February 8, 2022 that it had received an Additional Information letter from the FDA indicating that the FDA did not believe the Company provided sufficient clinical evidence to support its 510(k) submission to add the treatment of sebaceous hyperplasia to the CellFX System's current U.S. labeling, and the subsequent decline of the market price of the Company's common stock. The Company is currently evaluating the case and its allegations. The lawsuit seeks class certification, unspecified damages, fees, costs, and expenses. The Company expects to file a motion to dismiss the case later this year, and an estimate of possible loss or range of loss, if any, cannot be made.

14. 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, 2021, 2020 and 2019.

15. Supplementary Financial Information

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

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of senior management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our internal control over financial reporting based on the framework in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the evaluation under that framework and applicable SEC rules, our management concluded that our internal control over financial reporting was effective as of December 31, 2021.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal controls over financial reporting during the year ended December 31, 2021, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

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

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not Applicable.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 11. Executive Compensation

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 14. Principal Accounting Fees and Services

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Part IV

Item 15. Exhibits, Financial Statement Schedules

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

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

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

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

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	File No.	Exhibit(s)	Filing Date
2.1	Plan of Conversion of Pulse Biosciences, Inc.	8-K12B	001-37744	2.1	June 18, 2018
3.1	Articles of Conversion	8-K12B	001-37744	3.1	June 18, 2018
3.2	Certificate of Conversion	8-K12B	001-37744	3.2	June 18, 2018
3.3	Certificate of Incorporation of Pulse Biosciences, Inc.	8-K12B	001-37744	3.3	June 18, 2018
3.4	Bylaws of Pulse Biosciences, Inc.	8-K12B	001-37744	3.4	June 18, 2018
4.1	Specimen Common Stock Certificate	8-K12B	001-37744	4.1	June 18, 2018
4.2	Form of Warrant	S-3/A	333-237577	4.3	May 1, 2020
4.3	Form of Warrant Agent Agreement	S-3/A	333-237577	4.4	May 1, 2020
10.1	Lease for facilities at 3955 Point Eden Way, Hayward, California, dated January 26, 2017	10-K	001-37744	10.1	March 20, 2017
10.2#	License Agreement among Old Dominion University Research Foundation, Eastern Virginia Medical School and the Registrant	S-1/A	333-208694	10.12	May 3, 2016
10.3	Amendments No. 1 to License Agreement among Old Dominion University Research Foundation, Eastern Virginia Medical School and the Registrant	S-1/A	333-208694	10.13	March 7, 2016
10.4+*	Employment Agreement between Mitchell E. Levinson and the Registrant				
10.5+*	Employment Agreement between Kevin Danahy and the Registrant				
10.6	Securities Purchase Agreement, dated February 7, 2017, by and between Pulse Biosciences, Inc. and certain purchasers	8-K	001-37744	10.1	February 10, 2017
10.7	Securities Purchase Agreement, dated September 24, 2017, by and between Pulse Biosciences, Inc. and certain purchasers	8-K	001-37744	10.1	September 25, 2017
10.8+	2015 Stock Incentive Plan	S-1	333-208694	10.2	December 22, 2015
10.9+	2017 Inducement Equity Incentive Plan and forms of agreements thereunder	8-K	001-37744	10.1	November 28, 2017
10.10+	2017 Equity Incentive Plan and forms of agreements thereunder	10-K	001-37744	10.10	March 12, 2021
10.11+	2017 Employee Stock Purchase Plan and forms of agreements thereunder	8-K	001-37744	10.2	May 19, 2017
10.12+	Form of Director Option Agreement, not issued under the 2015 Stock Incentive Plan	S-1	333-208694	10.3	December 22, 2015
10.13+	Executive Employment Agreement between Darrin R. Uecker and the Registrant	S-1	333-208694	10.9	December 22, 2015
10.14+	Amendment to Employment Agreement between Darrin R. Uecker and Pulse Biosciences, Inc. dated October 5, 2016	8-K	001-37744	10.1	October 11, 2016
10.15+	Form of At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement for Employees	S-1	333-208694	10.10	December 22, 2015
10.16+	Form of Indemnification Agreement	8-K12B	001-37744	10.1	June 18, 2018
10.17+	Letter Agreement between Pulse Biosciences, Inc. and Robert W. Duggan, dated May 12, 2020.	10-Q	001-37744	10.1	August 10, 2020
10.18	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
10.19+	Employment Agreement between Sandra Gardiner and the Registrant	8-K	001-37744	10.1	November 7, 2019
10.20	At-the-Market Equity Offering Sales Agreement	8-K	001-37744	1.1	February 4, 2021
10.21+	Loan Agreement between Pulse Biosciences, Inc. and Robert W. Duggan, dated March 11, 2021	8-K	001-37744	10.1	March 11, 2021
10.22	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
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.				

31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of the Chief Executive and Chief Financial Officers pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith
+ Indicates a management contract or compensatory plan or arrangement.
# Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a grant of confidential treatment.

Item 16. Form 10-K Summary

None.

Signatures

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

PULSE BIOSCIENCES, INC.

Date: March 31, 2022

By: /s/ Sandra A. Gardiner

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

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ Darrin R. Uecker Darrin R. Uecker	President, Chief Executive Officer and Director (*Principal Executive Officer)*	March 31, 2022
/s/ Robert W. Duggan Robert W. Duggan	Chairman of the Board of Directors	March 31, 2022
/s/ Sandra A. Gardiner Sandra A. Gardiner	Chief Financial Officer, Executive Vice President, and Treasurer (*Principal Financial and Accounting Officer)*	March 31, 2022
/s/ Mitchell E. Levinson Mitchell E. Levinson	Chief Strategy Officer and Director	March 31, 2022
/s/ Shelley D. Spray Shelley D. Spray	Director	March 31, 2022
/s/ Manmeet S. Soni Manmeet S. Soni	Director	March 31, 2022
/s/ Mahkam Zanganeh Mahkam Zanganeh	Director	March 31, 2022
/s/ Richard A. van den Broek Richard A. van den Broek	Director	March 31, 2022

PULSE BIOSCIENCES, INC.

EMPLOYMENT AGREEMENT

This Employment Agreement (the "**Agreement**") is made and entered into by and between **Mitch Levinson** ("**Executive**") and Pulse Biosciences, Inc. (the "**Company**"), as of **August 17, 2021**.

1. Duties and Scope of Employment.

(a) Position and Duties. As of **August 19, 2021** (the "**Start Date**"), Executive will serve as the Company's **Chief Strategy Officer** operating from the Company's offices located in Hayward, California. Executive will render such business and professional services in the performance of his duties, consistent with Executive's position within the Company. Executive also will serve the Company in such other or alternative positions as may reasonably be assigned to him by the Company's Chief Executive Officer ("**CEO**") and Board of Directors (the "**Board**"), which positions may include director and additional or other officer positions of the Company and subsidiaries of the Company. The period of Executive's rendering of employment services under this Agreement is referred to herein as the "**Employment Term**."

