UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended **December 31, 2021**

or

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

For the transition period from _____.to _____.

Commission file number 1-11388

VIVEVE MEDICAL, INC.
(Exact name of Registrant as specified in its charter)

Delaware	**04-3153858**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

345 Inverness Drive South
Building B, Suite 250
Englewood, CO 80112
(Address of principal executive offices - Zip Code)

Registrant's telephone number, including area code: **(720)-696-8100**

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	VIVE	**The Nasdaq Capital Market**

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

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

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

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

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

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

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

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

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

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

As of June 30, 2021, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the last reported sales price of the Registrant's common stock, par value $0.0001 per share, on The Nasdaq Capital Market on such date, was approximately $31,351,000.

Number of shares outstanding of the Registrant's common stock, as of March 11, 2022: 10,619,846

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement relating to its 2022 Annual Meeting of Stockholders to be filed hereafter are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated.

VIVEVE MEDICAL, INC.

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Unless otherwise noted, the terms "Viveve", "the Company," "we," "us," "our" and similar designations in this Annual Report on Form 10-K refer to Viveve Medical, Inc. and its wholly-owned subsidiaries, Viveve, Inc. and Viveve BV.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements. Forward-looking statements give our current expectations or forecasts of future events. You can identify these statements by the fact that they do not relate strictly to historical or current facts. You can find many (but not all) of these statements by looking for words such as "approximates," "believes," "hopes," "expects," "anticipates," "estimates," "projects," "intends," "plans," "would," "should," "could," "may" or other similar expressions in this report. In particular, forward-looking statements include statements relating to future actions, prospective products, applications, customers and technologies, and future performance or future financial results. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from our historical experience and our present expectations or projections. Factors that could cause actual results to differ from those discussed in the forward-looking statements include, but are not limited to:

- our limited cash and our history of losses;
- our ability to achieve profitability;
- our limited operating history;
- emerging competition and rapidly advancing technology;
- the success, cost and timing of our product development activities and clinical trials of the Viveve System, including the initiation and progress of, and results from, our PURSUIT trial and whether the clinical trial will support the intended uses for treatment of stress urinary incontinence ("SUI") in the United States, and future clinical trials or these and any of our other product candidates;
- whether we are successful in having our medical device approved or cleared for sale by the U.S. Food and Drug Administration ("FDA") for the SUI indication;
  whether we can obtain regulatory approval in additional markets outside of the United States;
- whether demand develops for our medical device;
- the impact of competitive or alternative products, technologies and pricing;
- the adequacy of protection afforded to us by the patents that we own and the cost to us of maintaining, enforcing and defending those patents;
- our ability to obtain, expand and maintain protection in the future, and to protect our non-patented intellectual property;
- our ability to file and obtain additional patents;
- our ability to broaden our customer base;
- our exposure to and ability to defend third-party claims and challenges to our patents and other intellectual property rights;
- our ability to obtain adequate financing in the future, as and when we need it;
- our ability to continue as a going concern;
- the impact of the coronavirus on our clinical development and on the manufacturing, sales and patient utilization of our Viveve Systems and treatment tips;
- the impact of an economic recession, including as a result of the coronavirus, on our business, financial condition or results of operations;
- our ability to maintain compliance with The Nasdaq Capital Market continued listing standards;
  our success at managing the risks involved in the foregoing items; and
- other factors discussed in this report.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. The forward-looking statements are based upon management's beliefs and assumptions and are made as of the date of this report. We undertake no obligation to publicly update or revise any forward-looking statements included in this report to conform such statements to actual results or changes in our expectations. You should not place undue reliance on these forward-looking statements.

SUMMARY OF RISK FACTORS

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the Securities and Exchange Commission (the "SEC") before making investment decisions regarding our common stock.

- If we fail to maintain regulatory approvals and clearances, or if we are unable to obtain, or experience significant delays in obtaining, FDA clearances or approvals for the Viveve System or any future products we may develop or acquire, including product enhancements, our business and results of operations could be adversely affected.

- Our ongoing U.S. pivotal multicentered clinical trial (PURSUIT) for improvement of SUI in women may produce results that do not result in FDA clearance or approval of our FDA marketing application in the U.S. for SUI. In the event that we do not obtain FDA clearance or approval of the Viveve System for the treatment of SUI, we will be unable to promote it in the U.S. for that indication, and the ability to grow our revenue may be adversely affected.

- Our marketed products may be used by physicians for indications that are not cleared by the FDA. If the FDA finds that we marketed our products in a manner that promoted off-label use, we may be subject to civil or criminal penalties.

- Clinical trials necessary to support a 510(k) notification, de novo petition or premarket approval (" PMA") application will be expensive and will require the enrollment of large numbers of patients. Suitable patients may be difficult to identify and recruit. Delays or failures in our clinical trials may prevent us from commercializing our current product or any modified or new products and will adversely affect our business, operating results and prospects.

- If the third parties on which we rely to conduct our clinical trials and to assist us with preclinical development do not perform as contractually required or expected, we may not be able to obtain the regulatory clearance or approval which would permit us to commercialize our products.

- The results of our clinical trials, including the PURSUIT trial, may not support our proposed product claims or may result in the discovery of adverse side effects. Any of these events could have a material adverse impact on our business.

- The Viveve System may, in the future, be subject to product corrections, removals, or recalls that could harm our reputation, business and financial results.

- We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

- We are dependent upon the success of the Viveve System, which has a limited commercial history. If the device fails to gain or loses market acceptance, our business will suffer.

- We compete against companies that have more established products, longer operating histories and greater resources, which may prevent us from achieving significant market penetration or increased operating results.

- We have limited data regarding the efficacy of the Viveve procedure. If future data is not positive or consistent with our prior experience, rates of physician adoption will likely be harmed.

- We currently have clearance to market the Viveve System in the U.S. for use in general surgical procedures for electrocoagulation and hemostasis but not for vaginal laxity, sexual function, or SUI. If we want to sell our device and single-use treatment tips in the U.S. for the treatment of vaginal laxity, sexual function, or SUI, we will need to obtain additional FDA clearance or approval, which may not be granted.

- Our business is not currently profitable, and we may not be able to achieve profitability even if we are able to generate significant revenue.

- Our success depends on growing physician adoption of the Viveve System and continued use of treatment tips.

- Our revenue may suffer due to our transition of U.S. sales from a capital equipment sales model to a recurring revenue rental model.
- We depend on distributors to market and sell the Viveve System internationally. If they are not successful, our marketing and sales efforts will be harmed.
- The ongoing pandemic of COVID-19 and the future outbreak of other highly infectious or contagious diseases, could seriously harm our research and development, manufacturing and commercialization efforts, increase our costs and expenses and have a material adverse effect on our business, financial condition and results of operations.
- Competition among providers of devices for the medical device and aesthetics markets is characterized by rapid innovation, and we must continuously innovate technology and develop new products, or our revenue may decline.
- We outsource the manufacturing and repair of key elements of the Viveve System to manufacturing partners.
- Our manufacturing operations and those of our key manufacturing subcontractors are dependent upon third-party suppliers, making us vulnerable to supply shortages and price fluctuations, which could harm our business.
- We rely on a limited number of suppliers and third-party manufacturers, and if they are unable or unwilling to continue to work with us, our business could be materially adversely affected.
- We forecast sales to determine requirements for components and materials used in Viveve procedures, and if our forecasts are incorrect, we may experience delays in shipments or increased inventory costs.
- Product liability suits could be brought against us due to defective design, labeling, material or workmanship, or misuse of the Viveve System, and could result in expensive and time-consuming litigation, payment of substantial damages and an increase in our insurance rates.
- A data breach or cyberattack affecting our devices, information technology systems, or protected data could expose us to regulatory liability and litigation and dilute our brand quality.
- We depend on skilled and experienced personnel to operate our business effectively. If we are unable to recruit, hire and retain these employees, our ability to manage and expand our business will be harmed, which would impair our future revenue and profitability.
- Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations which could affect our ability to realize tax benefits from our net operating losses.
- We have been involved in and may be involved in future costly intellectual property litigation, which could impact our future business and financial performance.
- We are a holding company with no business operations of our own and we depend on cash flow from Viveve, Inc. to meet our obligations.
- Our shares of common stock are thinly traded, the price may not reflect our value, and there can be no assurance that there will be an active market for our shares of common stock either now or in the future.

PART I

Item 1. Business

Viveve designs, develops, manufactures and markets a platform medical technology, which we refer to as Cryogen-cooled Monopolar Radiofrequency ("CMRF"). Our proprietary CMRF technology is delivered through a radiofrequency generator, handpiece and treatment tip, that collectively, we refer to as the Viveve® System. The Viveve System is currently being marketed around the world (outside of the United States) for the non-invasive treatment of vaginal introital laxity, sexual function, vaginal rejuvenation, and SUI depending on the relevant country-specific clearance or approval, that we refer to as the Viveve treatment.

At this time, the Viveve System is indicated for use and being marketed for use in general surgical procedures for electrocoagulation and hemostasis in the United States; the device has not been cleared or approved for use for the treatment of vaginal laxity, to improve sexual function, for vaginal rejuvenation, or for SUI in the United States. Accordingly, the Company is prohibited under current U.S. regulations from promoting it to physicians or consumers for these unapproved uses. We believe the Viveve System and Viveve treatment provide a number of benefits for physicians and patients, including:

- a safe, minimally-invasive, non-ablative procedure;
- requiring only a single treatment;
- compelling physician economics; and
- ease of use.

In the U.S., the Viveve System is sold through a direct sales force. In other regions, we market and sell primarily through a network of distribution partners.

Currently, the Viveve System is cleared for marketing in 50 countries throughout the world under the following indications for use:

Indication for Use:	No. of Countries:
General surgical procedures for electrocoagulation and hemostasis	4 (including the U.S.)
General surgical procedures for electrocoagulation and hemostasis of vaginal tissue and the treatment of vaginal laxity	29
For treatment of vaginal laxity	5
For treatment of the vaginal introitus, after vaginal childbirth, to improve sexual function	9
General surgical procedures for electrocoagulation and hemostasis as well as for the treatment of vaginal laxity	1
For vaginal rejuvenation	1
For treatment of vaginal laxity and to improve mild urinary incontinence and sexual function	1

As of December 31, 2021, we have a global installed base of 884 Viveve Systems and we have sold approximately 61,000 single-use treatment tips worldwide.

On September 23, 2014, Viveve Medical, Inc. (formerly PLC Systems, Inc.), a Delaware corporation ("Viveve Medical", "Viveve", "we", "us" or "our") completed a reverse acquisition and recapitalization pursuant to the terms and conditions of an Agreement and Plan of Merger (the "Merger Agreement") by and among PLC Systems Acquisition Corp., a wholly-owned subsidiary of PLC Systems Inc., with and into Viveve, Inc., a Delaware corporation (the "Merger"). Viveve, Inc. is a Delaware corporation that was incorporated in 2005 by Jonathan Parmer, MD, an OBGYN physician, and is a wholly-owned subsidiary of Viveve Medical, Inc. In conjunction with the Merger, we changed our name from PLC Systems Inc. to Viveve Medical, Inc. to better reflect our new business. Viveve Medical competes in the women's health industry by marketing the Viveve System and the Viveve treatment as a way to improve the overall well-being and quality of life of women suffering from urinary incontinence and/or vaginal laxity, depending on the relevant country-specific clearance or approval. We are currently located at 345 Inverness Drive South, Building B, Suite 250, Englewood, Colorado 80112 and our telephone number is (720) 696-8100. Our website can be accessed at www.viveve.com. The information contained on or that may be obtained from our website is not a part of this report. Viveve, Inc. operates as a wholly-owned subsidiary of Viveve Medical and was incorporated in 2005.

Our Products

The Viveve System

The Viveve System consists of three main components: a radiofrequency ("RF") generator housed in a table-top console, a reusable handpiece and a single-use treatment tip. Included with the system are single-use accessories (e.g., return pad, coupling fluid), as well as a cryogen canister that can be used for approximately two to five procedures, and a foot pedal. Physicians or medical practitioners attach the single-use treatment tip to the handpiece, which is connected to the console. The generator authenticates the treatment tip and programs the system for the desired Viveve treatment without further intervention. The treatment is performed in a physician's office and does not require the use of anesthesia. The tissue remodeling effect resulting from the Viveve treatment has been demonstrated by our pre-clinical and clinical research.

- *RF Generator*. The generator produces a six-megahertz signal and is simple and efficient to operate. Controls are within easy reach, and important user information is clearly displayed on the console's built-in display, including energy delivered, tissue impedance, duration and feedback on procedure technique. Cooling is achieved, in conjunction with the generator, through the delivery of a coolant that helps to cool and protect the mucosa during a procedure.

- *Handpiece*. The reusable handpiece holds the treatment tip in place and processes information about temperature, contact, cooling system function and other important data. A precision control valve within the handpiece meters the delivery of coolant, which protects the mucosal surface tissue.

- *Treatment Tip*. The single-use treatment tip is available in two sizes and comes pre-sterilized. Each treatment tip contains a proprietary internal EEPROM or Electrically Erasable Programmable Read-Only Memory chip, which stores treatment parameters and safety limits in order to optimize performance and safety. To enhance procedural safety, we have programmed the EEPROM for single-use treatments. Using the same treatment tip to perform multiple procedures could result in injury, therefore, the EEPROM disables the treatment tip after a pre-programmed number of pulses to ensure that the treatment tip is not reused.