(b) Obligations. During the Employment Term, Executive will perform his duties faithfully and to the best of his ability and will devote his full business efforts and time to the Company. For the duration of the Employment Term, Executive agrees not to actively engage in any other employment, occupation or consulting activity for any direct or indirect remuneration without the prior approval of the Board.

(c) Automatic Resignation. At the end of the Employment Term, including upon any termination of employment for any reason, such ending or termination will be deemed to be an automatic resignation from all director and officer positions of the Company and any of its subsidiaries, unless the continuation of such appointments is specifically approved by a resolution of the Board of the respective corporation or its shareholders.

1. At-Will Employment. The parties agree that Executive's employment with the Company will be "at-will" employment and may be terminated at any time with or without cause or notice. Executive understands and agrees that neither his job performance nor promotions, commendations, bonuses or the like from the Company give rise to or in any way serve as the basis for modification, amendment, or extension, by implication or otherwise, of his employment with the Company. However, as described in this Agreement, Executive may be entitled to severance benefits depending on the circumstances of Executive's termination of employment with the Company.

2. Compensation.

(a) Base Salary. During the Employment Term, the Company will pay Executive an annual salary of **$360,000.00** 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 **50%** of his base salary (the "**Target Bonus**") less applicable withholdings, prorated for the year of hire, 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.

(c) Start Date Option. Subject to the approval of the Board, Executive will be granted an option (the "**Start Date Option**") under the 2017 Equity Incentive Plan ("**Plan**"), to acquire **65,510** shares of common stock of the Company. The stock options provided by the Start Date Option will have an exercise price per share equal to the closing price of a share of the Company's common stock at the date of grant. Subject to certain accelerated vesting provisions as described herein, the options provided by the Start Date Option will vest 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 subject to the Executive continuing to be a Service Provider (as defined in the Plan) through each applicable vesting date and vesting target achievement determination date.

3. Employee Benefits. During the Employment Term, Executive will be entitled to participate in the employee benefit plans currently and hereafter maintained by the Company of general applicability to other senior executives of the Company, subject to the eligibility requirements of such plans. The Company reserves the right to cancel or change the benefit plans and programs it offers to its employees at any time.

4. Paid Time Off. During the Employment Term, Executive will be entitled to accrue PTO of not less than three (3) weeks per year, in accordance with the Company's vacation policy, with the timing and duration of specific vacations mutually and reasonably agreed to by the parties hereto.

5. Expenses. The Company will reimburse Executive for reasonable travel, entertainment or other expenses incurred by Executive in the furtherance of or in connection with the performance of Executive's duties hereunder within 30 days of his submission of an expense report documenting said expenses, in accordance with the Company's expense reimbursement policy as in effect from time to time.

6. Severance.

(a) Termination other than for Cause, Death or Disability or Resignation for Good Reason. During the Employment Term, if (i) the Company (or any parent or subsidiary or successor of the Company) terminates Executive's employment for reasons other than Cause death, or Disability, or (ii) upon Executive's resignation from the Company (or any parent or subsidiary or successor of the Company) for Good Reason (each such termination, an "**Involuntary Termination**"), then, subject to the continued observance by Executive of Sections 8 (severance conditions), 11 (assignment), 12 (notices), 13 (confidential information agreement), 15 (litigation cooperation), and 17 (miscellaneous) below after the termination of the rendering of employment services, Executive will receive the following severance from the Company:

(i) Severance Payment

(1) If Executive has been employed for an Employment Term hereunder of less than one year from the Start Date, then Executive will receive the continuing payment of the Executive's Base Salary (as in effect immediately prior to the Executive's termination) equal to three (3) months. If Executive has been employed for an Employment Term hereunder of one year or more from the Start Date, then Executive will receive six (6) months of continuing payments of Executive's Base Salary (as in effect immediately prior to Executive's termination). The Executive will also receive a Target Bonus (if applicable) for the year of termination, prorated for the portion of the year served assuming 100% achievement, payable with the first severance payment. The payment of any severance pursuant to this Section 7(a)(i) will be paid in accordance with the Company's normal payroll practices and be subject to the usual required withholdings.

(ii) Accelerated Vesting.

(1) *Involuntary Termination not in connection with a Change of Control*. If the Involuntary Termination occurs prior to or more than twelve (12) months following Start Date, the unvested portion of Executive's outstanding Equity Awards that would normally vest over the following twelve (12) months from the date of Executive's termination had Executive remained an employee through such period will immediately accelerate and fully vest prior to Executive's termination.

(1) *Involuntary Termination in connection with a Change of Control*. If the Involuntary Termination occurs within the twelve (12) month period following a 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 Executive's then outstanding Equity Awards will immediately vest prior to Executive's 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 Executive's then outstanding Equity Awards will immediately vest prior to Executive's termination. If Executive elects continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("**COBRA**") for Executive and Executive's eligible dependents within the time period prescribed pursuant to COBRA, the Company will reimburse Executive for the monthly premiums under COBRA necessary to continue group health insurance benefits for Executive and Executive's eligible dependents (at the coverage levels in effect

immediately prior to Executive's termination) until the earlier of (A) the date upon which Executive and/or Executive's eligible dependents becomes covered under similar plans or (B) the date upon which Executive ceases to be eligible for coverage under COBRA(such reimbursements, the "**COBRA Premiums**"). However, if the Company determines in its sole discretion that it cannot pay the COBRA Premiums without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company will in lieu thereof provide to Executive a taxable monthly payment payable on the last day of a given month (except as provided by the following sentence), in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue Executive's group health coverage in effect on the date of Executive's termination of employment (which amount will be based on the premium for the first month of COBRA coverage), which payments will be made regardless of whether Executive elects COBRA continuation coverage and will commence on the month following Executive's termination of employment and will end on the earlier of (x) the date upon which Executive obtains other employment or (y) the date the Company has paid an amount equal to six (6) payments. For the avoidance of doubt, the taxable payments in lieu of COBRA Premiums may be used for any purpose, including, but not limited to continuation coverage under COBRA, and will be subject to all applicable tax withholdings. Notwithstanding anything to the contrary under this Agreement, if at any time the Company determines in its sole discretion that it cannot provide the payments contemplated by the preceding sentence without violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), Executive will not receive such payment or any further reimbursements for COBRA premiums. (Collectively, the Company's COBRA obligations in this paragraph are referred to as the "COBRA Payments").

(ii) Resignation without Good Reason; Termination for Cause; Disability. If Executive resigns (other than for Good Reason), or the Company terminates Executive's employment for Cause, or Executive's employment terminates upon Executive's Disability, then (i) Executive will no longer vest in any Equity Award held by Executive, (ii) all payments of compensation by the Company to Executive hereunder will terminate immediately (except as to amounts already earned), and (iii) Executive will not be entitled to any severance or other benefits except for those (if any) as may then be established under the Company's then existing written severance and benefits plans and practices or pursuant to other written agreements with the Company.