The Viveve System also includes other consumable components. The console houses a canister of coolant that can be used for approximately two to five procedures (depending on the procedure type and pulses used). Each procedure requires a new return pad, which is typically adhered to the patient's thigh or buttocks to allow a path of travel for the RF current through the body and back to the generator. We also sell proprietary single-use bottles of coupling fluid, a viscous liquid that helps ensure electrical and thermal contact with the treatment tip.

Technology Platform - Cryogen-cooled Monopolar Radiofrequency (CMRF)

The Viveve System uses a patented and proprietary method of delivering monopolar RF energy for treating tissue:

- *Monopolar RF Energy*. Monopolar RF delivery uses an active electrode applied to the target tissue and a passive return electrode adhered to the patient's thigh or buttocks. RF current is concentrated where the active electrode touches the body and expands as it is drawn through progressively deeper layers of tissue toward the return electrode. Providing both precise placement and deep energy penetration, the monopolar arrangement draws higher levels of therapeutic energy into deeper tissue layers than competing bipolar arrangements that rely on passive dispersion of current passing between two closely spaced electrodes on the tissue surface.

- *Capacitive Coupling Mechanism of Action for Collagen Heating.* Our single-use Viveve treatment tip contains patented technology that uses monopolar RF energy as a controlled tissue heating source through the use of a non-conducting material, known as a dielectric. Capacitive coupling is the use of the dielectric to create an electric field in the area where the treatment tip touches the body. The electric field induces a current within the surrounding tissue, resulting in volumetric heating of the tissue due to the tissue's natural resistance to electrical current flow. Collagen is an efficient conductor of electricity and therefore acts as a pathway for the electric current. This process results in heating of the fibrous septae, the strands of collagen fibers that permeate tissues and connect the outer mucosal layer to the underlying muscle. Delivery of heat to the fibrous septae located in deeper layers of the tissue shrinks and shortens them, resulting in tightening of the mucosal tissue. Over one to three months, as part of the body's natural response to the activation of fibroblasts that results from the application of low energy hyperthermic RF energy, aging collagen is reorganized into stronger, tighter bundles and can be supplemented with new collagen. This renewal of the tissue support matrix leads to improved tissue integrity and function.

The Viveve System also uses a proprietary, controlled cryogen surface cooling that enables deep volumetric heating of vaginal tissue:

- *Reverse Thermal Gradient.* With RF delivery, it is typical to expect higher temperatures closest to the surface electrode and a comparatively lower temperature distal to the electrode. However, with the Viveve System the opposite is true, hence a "reverse" thermal gradient. Maintaining a well-cooled, protected surface allows our treatment tips to safely remain on the tissue longer, allowing an optimal amount of RF energy penetration into the deeper tissue layers, while helping to ensure a comfortable patient experience.

- *Algorithmically-controlled Cryogen Delivery*. The Viveve System software actively monitors the temperature of the surface tissue and delivers the appropriate amount of cryogen necessary to keep the surface near normal body temperature. It does so consistently, automatically and completely independently of the actions of the operator, providing an important built-in safety mechanism to protect the delicate surface of vaginal tissue.

Market Overview

Overview of Stress Urinary Incontinence

Urinary incontinence ("UI") is the uncontrolled leakage of urine due to the loss of bladder control. Many people live in silence, either because they are embarrassed or because they mistakenly believe that UI is a normal consequence of aging or having children. Only half of these individuals who consider their UI symptoms to be problematic or bothersome will seek consultation or speak to their doctor. The reported prevalence for UI in adult women is as high as 40 million women in the U.S. Based on several published studies, we estimate that approximately 27 million women, age 25 to 55 years old, in the U.S. alone suffer from some form of urinary incontinence. There are multiple types of incontinence, including: Stress Urinary Incontinence ("SUI"), Urge Urinary Incontinence ("UUI"), and Mixed Incontinence, which is a combination of SUI and UUI.

SUI is defined as the uncontrolled leakage of urine due to sudden or increased intraabdominal pressure caused by activities such as exercising, sneezing, laughing, or coughing. There are two main causes of SUI: urethral hypermobility and intrinsic sphincter deficiency ("ISD"). Urethral hypermobility is the predominant cause of SUI and is due to weakness in the pelvic floor musculature and soft tissues that cannot stabilize the urethra causing the sphincter muscles to open briefly and leak urine. Based on published studies, we estimate that pure SUI is common in approximately 5 million women in the U.S. alone and that UUI or "Urge Urinary Incontinence," is common in approximately 4 million women in the U.S. and is defined as the sudden urge to urinate with a frequency greater than eight times per 24 hours. We believe approximately 18 million women have a combination of SUI and UUI referred to as mixed incontinence.

Current Treatments for Stress Urinary Incontinence and Their Limitations

The first-line treatment options for SUI and UUI begin with lifestyle changes, continence pessaries, and behavioral and physical therapies. However, based on our survey results, conservative treatment options result in low efficacy rates ranging from 40 to 50% in the United States. UUI patients currently have a wide range of pharmacological options to manage the condition, as well as sacral nerve stimulation devices. SUI, however, lacks sufficient pharmacologic and non-invasive treatments prior to patients seeking highly invasive procedures such as urethral bulking agents, pelvic floor sling surgery or colposuspension. Based on a 2016 to 2020 data set of the annual patient insurance claims for UI, 2 million patients had documented conservative therapies and 90,000 patients progress to invasive procedures. We believe a large unmet need remains for SUI patients seeking an effective, non-invasive treatment option. According to the published studies, approximately 80% of women with UI are "bothered" and receive no treatment option, equating to approximately 7 million women with predominant SUI who could be candidates for the Viveve treatment.

Overview of Vaginal Laxity and Sexual Function

Vaginal laxity and tissue architecture have often been overlooked as contributing etiological factors to female sexual function. Vaginal laxity can lead to diminished physical sensation during intercourse. This reduction in sensation is often coupled with a reduction in sexual satisfaction, all of which can also impact a woman's sense of sexual self-esteem and her relationship with her sexual partner.

Vaginal laxity is infrequently discussed in a clinical situation, yet most surveyed OB/GYNs and urogynecologists recognize that it is an underreported, yet bothersome, medical condition that impacts relationship happiness and sexual function. Another survey of OB/GYNs found that vaginal laxity is the most frequent physical change seen or discussed post-vaginal delivery. Additionally, in a survey of women ranging from 25-45 years of age, who had experienced at least one vaginal delivery, approximately half expressed some degree of concern over "looseness" of the vaginal introitus.

Women can develop vaginal laxity for a number of reasons, including aging, genetic predisposition, lifestyle, and/or trauma. As women age, slower cellular renewal coupled with reduced vascular and glandular networks contributes to loss of underlying supportive fibrous tissue. Some women may have underlying pathophysiological issues with collagen formation, remodeling and repair; and their lifestyle choices (e.g., alcohol consumption, tobacco use, and excessive food consumption) also play a role in the integrity of vaginal tissue. Vaginal trauma (e.g., childbirth, surgery, self-stimulation, or coitus) can also contribute to vaginal laxity.

All women who have given birth vaginally undergo stretching of the tissues of the vaginal opening to accommodate the fetal head. Often the effects are permanent, and many women have long-term physical and psychological consequences, including sexual dissatisfaction. One significant issue is the loosening of the introitus ─ the vaginal opening. This may happen with the first vaginal delivery and can be made worse with subsequent vaginal deliveries. Vaginal laxity can result in decreased sexual pleasure for both women and their partners during intercourse. We believe that this condition is not frequently discussed because women are embarrassed, fear that their concerns will be dismissed or fear that their physicians will not understand. Physicians hesitate to discuss the situation with their patients because historically there has been no safe and effective treatment options. Physicians frequently recommend Kegel exercises. However, these exercises only strengthen the pelvic floor muscles and do not address the underlying cause of vaginal laxity – loss of tissue elasticity. While surgery can be performed to tighten the vaginal canal, the formation of scar tissue from the surgery may lead to painful intercourse and permanent side effects.

As a consequence of the physical tissue damage that can result from childbirth, a significant decrease in sexual satisfaction has been reported in women who underwent vaginal delivery, when assessed two years after delivery, in comparison with those who underwent elective caesarian section. In the past several years there has been a marked increase in the number of women requesting delivery by caesarian section with the intention of preventing damage to the pelvic floor and introitus. Caesarian sections are not without risk to both the baby and mother. Whether or not to agree to a woman's request for an elective caesarian section has generated considerable controversy among obstetricians. If a procedure were available to address the concerns of women about vaginal laxity, we believe the perceived need to have a caesarian section to prevent vaginal tissue damage may decrease significantly.

Market for a Proven Solution for Vaginal Laxity & Sexual Function

In 2009, we sponsored several on-line marketing surveys in the U.S. with both OB/GYNs and women, ages 25-55, to assess attitudes of physicians and women about vaginal laxity and towards a safe, non-invasive solution to treat this condition.

- *Physician Survey*: An OB/GYN marketing survey was conducted by OB/GYN Alliance with nearly 525 practicing OB/GYNs from across the U.S. The objectives of the study were to: obtain insights from physicians on physical changes resulting from childbirth and the corresponding sexual health implications for patients; understand the perceptions and opinions of OB/GYN physicians on a procedure that could be offered to address vaginal laxity following childbirth; and gain an understanding of whom the early adopters may be of the Viveve treatment.

- *Consumer Survey*: In a consumer marketing survey conducted by Q&A Research, 421 women were screened for vaginal delivery, age (25-55), income, education and other factors. The objectives of the survey were to assess the need for the Viveve treatment and better understand the complexity of emotions and the psychological profile of women who experience, but do not discuss, vaginal changes post childbirth.

Results from these surveys suggested that vaginal laxity is a significant unmet medical need, and that patients and physicians would benefit significantly from a safe and effective non-invasive treatment that would also increase physical sensation and sexual satisfaction following vaginal childbirth. Of the 421 patient respondents, up to 48% felt that vaginal laxity was a concern post-childbirth. Furthermore, it is evident that patients and their OB/GYNs are not discussing vaginal laxity on a regular basis; in fact, we believe such conversations occur quite infrequently due to many factors, including patient embarrassment and fear of being ridiculed, lack of time and lack of solutions for physicians. Of the nearly 525 OB/GYNs surveyed, 84% indicated that vaginal laxity is the number one post-delivery physical change for women, being more prevalent than weight gain, UI and stretch marks, and believe that it is under-reported by their patients. Additionally, in a separate international survey of urogynecologists, 84% of the 563 respondents described vaginal laxity as underreported by their patients and the majority considered it a bothersome condition that impacts sexual function and relationships.

Applying U.S. census data, CDC Vital Statistics data and our projections from these studies, we estimate there are approximately 9 million post-partum women who are potential candidates for this procedure in the U.S. alone, approximately 4.5 million of whom could be candidates for the Viveve treatment for vaginal laxity or sexual function.

In 2012, we conducted a similar consumer study in Japan and Canada in order to understand cultural differences that may exist towards vaginal laxity and the Viveve treatment. The results corroborated our U.S. survey conclusions. Applying World Health Organization census data as well as data from individual countries, we estimate there are 25-30 million women outside the U.S. that could be candidates for the Viveve treatment for vaginal laxity or sexual function.

In January 2018, we sponsored a survey of 1,500 women in Great Britain having had a vaginal delivery, and nearly half (48%) worried before having a child about physical changes in their body from childbirth affecting their sex life; this increased to 67% of women in the age range of 25-34. Approximately 4 in 10 (38% overall, 44% ages 25-34) have experienced vaginal tissue changes impacting their physical sensation during sex, with the most common impacts consisting of feeling less confident overall, feeling embarrassed and self-conscious, and feeling less enjoyment or intimacy with their partner.

In a 2019 article in the Journal of Women's Health, the authors concluded that the social stigma for women from Western culture regarding sexuality remains and creates barriers of communication with their health care professionals. The women in the study were typically unaware or had misconceptions of conditions that could adversely affect their sexual life. Additionally, these women lacked awareness of safe and effective treatments. Despite the lack of awareness and communication regarding this issue, we believe there is a strong interest among patients and doctors to advance the conversation of women's sexual wellness and evolving options a treatment that are clinically proven and safe.

Current Treatments for Vaginal Laxity/Sexual Function and Their Limitations

Currently, few clinically proven medical treatments are available to effectively treat vaginal laxity or sexual function. The most widely prescribed treatments include pelvic floor muscle exercises, or Kegel exercises, and invasive surgical procedures, known as laser vaginal rejuvenation ("LVR") or vaginoplasty.

- *Kegel Exercises*: Kegels are an exercise that was developed by Dr. Arnold Kegel designed to strengthen the muscles of the pelvic floor - the pubococcygeal ("PC") muscles - to increase vaginal muscle tone, improve sexual response, and limit involuntary urine release due to SUI. These exercises are often prescribed following childbirth or during and after menopause. However, we are not aware of any validated evidence indicating that Kegels improve vaginal laxity or sexual function due to introital laxity.

- *Surgical Procedures*: Of the various alternatives for treating vaginal laxity, invasive surgical procedures, such as LVR, are the only modalities with any proven efficacy outcomes. Typically, they are performed by plastic surgeons with patients under general anesthesia. According to The International Society of Aesthetic Plastic Surgeons ("ISAPS"), 206,846 LVR surgeries were performed world-wide in 2017. However, these invasive surgical procedures are expensive, costing thousands of dollars, and can involve weeks of post-surgical recovery time for the patient. They also carry the risk of scarring, which can lead to uncomfortable or painful intercourse, long-term or permanent loss of sensation, serious infection, tissue necrosis, hematomas (fluid collection under the tissue that may require removal), and adverse reactions to anesthesia.