(d) Accrued Compensation. For the avoidance of any doubt, in the event of a termination of Executive's employment with the Company (or any parent or subsidiary or successor of the Company) for whatever reason, Executive will be entitled to receive all accrued but unpaid vacation, expense reimbursements, wages, and other benefits due to Executive under any Company-provided plans, policies, and arrangements.

(b) Exclusive Remedy. In the event of a termination of Executive's employment with the Company (or any parent or subsidiary or successor of the Company), the provisions of this Section 7 are intended to be and are exclusive and in lieu of any other rights or remedies to which Executive or the Company may otherwise be entitled, whether at law, tort or contract, in equity, or under this Agreement. Executive will be entitled to no severance or other benefits, compensation or other payments or rights upon termination of employment other than those benefits expressly set forth in this Section 7.

7. Conditions to Receipt of Severance; No Duty to Mitigate.

(a) Separation Agreement and Release of Claims. The receipt of any severance pursuant to Section 7(a) will be subject to Executive signing and not revoking a separation agreement and release of claims in a form reasonably satisfactory to the Company (the "**Release**") (including a mutual nondisparagement provision (the Company's obligations being limited to its then-current directors and officers and only for so long as each remains employed by the Company) (the "Release") and provided that such Release becomes effective and irrevocable no later than sixty (60) days following the termination date (such deadline, the "**Release Deadline**"). If the Release does not become effective and irrevocable by the Release Deadline, Executive will forfeit any rights to severance or benefits under this Agreement. In no event will severance payments or benefits be paid or provided until the Release becomes effective and irrevocable. Except as required by Section 8(c), any installment payments that would have been made to Executive prior to the Release becoming effective and irrevocable but for the preceding sentence will be paid to Executive on the first regularly scheduled Company payroll date following the date the Release becomes effective and irrevocable, and the remaining payments will be made as provided in the Agreement.

(e) Confidential Information Agreement. Executive's receipt of any payments or benefits under Section 7 will be subject to Executive continuing to comply with the terms of the At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement between the Executive and the Company.

(b) Section 409A.

(i) Notwithstanding anything to the contrary in this Agreement, no severance pay or benefits to be paid or provided to Executive, if any, pursuant to this Agreement that, when considered together with any other severance payments or separation benefits, are considered deferred compensation under Section 409A (together, the "**Deferred Payments**") will be paid or otherwise provided until Executive has a "separation from service" within the meaning of Section 409A. Similarly, no severance payable to Executive, if any, pursuant to this Agreement that otherwise would be exempt from Section 409A pursuant to Treasury Regulation Section 1.409A-1(b)(9) will be payable until Executive has a "separation from service" within the meaning of Section 409A.

(i) Any severance payments or benefits under this Agreement that would be considered Deferred Payments will be paid on, or, in the case of installments, will not commence until, the sixtieth (60th) day following Executive's separation from service, or, if later, such time as required by Section 8(c)(iii). Except as required by Section 8(c)(iii), any installment payments that would have been made to Executive during the sixty (60) day period immediately following Executive's separation from service but for the preceding sentence will be paid to Executive on the sixtieth (60th) day following Executive's separation from service and the remaining payments shall be made as provided in this Agreement**. In no event will Executive have discretion to determine the taxable year of payment for any Deferred Payments.**

(ii) Notwithstanding anything to the contrary in this Agreement, if Executive is a "specified employee" within the meaning of Section 409A at the time of Executive's termination (other than due to death), then the Deferred Payments, if any, that are payable within the first six (6) months following Executive's separation from service, will become payable on the first payroll date that occurs

on or after the date six (6) months and one (1) day following the date of Executive's separation from service. All subsequent Deferred Payments, if any, will be payable in accordance with the payment schedule applicable to each payment or benefit. Notwithstanding anything herein to the contrary, if Executive dies following Executive's separation from service, but prior to the six (6) month anniversary of the separation from service, then any payments delayed in accordance with this paragraph will be payable in a lump sum as soon as administratively practicable after the date of Executive's death and all other Deferred Payments will be payable in accordance with the payment schedule applicable to each payment or benefit. Each payment, installment and benefit payable under this Agreement is intended to constitute a separate payment for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations.

(iii) Any amount paid under this Agreement that satisfies the requirements of the "short-term deferral" rule set forth in Section 1.409A-1(b)(4) of the Treasury Regulations will not constitute Deferred Payments for purposes of clause (i) above. It is the intent of this Agreement that all cash severance payments under Section 7(a)(i) will satisfy the requirements of the "short-term deferral" rule.

(iv) Any amount paid under this Agreement that qualifies as a payment made as a result of an involuntary separation from service pursuant to Section 1.409A-1(b)(9)(iii) of the Treasury Regulations that does not exceed the Section 409A Limit (as defined below) will not constitute Deferred Payments for purposes of clause (i) above.

(ii) The foregoing provisions are intended to be exempt from or comply with the requirements of Section 409A so that none of the severance payments and benefits to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities or ambiguous terms herein will be interpreted to be exempt or so comply. The Company and Executive agree to work together in good faith to consider amendments to this Agreement and to take such reasonable actions which are necessary, appropriate or desirable to avoid imposition of any additional tax or income recognition prior to actual payment to Executive under Section 409A. In no event will the Company reimburse Executive for any taxes that may be imposed on Executive as a result of Section 409A.

(f) No Duty to Mitigate. Executive will not be required to mitigate the amount of any payment contemplated by this Agreement, nor will any earnings that Executive may receive from any other source reduce any such payment.

8. Limitation on Payments. In the event that the severance and other benefits provided for in this Agreement or otherwise payable to Executive (i) constitute "parachute payments" within the meaning of Section 280G of the Code and (ii) but for this Section 9, would be subject to the excise tax imposed by Section 4999 of the Code, then Executive's severance benefits will be either:

(a) delivered in full, or

(b) delivered as to such lesser extent which would result in no portion of such severance benefits being subject to the excise tax under Section 4999 of the Code,

whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the excise tax imposed by Section 4999, results in the receipt by Executive on an after-tax

basis, of the greatest amount of severance benefits, notwithstanding that all or some portion of such severance benefits may be taxable under Section 4999 of the Code. If a reduction in the severance and other benefits constituting "parachute payments" is necessary so that no portion of such severance benefits is subject to the excise tax under Section 4999 of the Code, the reduction shall occur in the following order: (1) reduction of the severance payments under Sections 7(a)(i) or 7(a)(ii); (2) reduction of other cash payments, if any; (3) cancellation of accelerated vesting of equity awards; and (4) reduction of continued employee benefits. In the event that acceleration of vesting of equity award compensation is to be reduced, such acceleration of vesting shall be cancelled in the reverse order of the date of grant of Executive's equity awards. If two or more equity awards are granted on the same date, each award will be reduced on a pro-rata basis. In no event shall the Executive have any discretion with respect to the ordering of payment reductions.

Unless the Company and Executive otherwise agree in writing, any determination required under this Section 9 will be made in writing by an independent firm immediately prior to a Change of Control (the "**Firm**"), whose determination will be conclusive and binding upon Executive and the Company for all purposes. For purposes of making the calculations required by this Section 9, the Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and Executive will furnish to the Firm such information and documents as the Firm may reasonably request in order to make a determination under this Section 9. The Company will bear all costs the Firm may reasonably incur in connection with any calculations contemplated by this Section 9.

9. Definition of Terms. The following terms referred to in this Agreement will have the following meanings:

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

(b) Change of Control. For purposes of this Agreement, "**Change of Control**" means the occurrence of any of the following events:

(i) any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) is or becomes the "beneficial owner" (as defined in Rule 13d-3 under said Act), directly or indirectly, of securities of the Company representing more than 50% of the total voting power represented by the Company's then outstanding voting securities, other than the

acquisition of 50% of the total voting power represented by the outstanding voting securities when sold by the Company in a capital raising transaction; or

(ii) the date of the consummation of a merger or consolidation of the Company with any other corporation that has been approved by the stockholders of the Company, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or its parent) at least fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity or its parent outstanding immediately after such merger or consolidation; or

(iii) the date of the consummation of the sale or disposition by the Company of all or substantially all the Company's assets in a transaction that has been approved by the stockholders of the Company.

Notwithstanding the foregoing provisions of this definition, a transaction will not be deemed a Change of Control unless the transaction qualifies as a "change in control event" within the meaning of Section 409A.

(g) Code. For purposes of this Agreement, "**Code**" means the Internal Revenue Code of 1986, as amended.

(c) Disability. For the purposes of this Agreement, "**Disability**" will mean that Executive has been unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than six (6) months. Alternatively, Executive will be deemed disabled if determined to be totally disabled by the Social Security Administration. Termination resulting from Disability may only be effected after at least thirty (30) days' written notice by the Company of its intention to terminate Executive's employment. In the event that Executive resumes the performance of substantially all of Executive's duties hereunder before the termination of Executive's employment becomes effective, the notice of intent to terminate based on Disability will automatically be deemed to have been revoked.

(h) Equity Awards. For purposes of this Agreement, "**Equity Awards**" means Executive's outstanding Company stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares, performance stock units and any other Company equity compensation awards.

(i) Good Reason. For the purposes of this Agreement, "**Good Reason**" means Executive'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 Executive's express written consent: (i) the assignment to Executive of any duties beyond the generally recognized scope of employment of a company **Chief Strategy Officer** or the reduction of Executive's duties or the removal of Executive from Executive's position and responsibilities as **Chief Strategy Officer**, either of which must result in a material diminution of Executive's authority, duties, or responsibilities with the Company in effect immediately prior to such assignment; provided, however, if the Executive 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 Executive'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.

(d) Section 409A. For purposes of this Agreement, "**Section 409A**" means Code Section 409A, and the final regulations and any guidance promulgated thereunder or any state law equivalent.

(j) Section 409A Limit. For purposes of this Agreement, "**Section 409A Limit**" will mean two (2) times the lesser of: (i) Executive's annualized compensation based upon the annual rate of pay paid to Executive during the Executive's taxable year preceding the Executive's taxable year of his or her separation from service, as determined under Treasury Regulation Section 1.409A-1(b)(9)(iii)(A)(1) and any Internal Revenue Service guidance issued with respect thereto; or (ii) the maximum amount that may be taken into account under a qualified plan pursuant to Section 401(a)(17) of the Internal Revenue Code for the year in which Executive's separation from service occurred.

10. Assignment. This Agreement will be binding upon and inure to the benefit of (a) the heirs, executors and legal representatives of Executive upon Executive's death and (b) any successor of the Company. Any such successor of the Company will be deemed substituted for the Company under the terms of this Agreement for all purposes. For this purpose, "successor" means any person, firm, corporation or other business entity which at any time, whether by purchase, merger or otherwise, directly or indirectly acquires all or substantially all of the assets or business of the Company. None of the rights of Executive to receive any form of compensation payable pursuant to this Agreement may be assigned or transferred except by will or the laws of descent and distribution. Any other attempted assignment, transfer, conveyance or other disposition of Executive's right to compensation or other benefits will be null and void.

11. Notice. All notices, requests, demands and other communications called for hereunder will be in writing and will be deemed given (i) on the date of delivery if delivered personally, (ii) one (1) day after being sent by a well-established commercial overnight service, or (iii) four (4) days after being mailed by registered or certified mail, return receipt requested, prepaid and addressed to the parties or their successors at the following addresses, or at such other addresses as the parties may later designate in writing.

If to the Company:

Pulse Biosciences, Inc.
3957 Point Eden Way
Hayward, CA 94545
Attn: Chief Executive Officer

If to Executive:

at the last residential address known by the Company.

12. Confidential Information. Executive agrees to enter into and comply with the Company's standard At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement (the "Confidential Information Agreement").

2. Business Opportunities. The Executive agrees, during the Employment Term, to offer or otherwise make known or available to it, as directed by the Chief Executive Officer or Board and without additional compensation or consideration, any business prospects, contracts or other business opportunities that Executive may discover, find, develop or otherwise have available to Executive in the Company's Field of Interest, and further agrees that any such prospects, contacts or other business opportunities shall be the property of the Company.

3. Litigation and Regulatory Cooperation. During and after the Executive's employment with the Company, the Executive shall cooperate fully with the Company and its affiliates in the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company and its affiliates which relate to events or occurrences that transpired while the Executive was employed by the Company. The Executive's full cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of the Company and its affiliates at mutually convenient times. During and after the Executive's employment, the Executive also shall cooperate fully with the Company and its affiliates in connection with any such investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while the Executive was employed by the Company. The Company shall reimburse the Executive for any reasonable out-of-pocket expenses incurred in connection with the Executive's performance of obligations pursuant to this Section. If assistance is required after Executive is no longer employed by the Company, the Company agrees to compensate Executive by paying Executive a mutually agreed upon hourly rate for all time spend beyond five (5) hours. The performance by the Executive under this Section after the termination of the Executive's employment with the Company shall be subject to Executive's other employment obligations.

4. Insurance. The Executive agrees that the Company or its affiliates may from time to time and for the Company's or the affiliates' own benefit apply for and take out life insurance covering the Executive, either independently or together with others, in any amount and form which the Company or an affiliate may deem to be in its best interests. The Company or the respective affiliate shall own all rights in such insurance and in the cash values and proceeds thereof, and the Executive shall not have any right, title or interest therein. The Executive agrees to assist the Company and its affiliates, at the Company's expense, in obtaining any such insurance by, among things, submitting to customary examinations and correctly preparing, signing and delivering such applications and other documents as reasonably may be required. Nothing contained in this Section shall be construed as a limitation on the Executive's right to procure any life insurance for Executive's own personal needs.