The Viveve Solution

RF energy has a long history of use in epithelial/mucosal tissue in the pharynx, skin, cornea, and vagina. Additionally, RF devices have been used to treat a variety of health-related concerns, including SUI. We believe our CMRF technology may offer an alternative to existing SUI treatment options. By regenerating collagen around the urethra's bladder neck, our treatment may help stabilize the underlying hypermobility of the urethra. Our innovative and proprietary CRMF procedure may also offer potential benefits and competitive advantages that do not currently exist in the non-invasive treatment market for SUI. Our endovaginal approach to regenerating collagen does not require anesthesia or numbing creams. The cryogen cooling feature protects the vaginal mucosa (surface tissue) while allowing the radiofrequency to heat deeper layers of the tissue (lamina propria) and stimulate collagen regrowth. The procedure typically takes approximately 45 minutes. To perform the procedure, a practitioner attaches the single-use treatment tip to the handpiece. As described above, the return pad is then adhered to the patient's upper leg to allow a path of travel for the RF current back to the generator. Prior to treatment, the treatment area is bathed in coupling fluid, which is used for conduction and lubrication.

Benefits of the Viveve Treatment

The Viveve treatment provides a number of benefits for physicians and patients:

- *Minimally-Invasive, Non-Ablative Treatment with a Demonstrated History of Safety.* The Viveve System has been tested in pre-clinical tissue studies and has been used to treat over 500 clinical study patients. To date, we estimate that physicians have treated over 30,000 patients. The procedure is non-invasive and offers a treatment option with little or no downtime from the patient's normal routine. It is also not a surgical procedure and does not damage either the mucosal, sub-mucosal tissue, or any extra vaginal tissues or require any form of anesthesia.

- *Single Treatment.* The Viveve treatment is normally performed in a medical office setting as a single treatment that takes approximately 45 minutes to complete depending on the indication being treated. Our studies have shown that the clinical effect from our procedure occurs within one to three months and patients continue to report improvement over a period of six months following treatment. In addition, the Viveve treatment maintains its effect for at least 12 months, based upon currently available data from our clinical studies.

- *Compelling Physician Economics*. We believe that in an era of declining government and insurance reimbursement, many physicians are seeking to add effective and safe, self-pay procedures to their practices. The Viveve treatment can be easily adapted into many physician practices and offers compelling per-procedure economics for the physician.

- *Ease of Use.* The Viveve System offers an easy-to-use, straightforward user interface that allows a trained physician or nurse (where permitted by law) to perform the treatment in approximately 45 minutes depending on the indication being treated. It provides real-time feedback, and the patient can be monitored during the treatment. The handpiece and single-use treatment tip are designed with a small profile for accurate placement during treatment, comfort, and ease of use.

Business Strategy

Our goal is to become the leading provider of non-invasive solutions to treat certain women's intimate health conditions by:

- *Broadening the Conditions We Treat Through Robust Clinical Trials and Regulatory Label Expansion.* In addition to clearances/approvals in many international countries for improvement of vaginal laxity and/or sexual function, we are conducting a pivotal U.S. clinical trial in SUI. If successful, we intend to submit for regulatory clearance/approval in the U.S. and abroad for the improvement of SUI. (See discussion under the heading "**Clinical Studies**")

- *Increasing the Number of Installed Base of Viveve Systems.* In our existing markets, we plan to (i) expand the number of Viveve Systems by leveraging our recurring revenue rental model, current and future clinical study results and through innovative marketing programs directed at both physicians and patients, where permissible by law, and (ii) expand our efforts and obtain regulatory approvals in additional markets, although there are no assurances that we will ever receive such approvals.

- *Driving Increased Treatment Tip Usage.* We work collaboratively with our physician customer base to increase treatment tip usage by enhancing customer awareness and facilitating the marketing efforts of our physician customers to their patients, where permitted by law. We intend to launch innovative marketing programs with physician customers, where permitted by law, to develop a high volume Viveve practice.

- *Developing New Treatment Tips and System Enhancements.* We intend to continue to expand our line of treatment tips that, in the future, may allow for shorter procedure times to benefit both physicians and patients. We also plan to pursue potential system modifications and next generation enhancements that will further increase the ease-of-use of the Viveve System.

- *Investing in Intellectual Property and Patent Protection.* We will continue to defend and invest in expanding our intellectual property portfolio, and we intend to file for additional patents to strengthen our intellectual property rights. Areas in which we may pursue additional patent protection include, but are not limited to, redesign of certain system components, disposable components and software algorithms. We believe that our intellectual property rights protect our position as the exclusive provider of a vaginal laxity treatment using monopolar RF technology in the U.S. and in many other countries. (See discussion under the heading "**Patents and Proprietary Technology**")

Our Customers

To date, we have focused our commercial efforts in markets where we have received regulatory clearances/approvals. Within each market, we target thought leaders across multiple specialties in order to increase awareness of the conditions we treat and accelerate patient acceptance of Viveve's treatments. Currently we target a broad number of physician specialties, with a primary focus on OBGYNs, Urogynecologists, and Urologists with a secondary focus on aesthetic and functional medicine practices.

Through our direct sales employees, and distributors, we currently target physicians who have a demonstrated commitment to building a high-volume, non-invasive treatment business within their practice. As sales of our product continue to expand globally, we intend to continue to utilize distribution partners in most countries.

Sales and Marketing

United States

In October 2016, we received clearance from the FDA to sell the Viveve System for use in general surgical procedures for electrocoagulation and hemostasis. From January 2017 through May 2019, the Company relied on a traditional capital sales model, including selling the Viveve Systems and disposable treatment tips. In June of 2019, in addition to a capital sales model, the Company began a new recurring revenue rental model, where we lease the Viveve System to customers in the United States market instead of selling it to them. The Company believes that the change in business model lowers the barrier to entry for physicians to adopt the procedures, shortens the sales cycle and improves the cost effectiveness of each sale. At the end of 2021, we had 4 direct sales representatives responsible for placing Viveve Systems in the market and 4 marketing support specialists to support customers' marketing efforts, ensure recuring revenue account retention, and increase system utilization. In 2022, we plan to continue to expand our direct sales efforts under the recurring revenue rental model as well as offering customers the ability to purchase the Viveve System under the capital sales model to achieve broader reach throughout the United States.

International

We currently market and sell the Viveve System, including the single-use treatment tips, in several countries internationally. At the present time, trained direct sales employees and distribution partners represent Viveve and its products mainly in the Asia Pacific region, Canada and several countries in Europe.

By using a consultative sales process, we form strong relationships with our customers through frequent interactions. Beyond performing initial system installation and on-site training, which can occur within two weeks of a physician's purchase decision, our sales consultants provide ongoing consultation to physicians on how to integrate the Viveve treatments into their practices and market procedures to their patients, to the extent permitted by law.

We, or our distribution partner, also provide comprehensive training and education to each physician upon delivery of the Viveve System. We are not required to provide training but do so to support our physician customers in safely and effectively performing the Viveve treatments.

Further, we intend to actively engage in promotional opportunities through participation in industry trade shows and clinical workshops, as permitted by law, as well as through trade journals, brochures, and our website. We intend to also actively engage in direct-to-consumer marketing of the Viveve treatments where permitted by law, including extensive use of social media, in many cases on a cooperative basis with our distribution partners.

Clinical Studies

We have completed several pre-clinical and human clinical studies in vaginal tissue to assess the safety and efficacy of the Viveve treatment in vaginal laxity/female sexual function ("FSD") and SUI. These include an FSD trial under an FDA-approved investigational device exemption ("IDE") in the U.S. (VIVEVE II) and, an international trial in Canada for SUI (LIBERATE-International). Currently, we are conducting an IDE clinical study in the U.S. for SUI (PURSUIT). While we believe that our pre-clinical and human clinical studies have, and will, show that the Viveve System and the Viveve treatment have a strong safety profile and are effective, there is risk that the FDA will not agree with this assessment. Notwithstanding the safety in trials to date of the Viveve System, patients may experience undesirable side effects such as temporary swelling or reddening of the treated tissue.

Clinical trials are time-consuming, expensive, and may produce results that do not result in FDA clearance or approval of our FDA marketing application in the U.S. for SUI. In the event that we do not obtain FDA clearance or approval of the Viveve System for the treatment of SUI, we will be unable to promote it in the U.S. for that indication, and the ability to grow our revenue may be adversely affected. Additionally, we have not conducted any head-to-head clinical studies that compare results from treatment with the Viveve System to surgery or treatment with other therapies. Without head-to-head studies against competing alternative treatments, which we have no current plans to conduct, potential customers may not find clinical studies of our technology sufficiently compelling to purchase the Viveve System. If we decide to pursue additional studies in the future, such studies could be expensive and time consuming, and the data collected may not produce favorable or compelling results. If the results of such studies do not meet physicians' expectations, the Viveve procedure may not become widely adopted, physicians may recommend alternative treatments for their patients, and our business may be harmed.

Pre-clinical Studies

In 2010, in collaboration with West Virginia University, we conducted an animal study in female sheep, or ewes, to assess the safety, and further understand the mechanism of action, of the Viveve treatment. The vaginal introitus of five parous ewes were treated once with the Viveve System using a variety of energy levels (75−90 Joules/cm2). Each ewe then underwent serial vaginal biopsies immediately after treatment, at approximately one week, and at one, three and six months (4-5 samples per occurrence). Control biopsies were also obtained from three untreated parous ewes. We examined the vaginal mucosa and underlying connective tissue for thermal changes and subsequent tissue responses over a six-month period through light microscopic examination of hematoxylin and eosin ("H&E") stained slides that were reviewed by pathologists who were blinded as to the treated and untreated ewes.

The results of the study indicated that the optimal level of RF energy delivered was 90 J/cm2 and the biopsies supported the hypothesis that the mechanism of action of our technology involves connective tissue remodeling with fibroblast activation and new collagen production. Given the post-treatment absence of ulcerations, regional necrosis or diffuse fibrosis, throughout the six-month follow-up period, we believe the studies help support the safety profile of the Viveve System.

As part of our clinical studies, we have studied and continue to study, the interaction of RF energy and tissue to further understand the mechanism of action of the Viveve procedure. We have used transmission electron microscopy on ovine biopsied tissue samples to corroborate that our product induces subtle collagen modification and the deposition of new collagen that leads to tissue tightening and restoration of tissue elasticity. We have developed histology techniques to investigate the depth of heat in tissue, fibroblast activation and collagen deposition that we believe is responsible for long-term improvement and tightening of tissue. We have also created three-dimensional computer models to study tissue heating with our product. Determining the effectiveness of this type of treatment is inherently a subjective evaluation, and the FDA could disagree. When performing our clinical studies, we attempt to utilize the most compelling measures we can in order to provide convincing evidence of efficacy.

In November 2019, we conducted a Good Laboratory Practice ("GLP") study in six ewes to evaluate the in vivo temperature-time profile and histopathology of vaginal and surrounding tissues in the ovine model after Viveve treatment. Five ewes were utilized for the in vivo energy application procedures while the remaining ewe was utilized as a control. During anesthesia, eight fluoroptic temperature probes were placed at different locations near the vaginal wall, rectum and bladder. After probe placement, five of the ewes received the Viveve SUI protocol (220 pulses of 90 J/cm2 of RF energy) and temperatures recorded. The control ewe did not receive energy application, but temperatures were recorded. In February 2020, study results showed temperature increases only at tissue locations where expected. Histopathology results showed normal histopathology of vaginal and surrounding tissues, and no adverse or other associated treatment-related responses, as evaluated histologically via H&E stain (in formalin fixed, paraffin embedded samples) and LDH/NBT vital stain (in frozen, OCT embedded samples). There were no macroscopic findings in either fresh or formalin-fixed tissues submitted for pathologic evaluation.

In response to the inconclusive results reported in July 2019 from the Company's LIBERATE-International SUI trial conducted in Canada (aimed at supporting SUI indications in Canada, the European Union and several other international countries), Viveve conducted an in-vivo preclinical temperature and immunohistochemistry study to evaluate a new inert sham treatment tip. The GLP study was initiated in June 2020 following several months of engineering, validation, and development work. The study assessed both in-vivo tissue temperature changes during treatment, and histopathology at 30 days post-treatment compared to baseline, in three parous ewes using Viveve's CMRF treatment tip (Active), cryogen-cooling only treatment tip ("Old" sham treatment used in previous LIBERATE-International SUI study), and a new inert sham treatment tip. Histopathology of vaginal biopsies were performed and included use of α-smooth muscle actin ("α-SMA") staining for fibroblast activation and formation. All tissue samples were evaluated by an independent and blinded pathologist.

The positive preclinical findings demonstrated, as reported in August 2020, that both temperature and immunohistochemistry results support the validity of the new inert sham treatment tip to provide a true inert or placebo treatment. Only minor tissue temperature change (less than 2 degrees centigrade) was generated by the new inert sham treatment tip and no fibroblast activation was shown through elevated a-SMA staining. In contrast, both the Active and cryogen-cooling sham treatment tips demonstrated meaningful tissue temperature changes during treatment and increased fibroblast activation 30 days post-treatment. We believe that the positive in-vivo preclinical study validates our new inert sham treatment tip for use in the U.S. pivotal PURSUIT trial that is currently underway.

Clinical Studies – Stress Urinary Incontinence

Canadian Pilot Study

In 2017, Viveve funded a single-arm investigator sponsored study to assess the effects of our CMRF technology in treating patients with mild-to-moderate SUI. The study was conducted in Calgary, Alberta and included 10 patients who underwent treatment with our CMRF technology under a proprietary treatment protocol. Patients were followed for 12 months with safety and clinical results reported at 4, 6, 9 and 12-months post-treatment. Clinical results included composite scores from the validated ICIQ-UI-SF (International Consultation on Incontinence Questionnaire–Urinary Incontinence-Short Form) and UDI-6 (Urogenital Distress Inventory-Short Form) outcome questionnaires.