5. Miscellaneous Provisions.

(a) Amendment. No provision of this Agreement will be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Executive and by an authorized officer of the Company (other than Executive) that is expressly designated as an amendment to this Agreement.

(b) Waiver. No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party will be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Headings. All captions and section headings used in this Agreement are for convenient reference only and do not form a part of this Agreement.

(a) Entire Agreement. This Agreement, together with the Plan, Option Agreement, and the Confidential Information Agreement (and its exhibits) represents the entire agreement and understanding between the parties as to the subject matter herein and supersedes all prior or contemporaneous agreements whether written or oral. With respect to stock options or other Equity Awards granted on or after the date of this Agreement, the acceleration of vesting provisions provided herein will apply to such stock options or other Equity Awards. This Agreement may be modified only by agreement of the parties by a written instrument executed by the parties that is designated as an amendment to this Agreement.

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

(e) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement will not affect the validity or enforceability of any other provision hereof, which will remain in full force and effect.

(f) Withholding. All payments made pursuant to this Agreement will be subject to all applicable withholdings, including all applicable income and employment taxes, as determined in the Company's reasonable judgment.

(g) Acknowledgment. Executive acknowledges that Executive has had the opportunity to discuss this matter with and obtain advice from Executive's private attorney, has had sufficient time to, and has carefully read and fully understands all the provisions of this Agreement, and is knowingly and voluntarily entering into this Agreement.

(h) Counterparts. This Agreement may be executed in counterparts, and each counterpart will have the same force and effect as an original and will constitute an effective, binding agreement on the part of each of the undersigned.

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the day and year set forth below.

COMPANY Pulse Biosciences, Inc.

/s/ Darrin R. Uecker

By: Darrin R. Uecker

Title: Chief Executive Officer

EXECUTIVE By: /s/ Mitch Levinson
Mitch Levinson

[SIGNATURE PAGE TO EXECUTIVE EMPLOYMENT AGREEMENT]

PULSE BIOSCIENCES, INC.

EMPLOYMENT AGREEMENT

This Employment Agreement (the "**Agreement**") is made and entered into by and between **Kevin Danahy** ("**Executive**") and Pulse Biosciences, Inc. (the "**Company**"), as of February 9, 2022.

1. Duties and Scope of Employment.

(a) Position and Duties. As of February 14, 2022 (the "**Start Date**"), Executive will serve as the Company's **Chief Commercial Officer** operating from the Company's offices located in Hayward, California. Executive will render such business and professional services in the performance of Executive's duties, consistent with Executive's position within the Company. Executive also will serve the Company in such other or alternative positions as may reasonably be assigned to Executive by the Company's Chief Executive Officer ("**CEO**") and Board of Directors (the "**Board**"), which positions may include director and additional or other officer positions of the Company and subsidiaries of the Company. The period of Executive's rendering of employment services under this Agreement is referred to herein as the "**Employment Term**."

(b) Obligations. During the Employment Term, Executive will perform Executive's duties faithfully and to the best of Executive's ability and will devote Executive's full business efforts and time to the Company. For the duration of the Employment Term, Executive agrees not to actively engage in any other employment, occupation or consulting activity for any direct or indirect remuneration without the prior approval of the Board.

(c) Automatic Resignation. At the end of the Employment Term, including upon any termination of employment for any reason, such ending or termination will be deemed to be an automatic resignation from all director and officer positions of the Company and any of its subsidiaries, unless the continuation of such appointments is specifically approved by a resolution of the Board of the respective corporation or its shareholders.

2. At-Will Employment. The parties agree that Executive's employment with the Company will be "at-will" employment and may be terminated at any time with or without cause or notice. Executive understands and agrees that neither Executive's job performance nor promotions, commendations, bonuses or the like from the Company give rise to or in any way serve as the basis for modification, amendment, or extension, by implication or otherwise, of Executive's employment with the Company. However, as described in this Agreement, Executive may be entitled to severance benefits depending on the circumstances of Executive's termination of employment with the Company.

3. Compensation.

(a) Base Salary. During the Employment Term, the Company will pay Executive an annual salary of **$395,000.00** 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 **50%** of Executive's base salary (the "**Target Bonus**") less applicable withholdings, prorated for the year of hire, 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.

(c) Start Date Option. Subject to the approval of the Board, Executive will be granted an option (the "**Start Date Option**") under the 2017 Inducement Equity Incentive Plan, as amended (the "**Plan**"), to acquire **300,000** shares of common stock of the Company. The Start Date Option will have an exercise price per share equal to the closing price of a share of the Company's common stock at the date of grant. Subject to certain accelerated vesting provisions as described herein, (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 the Start Date, (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. All vesting of the Start Date Option is subject to the Executive continuing to be a Service Provider (as defined in the Plan) through each applicable vesting date (including any applicable vesting target achievement determination date). The Start Date Option, including vesting provisions, will be subject to the terms of the Plan and a stock option agreement thereunder.

4. Employee Benefits. During the Employment Term, Executive will be entitled to participate in the employee benefit plans currently and hereafter maintained by the Company of general applicability to other senior executives of the Company, subject to the eligibility requirements of such plans. The Company reserves the right to cancel or change the benefit plans and programs it offers to its employees at any time.

5. Paid-Time Off "PTO". During the Employment Term, Executive will be entitled to accrue PTO of not less than three (3) weeks per year, subject to reasonable accrual caps in accordance with the Company's PTO policy for senior executive officers, with the timing and duration of specific PTO mutually and reasonably agreed to by the parties hereto.

6. Expenses. The Company will reimburse Executive for reasonable travel, entertainment or other expenses incurred by Executive in the furtherance of or in connection with the performance of Executive's duties hereunder within 30 days of Executive's submission of an expense report documenting said expenses, in accordance with the Company's expense reimbursement policy as in effect from time to time.

7. Severance.

(a) Termination other than for Cause, Death or Disability; or Resignation for Good Reason. During the Employment Term, if (i) the Company (or any parent or subsidiary or successor of the Company) terminates Executive's employment for reasons other than Cause, death, or Disability, or (ii) Executive resigns from the Company (or any parent or subsidiary or successor of the Company) for Good Reason (each such termination, an "**Involuntary Termination**"), then, subject to the continued observance by Executive of Sections 8 (severance conditions), 11 (assignment), 12 (notices), 13 (confidential information agreement), 15 (litigation cooperation), and 17 (miscellaneous) below after the termination of the rendering of employment services, Executive will receive the following severance from the Company:

(i) Severance Payment. Upon an Involuntary Termination, Executive will receive continuing payments of the Executive's Base Salary (as in effect immediately prior to the Executive's termination) for (x) three (3) months if Executive has been employed for an Employment Term hereunder of less than one (1) year from the Start Date, or (y) six (6) months if Executive has been employed for an Employment Term hereunder of one (1) year or more (the applicable period of time Executive receives continuing payments of Executive's Base Salary, the "**Severance Period**"). Executive will also receive a Target Bonus (if applicable) for the year of termination, prorated for the portion of the year served assuming 100% achievement, payable with the first severance payment. If the Involuntary Termination occurs at a point in time when the prior year's Target Bonus has yet to be paid out, Executive will also receive payment for any earned portion of Executive's Target Bonus for that prior year. The payment of any severance pursuant to this Section 7(a)(i) will be paid in accordance with the Company's normal payroll practices and be subject to the usual required withholdings.