Results at 12 months (n=9) included an 89% responder rate (percentage of patients showing an improvement from baseline) for the ICIQ-UI-SF and a 100% responder rate on the UDI-6. Additionally, patients showed a 40% mean improvement on the ICIQ-UI-SF and a 51% mean improvement on the UDI-6 at 12 months across both validated endpoints. No device-related safety issues were reported in any of the patients.

Canadian Feasibility Study

In December 2018, we reported the results of a Viveve supported, single-arm, open label feasibility study that was conducted to evaluate the efficacy and safety of our CMRF technology to improve urine leakage and quality of life associated with SUI. The study was conducted in Calgary, Alberta and included 37 patients who underwent treatment with our CMRF technology under a proprietary treatment protocol. Patients with mild to moderate SUI were treated with our proprietary treatment protocol and followed for 12 months with safety and clinical results reported at 3, 6, 9 and 12-months post-treatment. Clinical results included evaluation of the one-hour pad weight test, an FDA acceptable endpoint to assess the severity of and leakage associated with SUI, daily incontinence episodes, as well as composite scores from the validated UDI-6, IIQ-7 (Incontinence Impact Questionnaire), and ICIQ-UI-SF outcome questionnaires.

Results at 12 months (n=25) included a 72% responder rate (percentage of patients showing an improvement from baseline) on the one-hour pad weight test, a clinically meaningful benefit across all patient reported outcome measures, and a 64% reduction in daily incontinence episodes. Additionally, 52% of patients experienced greater than a 50% reduction in the one-hour pad weight test from baseline and 60% of patients had less than 1 gram of leakage at 12 months on the one-hour pad weight test. No device-related safety issues were reported in any of the patients.

This feasibility study showed a significant reduction of SUI symptoms by the 1-month time point and subjects reported durability of results lasting to the 12-month visit. While this study was on a small number of subjects, the Viveve treatment for SUI showed significant promise and as a result Viveve planned two additional trials in SUI.

LIBERATE - International

In January 2019, enrollment was completed for the LIBERATE-International study in SUI. The study was conducted in Canada to support SUI indications in Canada, the European Union and several other international countries. LIBERATE International, a randomized, double-blind, sham-controlled study in 99 patients with mild-to-moderate SUI was conducted at nine sites in Canada. Patients were randomized in a 2:1 ratio to either Active treatment (90 J/cm2 RF with cryogen cooling) or Sham treatment (sub-treatment dose of ≤1 J/cm2 with cryogen cooling). Patients were followed for six months post-treatment to assess the primary efficacy and safety of the treatment with data being collected at one, three and six months.

The primary efficacy endpoint was 6-month change from baseline in the one-hour pad weight test. Secondary endpoints included: 24-hour pad weight test, daily incontinence episodes (3-day diary), UDI-6, ICIQ-UI-SF, and FSFI.

Across all endpoints, the efficacy of both the Active and Sham treatments were highly clinically relevant and statistically significant compared to baseline. For the primary endpoint, median percentage decrease from baseline (CFB) to six months post-treatment in 1-hr pad weight for the Active group was 77.2% and 81.0% for the Sham group. However, the differences were no significant between the Active and Sham groups. The sham response consistently exceeded the 30 – 55% placebo response rates reported in the literature for SUI studies, suggesting that cryogen alone may have a therapeutic effect.

From a safety perspective, both Active and Sham treatments were safe and well tolerated. Only one adverse device event was noted, none of the 3 serious adverse events were identified as related to treatment and the percentage of patients with adverse events were comparable with the Viveve I study.

Three-Arm SUI Feasibility Study

In December 2019, the Company received approval of an Investigational Testing Application ("ITA") from the Canadian Ministry of Health and in January 2020 initiated a three-arm, three-month feasibility study to compare Viveve's CMRF treatment and a cryogen-only sham to an inert sham treatment for the improvement of SUI in women. Completion of subject enrollment in the study was reported in March 2020. Study subjects were randomized in a 1:1:1 ratio to the three arms and were assessed using the 1-hour Pad Weight Test, 3-day Voiding Diary, the 24-hour Pad Weight Test and I-QOL at five months post treatment. Due to patient, provider and medical facility health and safety concerns caused by the COVID-19 pandemic, the final subject follow-up visit was changed to 5 months from the initial 3-month design.

Final results were reported in August 2020, and showed the primary efficacy endpoint (i.e., change from baseline in the standardized 1-hour Pad Weight Test at five months post treatment) was positively achieved. The median change from baseline in the active CMRF treatment group (N=13) and the cryogen-only sham treatment group (N=12) was -9.5 grams and -6.8 grams respectively, as compared to -4.4 grams in the inert sham treatment group (N=11). The study also assessed several secondary endpoints but showed no differentiation between groups. No device-related safety issues were reported. The meaningful separation demonstrated between the CMRF treatment arm and the inert sham arm in the feasibility study is believed to help provide confidence in the potential to achieve positive separation between the two treatment arms in the ongoing U.S. pivotal PURSUIT trial.

PURSUIT – U.S. SUI Trial

The Company received FDA approval of its IDE application to conduct its U.S. pivotal, multicenter PURSUIT trial for improvement of SUI in women in July 2020, as well as FDA approval of requested amendments to the IDE protocol in December 2020. Initiation of the PURSUIT trial was announced by the Company on January 21, 2021 and completion of subject enrollment was reported on December 14, 2021. Topline results are anticipated at the end of 2022.

PURSUIT is a randomized, double-blinded, sham-controlled trial with an intended enrollment of approximately 390 female subjects with moderate SUI at up to 30 study sites in the U.S. Randomized in a 2:1 ratio for active and sham treatments, subjects in the active treatment arm (260 subjects) will receive CMRF treatment, while subjects in the control arm (130 subjects) will receive the Company's new inert sham treatment.

The primary efficacy endpoint of the PURSUIT trial is a comparison of the proportion of patients who experience greater than 50% reduction in urine leakage compared to baseline on the standardized 1-hour Pad Weight Test at 12 months post-treatment versus the new sham procedure. The study also includes several secondary endpoints, including: proportion of patients who experience greater than 50% reduction in urine leakage on the standardized 1-hour Pad Weight Test at three and six months post-treatment, percentage change from baseline in the 1-hour Pad Weight Test at three, six and 12 months, percent of subjects with no incontinence episodes at three, six and 12 months post treatment as assessed with the three-day bladder voiding diary, and change from baseline in the MESA Questionnaire (Medical, Epidemiologic and Social Aspects of Aging), Incontinence Quality of Life (I-QOL), Patient Global Impression of Improvement (PGI-1) Questionnaire, and International Consultation on Incontinence Modular Questionnaire-Urinary Incontinence Short Form (ICIQ-UI-SF) at three, six, and nine months post-treatment. Subject safety will be monitored throughout the study.

Clinical Studies – Vaginal Laxity and Female Sexual Function

United States Pilot Study

We conducted our first human study beginning in November 2008. The study was a single-arm study conducted in 24 female subjects, ages 25-44 years old, each of whom had experienced at least one full-term vaginal delivery. The study was designed to assess the safety and efficacy of the Viveve System for the treatment of vaginal laxity at three RF dosing levels. Each woman underwent a single Viveve treatment, three patients received 60 joules/cm2, three patients received 75 joules/cm2, and 18 patients received 90 joules/cm2. Patient outcomes were measured at baseline, one month, three months, six months, and 12 months using several validated patient-reported outcome measures, including a company-designed vaginal laxity/tightness questionnaire ("VSQ"), Female Sexual Function Index ("FSFI"), Female Sexual Distress Scale-Revised ("FSDS-R") and the Global Response Assessment.

Within one month after the Viveve treatment, patients reported a statistically significant improvement in vaginal laxity scores, sexual function and sexual satisfaction scores compared to baseline. These results continued throughout the 12-month follow-up period. Additionally, patients reported a statistically significant decrease at one month, and thereafter, in their personal distress scores from sexual activity.

The Viveve treatment also demonstrated a strong safety profile throughout the study. The treatment was well tolerated and there were no procedure-related adverse events or serious adverse events through the 12-month follow-up period.

Japan Pilot Study

Our second human clinical study began in March 2010. This study was an open-label study conducted in 30 female subjects, ages 21-55 years old, each of whom had experienced at least one full-term vaginal delivery and experiencing vaginal laxity. The study was designed to assess the safety and efficacy of the Viveve System for the treatment of vaginal laxity. Each woman was treated once with the Viveve System, using 90 joules/cm2 of RF energy as the therapeutic dose.

Patient reported outcomes were measured at baseline, one month, three months, six months, and 12 months using several validated patient-reported outcome measures, including VSQ, FSFI, FSDS-R and the Global Response Assessment.

Within one month after the Viveve procedure, patients reported a statistically significant improvement in vaginal laxity scores, sexual function and sexual satisfaction scores compared to baseline. These results continued throughout the 12-month follow-up period. Additionally, patients reported a statistically significant decrease at one month, and thereafter, in their personal distress scores from sexual activity.

The Viveve procedure continued to demonstrate a strong safety profile. The treatment was well tolerated and there were no procedure-related adverse events or serious adverse events through the 12-month follow-up period.

VIVEVE I Clinical Study

In the fourth quarter of 2014, we began the VIVEVE I clinical study (**VI**veve Treatment of the **V**aginal Introitus to **EV**aluate **E**ffectiveness), sometimes referred to in this report as the "OUS Clinical Trial," a randomized, blinded and sham-controlled trial designed to further demonstrate the efficacy and safety of the Viveve System versus a sham procedure for the treatment of vaginal laxity. Nine clinical sites in four countries (Canada, Italy, Spain and Japan) enrolled 174 patients, which included pre-menopausal females 18 years of age or older who experienced at least one full term vaginal delivery at least 12 months prior to enrollment date, randomized in a 2:1 ratio to either an active treatment group or sham-control group. Patients were followed for six months post-treatment to assess the primary effectiveness and safety endpoints of the study with data being collected at one, three and six-months. The study also included a prospective interim data analysis at the three-month endpoint of 50% of the patients enrolled. Patients randomized to the sham arm were offered the opportunity to receive a Viveve treatment once they had completed the six-month evaluation following the sham intervention.

The primary endpoint of the study was the proportion of subjects in the active arm as compared to the proportion of subjects in the sham arm reporting no vaginal laxity at six months post-intervention. "No vaginal laxity" was operationally defined as a score > 4 on the VSQ, a patient reported global assessment of vaginal laxity based on a 7-point scale. Additionally, the primary safety endpoint was the proportion of subjects in the active arm experiencing an adverse event ("AE") by six months post-treatment as compared to the proportion of the subjects in the sham arm experiencing an AE by six months post-intervention. Secondary endpoints included the adjusted change in mean score on the FSFI, FSDS-R and the Vaginal Laxity Inventory ("VALI"). The VALI was created specifically for the assessment of vaginal laxity by external medical experts.

In April 2016, we completed the VIVEVE I study and reported the following results:

At six months (n=155), the proportion of patients reporting "no vaginal laxity" in the active arm, as measured by the VSQ, was 41.7%, while the proportion of patients reporting "no vaginal laxity" in the sham arm on the VSQ was 19.2% (p=0.005). Moreover, the likelihood of having "no vaginal laxity" following treatment in the active arm was more than three times greater than for the sham arm (p=0.006). Further, nearly 80% of the subjects in the active arm experienced a positive change in VSQ score versus baseline.

At six months, for those patients who scored less than a 26.5 total score on the FSFI at baseline (n=103), the adjusted mean change from baseline score between the active arm and the sham arm was 3.2 (p=0.009). Moreover, for each of the six individual domains of the FSFI, subjects in the active group reported a greater increase in score than in the sham group. Change in scores from baseline for both the sexual arousal and orgasm domains were statistically significant and nearly 93% of subjects in the active arm experienced an increase in score versus baseline.

At six months, FSDS-R and VALI were also assessed as part of the secondary end-point analysis. While subjects in the active arm reported a greater increase in scores than the sham arm, the results for the FSDS-R and VALI were not statistically significant.

Safety for the study was assessed on the entire study population (n=174). Subjects reported the same level of unrelated (32.5% active versus 35.1% sham), related (11.1% active versus 12.3% sham) and serious (0.0% active versus 1.8% sham) adverse events in both the active and sham arm, further demonstrating that the Viveve treatment is well tolerated with no safety concerns.

VIVEVE II U.S. Sexual Function Trial

In 2020, we completed the VIVEVE II (**VI**veve treatment of the **V**aginal Introitus to **EV**aluate **E**ffectiveness) clinical study, which was a multicenter, randomized, double-blinded, sham-controlled study to evaluate the safety and efficacy of the Company's CMRF technology for the improvement of sexual function in women following vaginal childbirth. Topline results indicated that the study did not meet its primary endpoint of demonstrating a statistically significant improvement in the mean change from baseline in the total FSFI at 12 months. Although there was substantial improvement in the total FSFI score from baseline to the final 12-month follow-up in the active and sham groups indicating a significant treatment effect, there was not sufficient separation from the sham treatment group to achieve statistical significance.

The study included 220 subjects that successfully completed 12-month follow-up. Subjects were randomized in a 1:1 ratio for the active (N=114) and the sham (N=106) treatments at 17 clinical sites in the United States. Mean change in the total FSFI score at 12 months for the active group was 10.0 (12-month score of 27.9) and the mean change for the sham group was 9 (12-month score of 27.3), a difference of 0.6 (p=0.5). A total of 65.8% active and 63.2% sham achieved an FSFI > 26.5 at 12 months. There were no serious device-related adverse events reported. The treatment groups were well balanced, and the number of subjects lost to follow-up was as expected. No subjects dropped out due to an adverse event.