(ii) Accelerated Vesting.

(1) *Involuntary Termination not in connection with a Change of Control*. If the Involuntary Termination is not in connection with a Change of Control, the unvested portion of Executive's outstanding Equity Awards that would normally vest over the following twelve (12) months from the date of Executive's termination had Executive remained an employee through such period will immediately accelerate and fully vest prior to Executive's termination.

(2) *Involuntary Termination in connection with a Change of Control*. If the Involuntary Termination occurs within the twelve (12) month period following a Change of Control, then (i) (x) 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 Executive's then outstanding Equity Awards will immediately vest prior to Executive's termination, and (y) if the Employment Term as of the date of such termination is one year or more from the Start Date, then 100% of the unvested portion of Executive's then outstanding Equity Awards will immediately vest prior to Executive's termination.

(iii) COBRA. If Executive elects continuation coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("**COBRA**") for Executive and Executive's eligible dependents within the time period prescribed pursuant to COBRA, the Company will reimburse Executive for the monthly premiums under COBRA necessary to continue group health insurance benefits for Executive and Executive's eligible dependents (at the coverage levels in effect immediately prior to Executive's termination) until the earlier of (A) the date upon which Executive and/or Executive's eligible dependents becomes covered under similar plans or (B) the last day of the Severance Period (such reimbursements, the "**COBRA Premiums**"). However, if the Company determines in its sole discretion that it cannot pay the COBRA Premiums without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company will in lieu thereof provide to Executive a taxable monthly payment payable on the last day of a given month (except as provided by the following sentence), in an amount equal to the monthly COBRA premium that Executive would be required to pay to continue Executive's group health coverage in effect on the date of Executive's termination of employment (which amount will be based on the premium for the first month of COBRA coverage), which payments will be made regardless of whether Executive elects COBRA continuation coverage and will commence on the month following Executive's termination of employment and will end on the earlier of (x) the date upon which Executive obtains other employment or (y) the last day of the Severance Period. For the avoidance of doubt, the taxable payments in lieu of COBRA Premiums may be used for any purpose, including, but not limited to continuation coverage under COBRA, and will be subject to all applicable tax withholdings. Notwithstanding anything to the contrary under this Agreement, if at any time the Company determines in its sole discretion that it cannot provide the payments contemplated by the preceding sentence without violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), Executive will not receive such payment or any further reimbursements for COBRA premiums. (Collectively, the Company's COBRA obligations in this paragraph are referred to as the "COBRA Payments").

(b) Resignation without Good Reason; Termination for Cause; Disability. If Executive resigns (other than for Good Reason), or the Company terminates Executive's employment for Cause, or Executive's employment terminates upon Executive's Disability, then (i) Executive will no longer vest in any Equity Award held by Executive, (ii) all payments of compensation by the Company to Executive hereunder will terminate immediately (except as to amounts already earned), and (iii) Executive will not be entitled to any severance or other benefits except for those (if any) as may then be established under the Company's then existing written severance and benefits plans and practices or pursuant to other written agreements with the Company.

(c) Accrued Compensation. For the avoidance of any doubt, in the event of a termination of Executive's employment with the Company (or any parent or subsidiary or successor of the Company) for whatever reason, Executive will be entitled to receive all accrued but unpaid vacation, expense reimbursements, wages, and other benefits due to Executive under any Company-provided plans, policies, and arrangements as of Executive's termination date.

(d) Exclusive Remedy. In the event of a termination of Executive's employment with the Company (or any parent or subsidiary or successor of the Company), the provisions of this Section 7 are intended to be and are exclusive and in lieu of any other rights or remedies to which Executive or the Company may otherwise be entitled, whether at law, tort or contract, in equity, or under this Agreement.

Executive will be entitled to no severance or other benefits, compensation or other payments or rights upon termination of employment other than those benefits expressly set forth in this Section 7.

8. Conditions to Receipt of Severance; No Duty to Mitigate.

(a) Separation Agreement and Release of Claims. The receipt of any severance pursuant to Section 7(a) will be subject to Executive signing and not revoking a separation agreement and release of claims in a form reasonably satisfactory to the Company (the "**Release**") and provided that such Release becomes effective and irrevocable no later than sixty (60) days following Executive's termination date (such deadline, the "**Release Deadline**"). If the Release does not become effective and irrevocable by the Release Deadline, Executive will forfeit any rights to severance or benefits under this Agreement. In no event will severance payments or benefits be paid or provided until the Release becomes effective and irrevocable. Except as required by Section 8(c), any installment payments that would have been made to Executive prior to the Release becoming effective and irrevocable but for the preceding sentence will be paid to Executive on the first regularly scheduled Company payroll date following the date the Release becomes effective and irrevocable, and the remaining payments will be made as provided in the Agreement.

(b) Confidential Information Agreement. Executive's receipt of any payments or benefits under Section 7 will be subject to Executive continuing to comply with the terms of the At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement between the Executive and the Company.

(c) Section 409A.

(i) Notwithstanding anything to the contrary in this Agreement, no severance pay or benefits to be paid or provided to Executive, if any, pursuant to this Agreement that, when considered together with any other severance payments or separation benefits, are considered deferred compensation under Section 409A (together, the "**Deferred Payments**") will be paid or otherwise provided until Executive has a "separation from service" within the meaning of Section 409A. Similarly, no severance payable to Executive, if any, pursuant to this Agreement that otherwise would be exempt from Section 409A pursuant to Treasury Regulation Section 1.409A-1(b)(9) will be payable until Executive has a "separation from service" within the meaning of Section 409A.

(ii) Any severance payments or benefits under this Agreement that would be considered Deferred Payments will be paid on, or, in the case of installments, will not commence until, the sixtieth (60th) day following Executive's separation from service, or, if later, such time as required by Section 8(c)(iii). Except as required by Section 8(c)(iii), any installment payments that would have been made to Executive during the sixty (60) day period immediately following Executive's separation from service but for the preceding sentence will be paid to Executive on the sixtieth (60th) day following Executive's separation from service and the remaining payments shall be made as provided in this Agreement**. In no event will Executive have discretion to determine the taxable year of payment for any Deferred Payments.**

(iii) Notwithstanding anything to the contrary in this Agreement, if Executive is a "specified employee" within the meaning of Section 409A at the time of Executive's termination (other than due to death), then the Deferred Payments, if any, that are payable within the first six (6) months following Executive's separation from service, will become payable on the first payroll date that occurs on or after the date six (6) months and one (1) day following the date of Executive's separation from service. All subsequent Deferred Payments, if any, will be payable in accordance with the payment schedule applicable to each payment or benefit. Notwithstanding anything herein to the contrary, if Executive dies following Executive's separation from service, but prior to the six (6) month anniversary of the separation from service, then any payments delayed in accordance with this paragraph will be payable in a lump sum as soon as administratively practicable after the date of Executive's death and all other Deferred Payments will be payable in accordance with the payment schedule applicable to each payment or benefit. Each payment, installment and benefit payable under this Agreement is intended to constitute a separate payment for purposes of Section 1.409A-2(b)(2) of the Treasury Regulations.