The Company completed its final study report in December 2020, and due to the trial's outcome, we do not currently intend to pursue a FSD or vaginal laxity label in the U.S. at this time.

Research and Development

We intend to focus on various research and development efforts, including but not limited to:

- conducting additional human clinical trials, in order to support marketing applications for additional indications in the U.S. and internationally, including but not limited to SUI and vulvovaginal atrophy;
- implementing cost improvement programs to further increase gross margins and our gross profit opportunity;
- designing new treatment tips and system enhancements to further optimize ease-of-use and reduce procedure times for patients and physicians; and
- continuing to enhance the security within the Viveve System to prevent counterfeiting and refurbishment.

We have formed strategic relationships with outside contractors for assistance on research and development projects, and we work closely with experts in the medical community to supplement our research and development resources. Research and development expenses for the years ended December 31, 2021 and 2020 were $9,665,000 and $5,125,000, respectively. In the future, we expect to pursue further research and development initiatives to improve and extend our technological capabilities and to foster an environment of innovation and quality.

Manufacturing

Our manufacturing strategy involves the combined utilization of contract manufacturers, approved suppliers and internal manufacturing resources and expertise. We outsource the manufacture of components, subassemblies and finished products that are produced to our specifications and shipped to our Englewood, Colorado facility for inspection, testing and distribution. Our internal manufacturing activities include the testing of Viveve treatment tips and handpieces, as well as the final integration and system testing of the Viveve System. Our finished products are stored at and distributed from our Englewood, Colorado facility or from our contract manufacturer's location in Watertown, South Dakota.

We have arrangements with our suppliers that allow us to adjust the delivery quantities of components, subassemblies and finished products, as well as delivery schedules, to match our changing requirements. The forecasts we use are based on historical trends, current utilization patterns and sales forecasts of future demand. Lead times for components, subassemblies and finished products may vary significantly depending on the size of the order, specific supplier requirements and current market demand for the components and subassemblies. Most of our suppliers have no contractual obligations to supply us with, and we are not contractually obligated to purchase from them, the components used in our devices.

Our first generation Viveve System which consists of a generator, handpiece and disposable treatment tip was designed and manufactured by Stellartech Research Corporation ("Stellartech"). Stellartech was the sole source supplier for this version of the Viveve System. We no longer manufacture generators, handpieces or disposable treatment tips at Stellartech. We continue to have technology licenses with Stellartech that are discussed in the Patents and Proprietary Technology section of this document.

Our second generation Viveve System consists of a generator and handpiece designed and manufactured by Spartronics Corporation ("Spartronics" formerly known as Sparton Medical Systems Colorado LLC), and a disposable treatment tip designed and manufactured by Cirtec Corporation ("Cirtec"). Both Spartronics and Cirtec are sole source suppliers for their respective components. We have a Professional Services Agreement with Spartronics that governs the design and development relationship and a Manufacturing and Supply Agreement that defines our manufacturing, shipping and servicing relationship. We manage our relationship with Cirtec with long range (12 month) forecasts and purchase orders. Since December 2020, Cirtec has been cleared to serve as a supplier for the first-generation treatment tips.

As of November 2021, Viveve has implemented basic service and repair capabilities in our Englewood, Colorado facility. This additional capability will reduce the cost and time to perform maintenance and repairs on second generation Viveve Systems.

In addition to our primary system suppliers, we also have critical suppliers at the component level. We obtain proprietary flexible electronic circuits for our treatment tips and the coolant valve for the handpiece from single suppliers (AllFlex and Lee Valve Co.), for which we attempt to mitigate risks through inventory management and either long term supply agreements or 12 to 18-month purchase orders. Other products and components come from single suppliers, but alternate suppliers have been identified and qualified for critical path components, and have been indentified and we believe can readily be qualified for other components. Our suppliers periodically complete reviews of electronic components for any that are near end of life. If any are found to be near end of life, we initiate a last time buy to purchase enough of the components to complete the anticipated builds that require the component. To date, shipments of finished products to our customers have not been significantly delayed due to material delays in obtaining any of our components, subassemblies or finished products.

We are required to manufacture our product in compliance with Title 21 of the Code of Federal Regulations Part 820 ("21 CFR 820") enacted by the FDA (known as the Quality System Regulation or QSR). 21 CFR 820 regulates the methods and documentation relating to the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our product. We maintain quality assurance and quality management certifications to enable us to market our product in the member states of the European Union, the European Free Trade Association and countries which have entered into Mutual Recognition Agreements with the European Union. These certifications include EN ISO 9001:2015 and CAN/CSA ISO 13485:2016. We are also required to maintain our product registration in a number of other foreign markets such as Canada.

We use small quantities of common cleaning products in our manufacturing operations, which are lawfully disposed of through a routine waste management program. Except for costs that may be incurred in the future in connection with environmental regulations requiring the phase out of R134a, a hydrofluorocarbon ("HFC") upon which our cooling module relies, we do not anticipate any material costs due to compliance with environmental laws or regulations. In 2007, the European Union enacted directives aimed at the automotive industry for the removal of HFC's from air conditioning. As a result of these directives, we anticipate that similar directives may be imposed on the medical device industry over the next decade. In anticipation of future restrictions, we have qualified a more environmentally friendly HFC (1234ZE) for use in our generators. We do not anticipate that we will have to incur costs in the near future to develop an alternative cooling module for our device which is not dependent on HFCs. If and when we are required to do so, and if we do not do so in a timely or cost-effective manner, the Viveve System may not be in compliance with environmental regulations, which could result in fines, civil penalties and the inability to sell our products in certain major international markets.

We generally offer a one-year warranty providing for the repair, rework or replacement (at the Company's option) of products that fail to perform within stated specifications. To the extent that any of our components have performance related or technical issues in the field, we typically replace those components as necessary. We also sell a small number of extended service agreements on certain products for the period subsequent to the normal one-year warranty provided with the original product sale. Warranties are assessed for proper revenue recognition. Most warranties are classified as assurance type warranties thereby allowing immediate recognition of revenue with accrual for estimated future warranty expenses. Revenue from sale of such extended service agreements was immaterial for the years ended December 31, 2021 and 2020.

Patents and Proprietary Technology

We rely on patent, copyright, trade secret and trademark laws and confidentiality agreements to protect our technology and the Viveve System. We have an exclusive license (with a field of use limitation) to one issued U.S. patent and own 8 issued U.S. patents directed to our technology and the Viveve System. Additionally, as of March 11, 2022, we have 7 pending U.S. patent applications, 74 issued foreign patents, including patents that may have lapsed, and 6 pending foreign patent applications, some of which foreign applications may preserve an opportunity to pursue patent rights in multiple countries.

U.S. Patents		Foreign Patents	
Issued	**Pending**	**Issued**	**Pending**
8	**7**	**74**	**6**

All our employees and consultants are required to execute confidentiality agreements in connection with their employment and consulting relationships with us. We also require them to agree to disclose and assign to us all inventions conceived or made in connection with the employment or consulting relationship. We cannot provide any assurance that our employees and consultants will abide by the confidentiality or invention assignment terms of their agreements. All our manufacturing suppliers are required to execute confidentiality agreements and contracts for our approved suppliers include confidentiality provisions. Despite measures taken to protect our intellectual property, unauthorized parties may copy aspects of our product or obtain and use information that we regard as proprietary.

"Viveve," is a registered trademark in the U.S. and several foreign countries. As of the date of this report, we have various foreign registrations protecting the various marks in numerous countries outside of the U.S. We may file for additional trademarks to strengthen our trademark rights, but we cannot be certain that our trademark applications will issue or that our trademarks will be enforceable.

Edward Knowlton Licensed Patents

On February 10, 2006, Viveve, Inc. entered into an Intellectual Property Assignment and License Agreement with Edward W. Knowlton ("Knowlton"), as amended on May 22, 2006 and July 20, 2007 (collectively, the "Knowlton IP Agreement"), pursuant to which Knowlton granted to Viveve, Inc. an exclusive, royalty-free and perpetual worldwide sublicense to certain intellectual property and technology licensed to Knowlton from a third party, including rights to several patents and patent applications owned by Thermage, Inc. outside the field of contraction, remodeling and ablation of the skin through and including (but not beyond) the subcutaneous fat layer below the skin (collectively, the "Knowlton Licensed IP"). The sublicense under the Knowlton Licensed IP is fully-paid, transferable, sublicensable and permits us to make, have made, use, sell, offer for sale and import any product or technology solely for use in the field of transmucosal treatment of the vagina or vulva (the "Field") and to practice any process, method, or procedure solely in the Field. The Knowlton IP Agreement also assigns to us all technology and related intellectual property rights owned by Knowlton for the development and commercialization of devices, including any improvements, in the Field (the "Knowlton Assigned IP"). We are obligated to file and reasonably prosecute any patent applications that include a description of the Knowlton Assigned IP as prior art and maintain all patents included in the Knowlton Assigned IP, at our expense. In consideration of the sale, assignment, transfer, release and conveyance and other obligations of Knowlton under the Knowlton IP Agreement, Viveve, Inc. issued 20,000 shares of our common stock to Knowlton and agreed to engage the consulting services of Knowlton.

Also, on February 10, 2006, Viveve, Inc. entered into a Consulting Agreement with Knowlton ("Knowlton Consulting Agreement"), pursuant to which Knowlton assigned all rights to any inventions and intellectual property developed during the course of providing consulting services in the Field during the term of the agreement. Unless earlier terminated pursuant to the provisions described therein, the term of the Knowlton Consulting Agreement continued until the earlier to occur of (i) the date that is six months after the closing of an initial public offering of Viveve, Inc.'s stock; or (ii) the acquisition by a third party of all or substantially all of the business or assets of Viveve, Inc., whether by asset or stock acquisition, merger, consolidation or otherwise. The agreement could be renewed only upon the mutual written agreement of the parties prior to its expiration. The Knowlton Consulting Agreement expired by its terms on September 23, 2014. The assignment of the intellectual property developed during the term of the Knowlton Consulting Agreement survives termination.

Agreement with Stellartech Research Corporation

On June 12, 2006, Viveve, Inc. entered into the Stellartech Agreement, as amended and restated on October 4, 2007, with Stellartech for an initial term of three years in connection with the performance of development and manufacturing services by Stellartech and the license of certain technology and intellectual property rights to each party. Under the Stellartech Agreement, we agreed to purchase 300 units of generators manufactured by Stellartech. As of December 31, 2021, the Company has purchased 855 units. In conjunction with the Agreement, Stellartech purchased 38 shares of Viveve, Inc.'s common stock. Under the Stellartech Agreement, we paid Stellartech $205,000 and $1,051,000 for goods and services during the years ended December 31, 2021 and 2020, respectively. In addition, Stellartech granted to us a non-exclusive, nontransferable, worldwide, royalty-free license in the Field (defined above in the discussions titled "Edward Knowlton Licensed Patents") to use Stellartech's technology incorporated into deliverables or products developed, manufactured or sold by Stellartech to us pursuant to the Stellartech Agreement (the "Stellartech Products") to use, sell, offer for sale, import and distribute the Stellartech Products within the Field, including the use of software object code incorporated into the Stellartech Products. The Stellartech technology consists of know-how applicable to the manufacturing and repair of the Viveve System, including any other intellectual property which Stellartech developed or acquired separate and apart from the Stellartech Agreement and all related derivative works. In addition, once we purchase a minimum commitment of 300 units of the RF generator component (the "Minimum Commitment") and the Stellartech Agreement expires, Stellartech is to grant us a nonexclusive, nontransferable, worldwide, royalty-free, fully-paid license to use the Stellartech technology incorporated into the Stellartech Products to make and have made Stellartech Products in the Field.

Stellartech also granted (i) an exclusive (even as to Stellartech), nontransferable, worldwide, royalty-free license within the Field under those certain intellectual property rights licensed to Stellartech pursuant to a development and supply agreement between Stellartech and Thermage, dated October 1, 1997 (the "Thermage Technology"), to use any elements of the Thermage Technology incorporated into the Stellartech Products, solely for the use, sale, offer for sale, importation and distribution within the Field; (ii) upon our satisfaction of the Minimum Commitment and the expiration of the Stellartech Agreement, an exclusive, nontransferable, worldwide, royalty-free, fully-paid license within the Field under Stellartech's license rights in the Thermage Technology to use any elements of the Thermage Technology which are incorporated into the Stellartech Products to make and have made Stellartech Products in the Field; and (iii) the exclusive right within the Field to prosecute infringers of the portion of Stellartech's Thermage Technology rights exclusively licensed to us. Our license rights in Thermage Technology also include the use of software object code for Thermage Technology used in the Stellartech Products. As of the date of this report, the Stellartech Agreement has expired by its terms, however, the parties still continue to operate under the terms of the agreement. In addition, we have met the Minimum Commitment requirement, and therefore we are permitted to use the Stellartech technology with any other manufacturer. However, we no longer manufacture generators, handpieces or disposable treatment tips at Stellartech.

In March 2012, Viveve, Inc. entered into a Quality and Regulatory Agreement with Stellartech, pursuant to which the parties clarified their respective quality and regulatory responsibilities under the Stellartech Agreement. The Quality and Regulatory Agreement provides that we will serve as the legal manufacturer for all Stellartech Products developed and sold to us thereunder and that we are obligated to maintain all relevant quality assurance and regulatory processes and requirements required by any regulatory authority and to comply with the processes and requirements set forth in the schedule of responsibilities provided in the agreement.

Government Regulation

The Viveve System is a medical device subject to extensive and rigorous regulation by international regulatory bodies as well as the FDA. These regulations govern the following activities that we perform, or that are performed on our behalf, to ensure that medical products exported internationally or distributed domestically are safe and effective for their intended uses:

- product design, development and manufacture;
- product safety, testing, labeling and storage;
- record keeping procedures;
- product marketing, sales and distribution;
- pre-clinical and clinical experiences; and
- post-marketing surveillance, complaint handling, medical device reporting, reporting of deaths, serious injuries or device malfunctions and repair or recall of products.

In addition to the regulatory clearances/approvals already received in connection with the sale of the Viveve System in the foreign jurisdictions described below and the clearance of the Viveve System for coagulation and hemostasis already received in the United States, we will continue to seek regulatory clearances/approvals for the sale of our product in many other countries around the world upon the completion of the PURSUIT trial.

International

Sales of our product outside the U.S. are subject to foreign regulatory requirements that vary widely from country to country. In addition, exports of medical devices from the U.S. are regulated by the FDA. Complying with international regulatory requirements can be an expensive and time-consuming process and approval is not certain. The time required to obtain registrations or approvals, as required by other countries, may be longer than that required for FDA clearance, and requirements for such registrations or approvals may significantly differ from FDA requirements. We may be unable to obtain or maintain registrations or approvals in other countries. We may also incur significant costs in attempting to obtain and in maintaining foreign regulatory approvals. If we experience delays in receiving necessary registrations or approvals to market our product outside the U.S., or if we fail to receive those registrations or approvals, we may be unable to market our product or enhancements in international markets effectively, or at all, which could have a material adverse effect on our business and growth strategy.

An entity that seeks to export a medical device that is legally marketed in the U.S. (e.g., an FDA cleared Class II medical device) may do so without prior FDA notification or approval.

Because the Viveve System has been cleared by the FDA for "use in general surgical procedures for electrocoagulation and hemostasis," Viveve does not obtain approval from the FDA prior to exporting the device to foreign countries. Additionally, products exported from the U.S. and those with certain levels of U.S. content are subject to the U.S. export control and sanctions laws and regulations, which may restrict proposed transactions to certain countries, end-users and end-uses. Certain products may be controlled for export and reexport and may require licensing or other authorization from the U.S. government prior to engaging in the export or reexport transaction. Changes to these regulations may impact the ability to pursue potential opportunities to export and reexport the products overseas.

Moreover, entities legally exporting products from the U.S. are often asked by foreign customers or foreign governments to supply an export certificate issued by the FDA to accompany a device. An export certificate is a document prepared by the FDA containing information about a product's regulatory or marketing status in the U.S. We have requested the issuance of export certificates to allow exports into many countries around the world, and the FDA has issued those export certificates to us. Accordingly, we provide export certificates to many of our foreign customers.

Currently, the Viveve System is cleared for marketing in 50 countries throughout the world under the following indications for use:

Indication for Use:	**No. of Countries:**
General surgical procedures for electrocoagulation and hemostasis	4 (including the U.S.)
General surgical procedures for electrocoagulation and hemostasis of vaginal tissue and the treatment of vaginal laxity	29
For treatment of vaginal laxity	5
For treatment of the vaginal introitus, after vaginal childbirth, to improve sexual function	9
General surgical procedures for electrocoagulation and hemostasis as well as for the treatment of vaginal laxity	1
For vaginal rejuvenation	1
For treatment of vaginal laxity and to improve mild urinary incontinence and sexual function	1

Outside the U.S., we market and sell through an extensive network of distribution partners. In the U.S., the Viveve System is indicated for use in general surgical procedures for electrocoagulation and hemostasis and we market and sell primarily through a direct sales force.

United States

FDA's Premarket Clearance and Approval Requirements

Unless an exemption applies, any medical device we wish to commercially distribute in the U.S. will require premarket clearance or approval from the FDA. The FDA classifies medical devices into one of three classes. The classification system is risk based, with devices deemed to pose the lowest risk being Class I, and devices posing the most risk being Class III. Most Class I devices are exempt from the requirement to obtain FDA premarket clearance or approval. For most Class II devices (and a small number of Class I devices), a company must submit to the FDA a premarket notification (known as 510(k) submission) requesting clearance to commercially distribute the device. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) devices, are placed in Class III, requiring either FDA premarket approval via a Premarket Approval ("PMA") application or a De Novo petition requesting that the FDA reclassify the device into a lower class (i.e., Class II or Class I). The FDA has issued regulations identifying the Class into which different types of devices fall and identifying whether the device type is exempt from the 510(k) process or if a 510(k) is needed.

510(k) Clearance Pathway

When a 510(k) clearance is required, we must submit a premarket notification to the FDA demonstrating that our device is substantially equivalent to a previously cleared and legally marketed device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of PMAs (known as a predicate device). The FDA strives to make a determination that the device is substantially equivalent (SE) (*i.e.,* clear the device) or not substantially equivalent ("NSE") within 90 days of submission of the notification. As a practical matter, clearance often takes significantly longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. If the FDA determines that the device is not substantially equivalent to a previously cleared device, the FDA will issue an NSE letter and place the device into Class III. If the device is placed into Class III automatically based only on the lack of a predicate device and the device is lower risk, a De Novo submission may be submitted petitioning the FDA to reclassify the device into Class II or Class I, as appropriate.

Any modification to a 510(k)-cleared device that would constitute a major change in its intended use, or any change that could significantly affect the safety or effectiveness of the device, requires a new 510(k) clearance and may even, in some circumstances, require a PMA, if the change raises complex or novel scientific issues or the product has a new intended use. The FDA requires every manufacturer to make the determination regarding the need for a new 510(k) submission in the first instance, but the FDA may review any manufacturer's decision. If the FDA were to disagree with a manufacturer's determination that changes did not require a new 510(k), the FDA could require the manufacturer to cease marketing and distribution and/or recall the modified device until 510(k) clearance or PMA clearance is obtained and the manufacturer could be subject to significant regulatory fines or penalties.

In December 2008, a predecessor company to Viveve received 510(k) clearance for a previous version of the Viveve System. Since then, we have made design modifications to the original 510(k)-cleared device. In March 2015, we submitted a Special 510(k) to the FDA seeking clearance for the updated Viveve System to take into account the design modifications to the original 510(k)-cleared device, which included improved user interface capabilities and enhanced manufacturability. In October 2016, we received clearance from the FDA to sell the updated device for use in general surgical procedures for electrocoagulation and hemostasis. In 2017 we received clearance to add an 8 cm treatment tip to the product family. The second generation Viveve 2.0 System was cleared by FDA under 510(k) on June 12, 2019 with no change to the intended use or indication from the original first generation Viveve System.

De Novo Process

If FDA has not issued a regulation classifying a particular type of device as Class I, and if there is no known predicate for a device (*i.e.,* a legally marketed device that is not subject to premarket approval with comparable indications for use and technological characteristics), the device is automatically Class III, regardless of the risk the device poses. If a device is automatically/statutorily classified into Class III in this manner, a company can petition FDA to reclassify the category of devices into Class II or Class I via a process known as "Evaluation of Automatic Class III Designation," which is typically referred to as the "*de novo* process." The direct de novo process allows a company to request that a new product classification be established without the company first submitting a 510(k) notification for the device. The reclassification petition should include a risk-benefit analysis demonstrating that, when subject to general controls or general and special controls, the probable benefits to health from use of the device outweigh any probable injury or illness from such use. The submitter also must describe why general controls or general and special controls are adequate to provide reasonable assurance of safety and effectiveness and for proposed Class II devices, provide proposed special controls. If a product is classified as Class II through the de novo review process, then that device may serve as a predicate device for subsequent 510(k) premarket notifications, including by competitors.

We intend to seek FDA authorization to market the Viveve System for the treatment of vaginal tissue to improve SUI by utilizing the direct de novo process. However, we cannot predict when or if FDA approval of such a de novo classification request will be obtained. In addition, if FDA fails to grant our de novo classification request, we will be required to seek FDA premarket approval (via the more stringent PMA process). Delays in receipt of FDA clearance or approval (or failure to receive FDA clearance or approval) for expanded indication could reduce our sales, profitability and future growth prospects.

Clinical Trials

Clinical trials are almost always required to support an FDA de novo classification and are sometimes required for 510(k) clearance. With respect to the Viveve System, the FDA has asked us to conduct a clinical study under an IDE, to support a future product submission (e.g., a 510(k) or a de novo petition) for the sexual function indication. In the U.S., clinical trials on medical devices generally require submission of an application for an IDE to the FDA if the device is a "significant risk" device. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specific number of patients. Clinical trials for significant risk devices may not begin until the IDE application is approved by both the FDA and the appropriate institutional review boards ("IRBs") at the clinical trial sites. Our clinical trials must be conducted under the oversight of an IRB at the relevant clinical trial sites and in accordance with FDA regulations, including, but not limited to, those relating to good clinical practices. We are also required to obtain the patients' informed consent, in compliance with both FDA requirements and state and federal privacy regulations. We, the FDA, or the IRB at each site at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the benefits. Even if a trial is completed, the results of clinical testing may not demonstrate the safety and efficacy of the device, may be equivocal or may otherwise not be sufficient to obtain clearance or approval of the product. Similarly, in Europe and other regions, clinical study protocols must be approved by the local ethics committee and in some cases, including studies with high-risk devices, by the Ministry of Health in the applicable country.

The Company received FDA approval of its IDE application to conduct its U.S. pivotal, multicenter PURSUIT trial for improvement of SUI in women in July 2020, as well as FDA approval of requested amendments to the IDE protocol in December 2020. Initiation of the PURSUIT trial was announced by the Company on January 21, 2021 and completion of subject enrollment was reported on December 14, 2021. Topline results are anticipated at the end of 2022. PURSUIT is a randomized, double-blinded, sham-controlled trial with an intended enrollment of approximately 390 female subjects with moderate SUI at up to 30 study sites in the U.S. Randomized in a 2:1 ratio for active and sham treatments, subjects in the active treatment arm (260 subjects) will receive CMRF treatment, while subjects in the control arm (130 subjects) will receive the Company's new inert sham treatment.

The primary efficacy endpoint of the PURSUIT trial is a comparison of the proportion of patients who experience greater than 50% reduction in urine leakage compared to baseline on the standardized 1-hour Pad Weight Test at 12 months post-treatment versus the new sham procedure.

In 2020, we completed the VIVEVE II (**VI**veve treatment of the **V**aginal Introitus to **EV**aluate **E**ffectiveness) clinical study, which was a multicenter, randomized, double-blinded, sham-controlled study to evaluate the safety and efficacy of the company's CMRF technology for the improvement of sexual function in women following vaginal childbirth. Topline results indicated that the study did not meet its primary endpoint of demonstrating a statistically significant improvement in the mean change from baseline in the total FSFI at 12 months.

The Company completed its final study report in December 2020, and due to the trial's outcome, we do not currently intend to pursue a female sexual dysfunction or vaginal laxity label in the U.S. at this time.

Continuing Regulation

After a device is placed on the market, numerous regulatory requirements continue to apply. These include:

- product listing and establishment registration, which helps facilitate regulatory inspections and other regulatory action;
- submission of Unique Device Identifiers ("UDIs") or the equivalent to regulatory authorities;
- Good Manufacturing Practice ("GMP") and Quality System Regulations ("QSRs"), which require those who design, manufacture, package, label, store, install, and service devices to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of these processes;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or "off-label" uses to both physician and consumers;
- regulations governing our interactions with healthcare practitioners;
- U.S. export control and sanctions regulations associated with the export and reexport of the products;
- complaint handling and adverse event reporting requirements, such as the Medical Device Reporting ("MDR"), regulations in the U.S., which require that a manufacturer report to the FDA if its 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;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- regulations pertaining to recalls and notices of corrections or removals; and
- any other post-market requirements that the FDA or foreign regulatory bodies might impose as part of the device approval or clearance process.

The FDA has broad post-market and regulatory enforcement powers. We and our third-party manufacturers are subject to announced and unannounced inspections by the FDA and foreign governments or designated representatives to determine compliance with the quality system requirements and other regulations. In the past, our Sunnyvale, California facility (now closed) was inspected, and observations were noted, including an April 2012 California Department of Public Health ("CDPH") inspection that cited deficiencies related to signature authority of inspection documentation, incomplete corrective action responses, and labeling indicating that our product contained no latex without proper objective evidence. The FDA and CDRH have accepted our responses to these observations, and we believe that we and our third-party manufacturer are in substantial compliance with the QSR.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, states, or foreign governments, which may include any of the following actions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall, market withdrawal or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for 510(k) clearance, de novo reclassification, or premarket approval of new products or new intended uses;
- refusing to grant export certificates for our product;
- reclassifying a device that previously received a 510(k) clearance or withdrawing premarket approvals that are already granted; and
- criminal prosecution.

If any of these events were to occur, it could have a material adverse effect on our business.

We are also subject to a wide range of federal, state and local laws and regulations, including those related to distribution of medical devices, the environment, health and safety, fraud and abuse, land use, advertising, and quality assurance. We believe that compliance with these laws and regulations as currently in effect will not have a material adverse effect on our capital expenditures, earnings and competitive and financial position.