(iv) Any amount paid under this Agreement that satisfies the requirements of the "short-term deferral" rule set forth in Section 1.409A-1(b)(4) of the Treasury Regulations will not constitute Deferred Payments for purposes of clause (i) above. It is the intent of this Agreement that all cash severance payments under Section 7(a)(i) will satisfy the requirements of the "short-term deferral" rule.

(v) Any amount paid under this Agreement that qualifies as a payment made as a result of an involuntary separation from service pursuant to Section 1.409A-1(b)(9)(iii) of the Treasury Regulations that does not exceed the Section 409A Limit (as defined below) will not constitute Deferred Payments for purposes of clause (i) above.

(vi) The foregoing provisions are intended to be exempt from or comply with the requirements of Section 409A so that none of the severance payments and benefits to be provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities or ambiguous terms herein will be interpreted to be exempt or so comply. The Company and Executive agree to work together in good faith to consider amendments to this Agreement and to take such reasonable actions which are necessary, appropriate or desirable to avoid imposition of any additional tax or income recognition prior to actual payment to Executive under Section 409A. In no event will the Company reimburse Executive for any taxes that may be imposed on Executive as a result of Section 409A.

(a) No Duty to Mitigate. Executive will not be required to mitigate the amount of any payment contemplated by this Agreement, nor will any earnings that Executive may receive from any other source reduce any such payment.

9. Limitation on Payments. In the event that the severance and other benefits provided for in this Agreement or otherwise payable to Executive (i) constitute "parachute payments" within the meaning of Section 280G of the Code and (ii) but for this Section 9, would be subject to the excise tax imposed by Section 4999 of the Code, then Executive's severance benefits will be either:

(a) delivered in full, or

(b) delivered as to such lesser extent which would result in no portion of such severance benefits being subject to the excise tax under Section 4999 of the Code, whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the excise tax imposed by Section 4999, results in the receipt by Executive on an after-tax basis, of the greatest amount of severance benefits, notwithstanding that all or some portion of such severance benefits may be taxable under Section 4999 of the Code. If a reduction in the severance and other benefits constituting "parachute payments" is necessary so that no portion of such severance benefits is subject to the excise tax under Section 4999 of the Code, the reduction shall occur in the following order: (1) reduction of the severance payments under Sections 7(a)(i) or 7(a)(ii); (2) reduction of other cash payments, if any; (3) cancellation of accelerated vesting of equity awards; and (4) reduction of continued employee benefits. In the event that acceleration of vesting of equity award compensation is to be reduced, such acceleration of vesting shall be cancelled in the reverse order of the date of grant of Executive's equity awards. If two or more equity awards are granted on the same date, each award will be reduced on a pro-rata basis. In no event shall the Executive have any discretion with respect to the ordering of payment reductions.

Unless the Company and Executive otherwise agree in writing, any determination required under this Section 9 will be made in writing by an independent firm immediately prior to a Change of Control (the "**Firm**"), whose determination will be conclusive and binding upon Executive and the Company for all purposes. For purposes of making the calculations required by this Section 9, the Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and Executive will furnish to the Firm such information and documents as the Firm may reasonably request in order to make a determination under this Section 9. The Company will bear all costs the Firm may reasonably incur in connection with any calculations contemplated by this Section 9.

10. Definition of Terms. The following terms referred to in this Agreement will have the following meanings:

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

(b) Change of Control. For purposes of this Agreement, "**Change of Control**" means the occurrence of any of the following events:

(i) any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) is or becomes the "beneficial owner" (as defined in Rule 13d-3 under said Act), directly or indirectly, of securities of the Company representing more than 50% of the total voting

power represented by the Company's then outstanding voting securities, other than the acquisition of 50% of the total voting power represented by the outstanding voting securities when sold by the Company in a capital raising transaction; or

(ii) the date of the consummation of a merger or consolidation of the Company with any other corporation that has been approved by the stockholders of the Company, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or its parent) at least fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity or its parent outstanding immediately after such merger or consolidation; or

(iii) the date of the consummation of the sale or disposition by the Company of all or substantially all the Company's assets in a transaction that has been approved by the stockholders of the Company.

Notwithstanding the foregoing provisions of this definition, a transaction will not be deemed a Change of Control unless the transaction qualifies as a "change in control event" within the meaning of Section 409A.

(c) Code. For purposes of this Agreement, "**Code**" means the Internal Revenue Code of 1986, as amended.

(d) Disability. For the purposes of this Agreement, "**Disability**" will mean that Executive has been unable to engage, with or without reasonable accommodation, in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or can be expected to last for a continuous period of not less than six (6) months. Alternatively, Executive will be deemed disabled if determined to be totally disabled by the Social Security Administration. Termination resulting from Disability may only be effected after at least thirty (30) days' written notice by the Company of its intention to terminate Executive's employment. In the event that Executive resumes the performance of substantially all of Executive's duties hereunder before the termination of Executive's employment becomes effective, the notice of intent to terminate based on Disability will automatically be deemed to have been revoked.

(e) Equity Awards. For purposes of this Agreement, "**Equity Awards**" means Executive's outstanding Company stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares, performance stock units and any other Company equity compensation awards.

(f) Good Reason. For the purposes of this Agreement, "**Good Reason**" means Executive'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 Executive's express written consent: (i) the assignment to Executive of any duties beyond the generally recognized scope of employment of a company **Chief Commercial Officer** or the reduction of Executive's duties or the removal of Executive from Executive's position and responsibilities as **Chief Commercial Officer** either of which must result in a material diminution of Executive's authority, duties, or responsibilities with the Company in effect immediately prior to such assignment; provided, however, if the Executive 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 is solely by virtue of the Company being acquired and made part of a larger entity will not constitute "Good Reason"; (ii) a material reduction in Executive'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.

(g) Section 409A. For purposes of this Agreement, "**Section 409A**" means Code Section 409A, and the final regulations and any guidance promulgated thereunder or any state law equivalent.

(h) Section 409A Limit. For purposes of this Agreement, "**Section 409A Limit**" will mean two (2) times the lesser of: (i) Executive's annualized compensation based upon the annual rate of pay paid to Executive during the Executive's taxable year preceding the Executive's taxable year of Executive's separation from service, as determined under Treasury Regulation Section 1.409A-1(b)(9)(iii)(A)(1) and any Internal Revenue Service guidance issued with respect thereto; or (ii) the maximum amount that may be taken into account under a qualified plan pursuant to Section 401(a)(17) of the Internal Revenue Code for the year in which Executive's separation from service occurred.

11. Assignment. This Agreement will be binding upon and inure to the benefit of (a) the heirs, executors and legal representatives of Executive upon Executive's death and (b) any successor of the Company. Any such successor of the Company will be deemed substituted for the Company under the terms of this Agreement for all purposes. For this purpose, "successor" means any person, firm, corporation or other business entity which at any time, whether by purchase, merger or otherwise, directly or indirectly acquires all or substantially all of the assets or business of the Company. None of the rights of Executive to receive any form of compensation payable pursuant to this Agreement may be assigned or transferred except by will or the laws of descent and distribution. Any other attempted assignment, transfer, conveyance or other disposition of Executive's right to compensation or other benefits will be null and void.

12. Notice. All notices, requests, demands and other communications called for hereunder will be in writing and will be deemed given (i) on the date of delivery if delivered personally, (ii) one (1) day after being sent by a well-established commercial overnight service, or (iii) four (4) days after being mailed by registered or certified mail, return receipt requested, prepaid and addressed to the parties or their successors at the following addresses, or at such other addresses as the parties may later designate in writing.

If to the Company:

Pulse Biosciences, Inc.

3957 Point Eden Way

Hayward, CA 94545

Attn: Chief Executive Officer

If to Executive:

at the last residential address known by the Company.

13. Confidential Information. Executive agrees to enter into and comply with the Company's standard At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement (the "Confidential Information Agreement").

14. Business Opportunities. The Executive agrees, during the Employment Term, to offer or otherwise make known or available to it, as directed by the Chief Executive Officer or Board and without additional compensation or consideration, any business prospects, contracts or other business opportunities that Executive may discover, find, develop or otherwise have available to Executive in the Company's Field of Interest, and further agrees that any such prospects, contacts or other business opportunities shall be the property of the Company. For purposes of this section, "**Field of Interest**" shall include the development, implementation or licensing or sale of methods of using nanopulse electricity for bio-medical applications, including for diagnosis, detection, prevention, treatment or cure of tumors or cancers of internal organs, or benign diseases that can be treated by the ablation of internal tissue as well as other dermatologic applications and any other business activity engaged in, conducted by or in active planning by the Company or its subsidiaries or affiliates, and known to Executive during the Employment Term.

15. Litigation and Regulatory Cooperation. During and after the Executive's employment with the Company, the Executive shall cooperate fully with the Company and its affiliates in the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company and its affiliates which relate to events or occurrences that transpired while the Executive was employed by the Company. The Executive's full cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of the Company and its affiliates at mutually convenient times. During and after the Executive's employment, the Executive also shall cooperate fully with the Company and its affiliates in connection with any such investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while the Executive was employed by the Company. The Company shall reimburse the Executive for any reasonable out-of-pocket expenses incurred in connection with the Executive's performance of obligations pursuant to this Section. If assistance is required after Executive is no longer employed by the Company, the Company agrees to compensate Executive by paying Executive a mutually agreed upon hourly rate for all time spend beyond five (5) hours. The performance by the Executive under this Section after the termination of the Executive's employment with the Company shall be subject to Executive's other employment obligations.

16. Insurance. The Executive agrees that the Company or its affiliates may from time to time and for the Company's or the affiliates' own benefit apply for and take out life insurance covering the Executive, either independently or together with others, in any amount and form which the Company or an affiliate may deem to be in its best interests. The Company or the respective affiliate shall own all rights in such insurance and in the cash values and proceeds thereof, and the Executive shall not have any right, title or interest therein. The Executive agrees to assist the Company and its affiliates, at the Company's expense, in obtaining any such insurance by, among things, submitting to customary examinations and correctly preparing, signing and delivering such applications and other documents as reasonably may be required. Nothing contained in this Section shall be construed as a limitation on the Executive's right to procure any life insurance for Executive's own personal needs.

17. Miscellaneous Provisions.

(a) Amendment. No provision of this Agreement will be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by Executive and by an authorized officer of the Company (other than Executive) that is expressly designated as an amendment to this Agreement.

(b) Waiver. No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party will be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Headings. All captions and section headings used in this Agreement are for convenient reference only and do not form a part of this Agreement.

(d) Entire Agreement. This Agreement, together with the Plan, Option Agreement, and the Confidential Information Agreement (and its exhibits) represents the entire agreement and understanding between the parties as to the subject matter herein and supersedes all prior or contemporaneous agreements whether written or oral. With respect to stock options or other Equity Awards granted on or after the date of this Agreement, the acceleration of vesting provisions provided herein will apply to such stock options or other Equity Awards. This Agreement may be modified only by agreement of the parties by a written instrument executed by the parties that is designated as an amendment to this Agreement.

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

(f) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement will not affect the validity or enforceability of any other provision hereof, which will remain in full force and effect.

(g) Withholding. All payments made pursuant to this Agreement will be subject to all applicable withholdings, including all applicable income and employment taxes, as determined in the Company's reasonable judgment.

(h) Acknowledgment. Executive acknowledges that Executive has had the opportunity to discuss this matter with and obtain advice from Executive's private attorney, has had sufficient time to, and has carefully read and fully understands all the provisions of this Agreement, and is knowingly and voluntarily entering into this Agreement.

(i) Counterparts. This Agreement may be executed in counterparts, and each counterpart will have the same force and effect as an original and will constitute an effective, binding agreement on the part of each of the undersigned.

[REMAINDER OF PAGE BLANK; SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, each of the parties has executed this Agreement, in the case of the Company by its duly authorized officer, as of the day and year set forth below.

COMPANY Pulse Biosciences, Inc.

By: /s/ Darrin Uecker

Darrin Uecker

Title: President & Chief Executive Officer

EXECUTIVE By: /s/ Kevin Danahy

Kevin Danahy

List of Subsidiaries

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

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-259330, 333-246346, 333-237577, 333-227974, 333-224800, 333-219104, and 333-219096 on Form S-3 and Registration Statement Nos. 333-256992, 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, 2022, relating to the financial statements of Pulse Biosciences, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2021.

/s/ *Deloitte & Touche LLP*

San Jose, California
March 31, 2022

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECURITIES EXCHANGE ACT RULES 13a-14(a) and 15d-14(a), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Darrin R. Uecker, certify that:

1. I have reviewed this Annual Report on Form 10-K of Pulse Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   a) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2022

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

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECURITIES EXCHANGE ACT RULES 13a-14(a) and 15d-14(a), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sandra Gardiner, certify that:

1. I have reviewed this Annual Report on Form 10-K of Pulse Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2022

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

Exhibit 32.1

CERTIFICATIONS PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002*

In connection with the Annual Report of Pulse Biosciences, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his or her 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, 2022

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

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

* This certification is deemed furnished and not filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Pulse Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this report, irrespective of any general incorporation language contained in such filing, except to the extent the Company specifically incorporates these certifications by reference therein.