Competition

The medical device industry is characterized by intense competition and rapid innovation. While we believe that our solutions are unique and offer a more effective treatment options from that which is on the market currently, we also believe that the market for the treatment of SUI remains a tremendous, under-developed opportunity. Therefore, competition is expected to increase, particularly as the market becomes further developed with additional treatment options. Aside from Kegel exercises and invasive surgical procedures, such as LVR, fillers, bulking agents, slings, and mesh there are many companies that may be developing or that have developed energy-based technologies for vaginal use as well as others developing modalities for the treatment of SUI. Further, the overall size and attractiveness of the market may compel larger companies focused in the Urology, OB/GYN, aesthetic or women's health markets, and with much greater capital and other resources, to pursue development of or acquire technologies that may address these indications. Potential energy-based competitors include, but are not limited to, Inmode, Venus Concepts, BTL, Cynosure, Fotona, Syneron, Thermi Aesthetics, Cutera, and others, some of whom have more established products and customer relationships than we have.

Human Capital Resources

As of March 11, 2022, we had 47 full-time employees and we retain the services of several qualified consultants. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel. None of our employees is represented by a labor union, and we believe that our employee relations are good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Continuance into Delaware

On July 22, 2015, at our 2015 Annual and Special Meeting of Stockholders, our stockholders approved a special resolution authorizing a continuance of the Company (the "Continuance") into the State of Delaware under the Delaware General Corporation Law (the "DGCL") and the adoption of charter documents that comply with the DGCL in connection therewith, effective as of a date to be determined by the Board, in its sole discretion, no more than 12 months from the date of the meeting. On May 9, 2016, the Company filed the necessary Application for Authorization to Continue into Another Jurisdiction and Statutory Declaration with the Yukon registrar. On May 10, 2016, the Company filed a Certificate of Conversion and Certificate of Incorporation with the Secretary of State of the State of Delaware to move its domicile from the Yukon Territory to Delaware.

The Continuance did not involve any change in our business, properties, corporate headquarters or management. The officers of the Company immediately prior to the Continuance continued to serve as our officers following the Continuance, and the current members of the Board of Directors continued to serve as the members of the Board following the Continuance. There was no change in our operations, assets, liabilities or obligations as a result of the Continuance. Other than the approval of our stockholders and the filings with the Yukon Registrar of Corporations and the Secretary of State of Delaware, there were no federal or state regulatory requirements that we were required to comply with or approvals that we were required to obtain in connection with the Continuance.

Upon the effectiveness of the Continuance, each outstanding share of our common stock continued to be an outstanding share of our common stock as incorporated in Delaware and each outstanding option, right or warrant to acquire shares of our common stock continued to be an option, right or warrant to acquire an equal number of shares of common stock under the same terms and conditions. Upon effectiveness of the Continuance, we were governed by the Certificate of Incorporation filed with the Secretary of State of Delaware and by bylaws prepared in accordance with the DGCL, which were approved by our stockholders at the 2015 Annual and Special Meeting. Following the Continuance, we were governed by the DGCL instead of the Yukon Business Corporation Act.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Prospective investors should carefully consider the risks described below, together with all of the other information included or referred to in this Annual Report on Form 10-K, before purchasing shares of our common stock. There are numerous and varied risks that may prevent us from achieving our goals. If any of these risks actually occurs, our business, financial condition or results of operations may be materially adversely affected. In such case, the trading price of our common stock could decline and investors in our common stock could lose all or part of their investment.

Risks Related to Regulatory Matters

We or our distributors may be unable to obtain or maintain international regulatory clearances or approvals for our current or future products, or our distributors may be unable to obtain necessary qualifications, which could harm our business.

Sales of the Viveve System internationally are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the U.S. Complying with international regulatory requirements can be an expensive and time-consuming process, and marketing approval or clearance is not certain. The time required to obtain clearances or approvals, if required by other countries, may be longer than that required for FDA clearance or approvals, and requirements for such clearances or approvals may significantly differ from FDA requirements. We may rely on third-party distributors to obtain regulatory clearances and approvals required in other countries, and these distributors may be unable to obtain or maintain such clearances or approvals. Our distributors may also incur significant costs in attempting to obtain and in maintaining foreign regulatory approvals or clearances, which could increase the difficulty of attracting and retaining qualified distributors. If our distributors experience delays in receiving necessary qualifications, clearances or approvals to market our products outside the U.S., or if they fail to receive those qualifications, clearances or approvals, we may be unable to market our products or enhancements in international markets effectively, or at all.

Foreign governmental authorities that regulate the manufacture and sale of medical devices have become increasingly stringent and, to the extent we market and sell our products outside of the U.S., we may be subject to rigorous international regulation in the future. In these circumstances, we would be required to rely on our foreign independent distributors to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our product in foreign countries.

If we fail to maintain regulatory approvals and clearances, or if we are unable to obtain, or experience significant delays in obtaining, FDA clearances or approvals for the Viveve System or any future products we may develop or acquire, including product enhancements, our business and results of operations could be adversely affected.

The Viveve System is, and any future products we may acquire or develop will be, subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In particular, the FDA permits commercial distribution of a new medical device only after the device has received clearance under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the "FDCA") (unless the device is exempt from the 510(k) requirements), has been classified pursuant to a de novo classification request, or is the subject of an approved premarket approval application ("PMA"). The FDA will permit marketing of a lower risk medical device through the 510(k) process if the manufacturer demonstrates that the new product is substantially equivalent to a previously cleared and legally marketed device or a device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for the submission of PMA, referred to as a predicate device. Devices deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or devices not deemed substantially equivalent to a previously cleared device, require the approval of a PMA, unless a de novo submission is appropriate. The PMA process is more costly, lengthy and uncertain than the 510(k) clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA a reasonable assurance of the safety and efficacy of the device for its intended use.

If the FDA has not issued a regulation classifying a particular type of device as Class I, and if there is no known predicate for a device and/or its indication, the device is automatically Class III, regardless of the risk the device poses. If a device is automatically/statutorily classified into Class III in this manner, a company can petition FDA to reclassify the category of devices into Class II or Class I via a process known as "Evaluation of Automatic Class III Designation," which is typically referred to as the de novo process. The direct de novo process allows a company to request that a new product classification be established without the company first submitting a 510(k) notification for the device. Our plan is to seek FDA authorization to market the Viveve System for the treatment of SUI by utilizing the direct de novo process. However, we cannot predict when or if such de novo classification will be obtained. If FDA fails to reclassify the device pursuant to the de novo process, we will be required to seek FDA premarket approval (via the more stringent PMA process) for the Viveve System, which will be extremely costly and very time-consuming, often taking as long as several years. Delays in receipt of FDA clearance or approval or failure to receive FDA clearance or approval could adversely affect our business, results of operations and future growth prospects.

Our marketed products may be used by physicians for indications that are not cleared by the FDA. If the FDA finds that we marketed our products in a manner that promoted off-label use, we may be subject to civil or criminal penalties.

Under the FDCA and other laws, we are prohibited from promoting our products for off-label uses. This means that we may not make claims about the use of any of our marketed medical device products outside of their approved or cleared indications, and that our website, advertising promotional materials and training methods may not promote or encourage unapproved uses. The Viveve System is currently indicated for use, and being marketed for use, in general surgical procedures for electrocoagulation and hemostasis in the United States. The device has not been cleared or approved for use for SUI, vaginal laxity, to improve sexual function, or for vaginal rejuvenation in the United States. Therefore, we may not provide information to physicians or patients that promote the Viveve System for SUI, vaginal laxity, to improve sexual function, or for vaginal rejuvenation. Note, however, that the FDA does not generally restrict physicians from prescribing products for off-label uses (or using products in an off-label manner) in their practice of medicine. We are also permitted to engage in non-promotional scientific exchange in response to unsolicited questions by physicians about our products. Should the FDA determine that our activities constitute the promotion of off-label uses, the FDA could bring action to prevent us from distributing our devices for the off-label use and could impose fines and penalties on us and our executives. In addition, failure to follow FDA rules and guidelines relating to promotion and advertising can result in, among other things, the FDA's refusal to approve or clear other products in our pipeline such as clearance or approval to treat SUI, the withdrawal of an approved product from the market, product recalls, fines, disgorgement of profits, operating restrictions, injunctions or criminal prosecutions. Any of these adverse regulatory actions could result in substantial costs and could significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business.

If the Office of Inspector General within the Department of Health and Human Services, the U.S. Department of Justice ("DOJ"), or another federal or state agency determines that we have promoted off-label use of our products, we may be subject to various penalties, including civil or criminal penalties, and the off-label use of our products may result in injuries that lead to product liability suits, which could be costly to our business.

In addition to the FDA restrictions on our marketed products, other state and federal healthcare laws have been applied by DOJ and state attorneys general to restrict certain marketing practices in the medical device industry. While physicians may generally prescribe and administer products for off-label uses, if we engage in off-label promotion, we may be subject to civil or criminal penalties including significant fines and could be prohibited from participating in government healthcare programs such as Medicaid and Medicare. Even if we are successful in resolving such matters without incurring penalties, responding to investigations or prosecutions will likely result in substantial costs and could significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results, financial condition and ability to finance our operations. In addition, the off-label use of our products may increase the risk of injury to patients, and, in turn, the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention and result in substantial damage awards against us.

If we modify an FDA-cleared device, we may need to seek and obtain new clearances, which, if not granted, would prevent the sale of our modified product or require us to redesign the product.

Any modifications to an FDA-cleared device that could significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a premarket approval. We may not be able to obtain additional 510(k) clearances or premarket approvals for new products or for modifications to, or additional indications for, our existing product in a timely fashion, or at all. Delays in obtaining future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn could harm our revenue and potential future profitability. We have made modifications to our device in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified device, which could harm our operating results and require us to redesign the product.

Clinical trials necessary to support a 510(k) notification, de novo petition or PMA application will be expensive and will require the enrollment of large numbers of patients. Suitable patients may be difficult to identify and recruit. Delays or failures in our clinical trials may prevent us from commercializing our current product or any modified or new products and will adversely affect our business, operating results and prospects.

The FDA has asked us to conduct a clinical study, pursuant to the agency's IDE regulations, to support a future product submission for the Viveve System. Initiating and completing clinical trials necessary to support a 510(k) notification, de novo petition, or PMA application for the Viveve System, as well as other possible future product candidates, is time consuming and expensive and the outcome is uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials.

Conducting successful clinical studies will require the enrollment of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the desirability of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators and support staff, the proximity of patients to clinical sites, the ability of patients to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our product or if they determine that the treatments received under the trial protocols are not desirable or involve unacceptable risk or discomfort.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance or approval. Further, the FDA may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval or clearance and attempted commercialization of our product or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in clinical trials, the FDA may not consider our data adequate to demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

Finally, even if our clinical trials receive IDE approval from FDA, this does not guarantee that FDA will find our clinical trial data sufficient to support an application for FDA clearance or approval. For example, after submitting an application to FDA, the agency may raise questions during the review process regarding the clinical trial data, including those related to clinical trial design considerations. If FDA has questions regarding the clinical study design or clinical trial results, FDA may issue an Additional Information ("AI") request to Viveve as part of the review process. If FDA issues an AI request, FDA's review clock is stopped until Viveve provides information responsive to FDA's requests. An AI request may delay the process for obtaining FDA clearance or approval. Further, if FDA ultimately does not find Viveve's clinical trial design or clinical data to be sufficient to support the safety and efficacy of the Viveve System for proposed indication, there is a risk that FDA may not grant clearance or approval of our application.

If the third parties on which we rely to conduct our clinical trials and to assist us with preclinical development do not perform as contractually required or expected, we may not be able to obtain the regulatory clearance or approval which would permit us to commercialize our products.

We do not have the ability to independently conduct the preclinical studies and clinical trials for our product, therefore we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct the studies and trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory clearance or approval for, or be able to successfully commercialize, our product on a timely basis, if at all. In that event, our business, operating results and prospects may be adversely affected.

The results of our clinical trials such as our PURSUIT trial may not support our proposed product claims or may result in the discovery of adverse side effects. As our business prospects depend substantially on the success of our PURSUIT trial, any of these events with respect to our PURSUIT trial could have a material adverse impact on our business and affect our ability to continue as a going concern.

Even if our clinical trials, including the PURSUIT trial, are completed as planned, it cannot be certain that the results of the clinical trials will support our proposed claims for the Viveve System, that the FDA or foreign authorities will agree with our conclusions regarding them or that even if our product receives regulatory approval or clearance, that it will not later result in adverse side effects that limit or prevent its use. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and preclinical studies. The clinical trial process may fail to demonstrate that our product is safe and effective for the proposed indicated uses. Any delay of our clinical trials or failure by the FDA or other foreign authorities to accept our product claims will delay, or even prevent, our ability to commercialize our product and generate revenue.

For example, in April 2020, we reported the topline results of our VIVEVE II clinical trial consisting of a multicenter, randomized, double-blinded, sham-controlled study to evaluate the safety and efficacy of the company's proprietary, CMRF technology for the improvement of sexual function in women following vaginal childbirth. The data showed that the VIVEVE II study did not meet its primary endpoint of demonstrating a statistically significant improvement in the mean change from baseline in total FSFI score at 12 months.

We continue to advance our clinical development program in SUI in the United States under our PURSUIT clinical trial. The top-line results of this clinical trial are anticipated at the end of 2022. If the data is not positive, our clinical trial may not support our proposed product claims for FDA clearance or approval of the Viveve System for the treatment of SUI. In such a case, we will be unable to promote the Viveve System in the United States for the SUI indication, our business prospects will be substantially affected and we may need to reevaluate our ability to continue as a going concern and/or seek strategic alternatives.

Even if our product is approved by regulatory authorities, if we or our suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our product, the product could be subject to restrictions or withdrawal from the market.

Any product for which we obtain clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies, such as the Food and Drug Branch of the California Department of Public Health ("CDPH"). In particular, we and our suppliers are required to comply with the FDA's QSR, and International Standards Organization ("ISO") standards for the manufacture of our product and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain clearance or approval. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic inspections. In the past, our Sunnyvale, California facility has been inspected by the FDA and CDPH, and observations were noted. The FDA and CDPH have accepted our responses to these observations, and we believe that we are in substantial compliance with the QSR. Any future failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions and unanticipated expenditures to address or defend such actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications for repair, replacement or refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance, de novo classification, or premarket approval of new products or modified products;
- operating restrictions;
- reclassifying a device that previously received a 510(k) clearance or withdrawing a PMA approval that was previously granted;
- refusal to grant export approval for our product; or
- criminal prosecution.

If any of these actions were to occur, it would harm our reputation and cause our product sales to suffer and may prevent us from generating revenue. Furthermore, our third-party manufacturers may not currently be, or may not continue to be, in compliance with all applicable regulatory requirements which could result in a failure to produce our product on a timely basis and in the required quantities, if at all.

Even if regulatory clearance or approval of a product is granted for the Viveve System or future products, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

In addition, we may be required by the FDA or other foreign regulatory bodies to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as the QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

The Viveve System may also be subject to state regulations which are, in many instances, in flux. Changes in state regulations may impede sales. For example, federal regulations may allow the device to be sold to, or on the order of, "licensed practitioners," as determined on a state-by-state basis. As a result, in some states, non-physicians may legally purchase and operate our device. However, a state could change its regulations at any time, disallowing sales to particular types of end users. We cannot predict the impact or effect of future legislation or regulations at the federal or state levels.

If we or our third-party manufacturers fail to comply with the FDAs QSR, our business would suffer.

We and our third-party manufacturers are required to demonstrate and maintain compliance with the FDA's QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our product. The FDA enforces the QSR through periodic unannounced inspections. We anticipate that in the future we will be subject to such inspections. Our failure, or the failure of our third-party manufacturers, to take satisfactory corrective action in response to an adverse QSR inspection could result in enforcement actions, including a public warning letter, a shutdown of our manufacturing operations, a recall of our product, civil or criminal penalties or other sanctions, which would cause our reputation, sales and business to suffer.

If our product causes or contributes to a death or a serious injury, or malfunctions in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA's medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would be likely to cause or contribute to death or serious injury if the malfunction of the device were to recur. If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving the Viveve System or future products 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 mounting a defense to a legal action, if one were to be brought, would require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

The Viveve System may, in the future, be subject to product corrections, removals, or recalls that could harm our reputation, business and financial results.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious, adverse health consequences or death. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. A recall of our product would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. In the future, we may initiate one or more voluntary correction or removal actions involving our product that we determine do not require notification to the FDA. If the FDA disagrees with our determinations, the FDA could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the corrections, removals, or recalls when they were conducted.

Federal and state regulatory reforms may adversely affect our ability to sell our product profitably.

From time to time, legislation is drafted and introduced in the U.S. Congress that could significantly change the statutory provisions governing the clearance or approval, manufacture and marketing of a medical device. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our product. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations will be changed, and what the impact of such changes, if any, may be.

For example, in August 2010, the FDA issued its preliminary recommendations on reform of the 510(k) pre-market notification process for medical devices. On January 19, 2011, the FDA announced its "Plan of Action" for implementing these recommendations. The Plan of Action included 25 action items, most of which have now been implemented by the agency. In August 2016, the FDA released its proposals for reforming long-standing procedures and requirements related to modifications to medical devices already on the market. In December 2016, Congress passed the 21st Century Cures Act, which makes multiple changes to FDA's rules for medical devices as well as for clinical trials, and Congress (passed the Medical Device User Fee reauthorization package in 2017.

The FDA or Congress may implement other reforms in the future. Future reforms could have the effect of making it more difficult and expensive for us to obtain FDA clearance or approval. Such changes may also be made by legislators or regulators in the foreign jurisdictions in which we do business and could similarly affect our operations and profitability in those markets.

In addition, a state could change its statutes or regulations at any time, disallowing sales to particular types of end users or placing restrictions on certain chemicals, such as those used in our cryogen. We cannot predict the impact or effect of future legislation or regulations at the federal or state levels, or in any foreign jurisdiction in which we do business.

Failure to comply with the U.S. Foreign Corrupt Practices Act and similar laws associated withour activities outside the U.S. could subject us to penalties and other adverse consequences.

A significant portion of our revenue is and will be from jurisdictions outside of the U.S. We are subject to the U.S. Foreign Corrupt Practices Act (the "FCPA") which generally prohibits U.S. companies and their intermediaries from making payments to foreign officials for the purpose of directing, obtaining or keeping business, and requires companies to maintain reasonable books and records and a system of internal accounting controls. The FCPA applies to companies and individuals alike, including company directors, officers, employees and agents. Under the FCPA, U.S. companies may be held liable for the corrupt actions taken by employees, strategic or local partners or other representatives. In addition, the government may seek to rely on a theory of successor liability and hold us responsible for FCPA violations committed by companies or associated with assets which we acquire. In recent years, the medical device and pharmaceutical industries have been a focus of the U.S. government's FCPA enforcement priorities, and settlements often include very significant payments potentially consisting of millions of dollars. Other countries have similar laws to which we may be subject, including the United Kingdom Bribery Act.

In many foreign countries where we operate, particularly in countries with developing economies, it may be a local custom for businesses to engage in practices that are prohibited by the FCPA or other similar laws and regulations. In contrast, we have implemented a company policy requiring our employees and consultants to comply with the FCPA and similar laws. At the present time, we have not conducted formal FCPA compliance training for our foreign distributors and partners, but we are in the process of devising a training schedule for certain of our employees, agents and partners. Nevertheless, there can be no assurance that our employees, partners and agents, as well as those companies to which we outsource certain of our business operations, will not take actions in violation of the FCPA or our policies for which we may be ultimately held responsible. As a result of our anticipated growth, our development of infrastructure designed to identify FCPA matters and monitor compliance is at an early stage. If we or our intermediaries fail to comply with the requirements of the FCPA or similar legislation, governmental authorities in the U.S. and elsewhere could seek to impose civil and/or criminal fines and penalties which could have a material adverse effect on our reputation, business, operating results and financial conditions. We may also face collateral consequences, such as debarment and the loss of our export privileges.

Viveve's relationships with customers and healthcare providers and professionals may be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, as well as comparable state and foreign laws, which could expose Viveve to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers and physicians play a primary role in the recommendation and prescription of any medical product, including the Viveve System marketed by the Company. Viveve's future arrangements with customers, healthcare providers and other medical professionals could expose Viveve to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which Viveve markets, sells and distributes its medical device products. There are various federal and state healthcare laws and regulations that impose restrictions that may apply to Viveve, and there may also be comparable foreign laws and regulations that similarly could apply to the Company.

The federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward 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 federally funded healthcare programs. This statute has been broadly interpreted to apply to manufacturer arrangements with prescribers and purchasers, among others. There are similar laws at the state level in the U.S., and several other countries, including the United Kingdom, have enacted similar anti-kickback, fraud and abuse, and healthcare laws and regulations.

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HIPAA also imposes criminal liability for 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.

The federal Physician Sunshine Act requirements under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, referred to together as the Affordable Care Act, require manufacturers of drugs, devices, biologics and medical supplies for which payment is available under title XVIII of the Social Security Act [Medicare] or under a State plan under title XIX [Medicaid] or XXI [SCHIP] of the Social Security Act (or a waiver of such a plan) to report to the Department of Health and Human Services information related to payments and other transfers of value made to or at the request of covered recipients, such as physicians and teaching hospitals, and physician ownership and investment interests in such manufacturers. Payments made to physicians and research institutions for clinical trials are included within the scope of this federal disclosure law.

Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by nongovernmental third-party payors, including private insurers. Some state laws also require pharmaceutical and medical device companies to comply with the relevant industry's voluntary compliance guidelines, in addition to requiring manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. There may also be comparable foreign laws and regulations that could impact Viveve's business and operations.

If Viveve's operations are found to be in violation of any of these laws or any other governmental regulations that may apply to it, the Company may be subject to significant civil, criminal and administrative penalties, damages, or fines. Moreover, if any of the physicians or other providers or entities with whom Viveve expects to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, or potentially to other sanctions in foreign jurisdictions.

Risks Related to Our Business

We are dependent upon the success of the Viveve System, which has a limited commercial history. If the device fails to gain or loses market acceptance, our business will suffer.

In 2012, we began marketing the Viveve System (RF generator, handpiece and single-use treatment tips) and other ancillary consumables, in Canada, Hong Kong and Japan. Since then, we have expanded our market to a total of 50 countries, including the United States. Our continued success depends on our ability to significantly penetrate current or new markets. If demand for the Viveve System and Viveve treatment does not expand in new markets or does not increase in existing markets as we anticipate, or if demand declines, our business, financial condition and results of operations will be harmed.

We compete against companies that have more established products, longer operating histories and greater resources, which may prevent us from achieving significant market penetration or increased operating results.

The medical device and aesthetics markets are highly competitive and dynamic and are marked by rapid and substantial technological development and product innovations. Demand for the Viveve System could be diminished by equivalent or superior products and technologies developed by competitors. Specifically, Viveve competes against other offerings in these markets, including laser and other light-based medical devices, pharmaceutical and consumer products, surgical procedures and exercise therapies.

Competing in these markets could result in price-cutting, reduced profit margins and loss of market share, any of which would harm our business, financial condition and results of operations. Our ability to compete effectively depends upon our ability to distinguish our company, the Viveve System, and the Viveve treatment from our competitors and their products, on such factors as:

- safety and effectiveness;
- product pricing;
- success of our marketing initiatives;
- compelling clinical data;
- intellectual property protection;
- quality of customer support; and
- development of successful distribution channels, both domestically and internationally.

Some of our competitors have more established products and customer relationships than we have, which could inhibit our market penetration efforts. For example, we may encounter situations where, due to pre-existing relationships, potential customers decide to purchase additional products from our competitors. Potential customers may need to recoup the cost of expensive products that they have already purchased to perform general surgical procedures for electrocoagulation and hemostasis, LVR surgery or vaginoplasty and thus may decide not to purchase, or to delay the purchase of, the Viveve System. If we are unable to achieve continued market penetration, we will be unable to compete effectively, and our business will be harmed.

In addition, potential competitors could have significantly greater financial, research and development, manufacturing, and sales and marketing resources than we have and could utilize their greater resources to acquire or develop new technologies or products that could effectively compete with our existing product. Given the relatively few competitors currently in the market, any such action could exacerbate existing competitive pressures, which could harm our business.

We have limited data regarding the efficacy of the Viveve procedure. If future data supporting additional indications is not positive or consistent with our prior experience, rates of physician adoption will likely be harmed.

Current reported studies of Viveve's CMRF technology have investigated improvement in vaginal laxity, sexual function and SUI, where all patients enrolled in the trial received the same treatment without comparison to a control group. Clinical studies designed in a randomized, blinded and controlled fashion (e.g., assessing the efficacy of a product or therapy versus a placebo or sham group) represent the gold-standard in clinical trial design. A sham-controlled treatment or procedure refers to a procedure performed as a control and that is similar to the treatment or procedure under investigation without the key therapeutic element being investigated. Future clinical studies, which may be required to drive physician adoption or support regulatory clearance or approval, will likely require randomized, blinded and controlled trial designs. Since 2014, we conducted several randomized, blinded and sham-controlled clinical trials in Europe, Canada and the U.S. designed to demonstrate the efficacy of the Viveve procedure versus a sham-controlled procedure for the treatment of vaginal laxity and sexual function. In 2019, we reported clinical results for a randomized, double-blind, sham-controlled study conducted in Canada evaluating patients suffering from mild-to-moderate SUI. Statistical significance was not achieved on the primary endpoint of mean change from baseline on the one-hour Pad Weight Test at six months post-treatment compared to the control group, nor was statistical significance achieved for the exploratory endpoints. In April 2020, we reported the topline results of our VIVEVE II clinical trial consisting of a multicenter, randomized, double-blinded, sham-controlled study to evaluate the safety and efficacy of the company's proprietary, CMRF technology for the improvement of sexual function in women following vaginal childbirth. The data showed that the VIVEVE II study did not meet its primary endpoint of demonstrating a statistically significant improvement in the mean change from baseline in total FSFI score at 12 months. In July 2020, the Company received FDA approval of its IDE application to conduct its U.S. pivotal, multicenter PURSUIT trial for improvement of SUI in women, as well as FDA approval of requested amendments to the IDE protocol in December 2020. PURSUIT is a randomized, double-blinded, sham-controlled trial with an intended enrollment of approximately 390 subjects at up to 30 study sites in the U.S.

Additionally, we have not conducted any head-to-head clinical studies that compare results from treatment with the Viveve System to surgery or treatment with other therapies. Without head-to-head studies against competing alternative treatments, which we have no current plans to conduct, potential customers may not find clinical studies of our technology sufficiently compelling to purchase the Viveve System. If we decide to pursue additional studies in the future, such studies could be expensive and time consuming, and the data collected may not produce favorable or compelling results. If the results of such studies do not meet physicians' expectations, the Viveve procedure may not become widely adopted, physicians may recommend alternative treatments for their patients, and our business may be harmed.

We currently have clearance to market the Viveve System in the U.S. for use in general surgical procedures for electrocoagulation and hemostasis but not for vaginal laxity, sexual function, or SUI. If we want to sell our device and single-use treatment tips in the U.S. for the treatment of vaginal laxity, sexual function, or SUI, we will need to obtain additional FDA clearance or approval, which may not be granted.

Developing and promoting our CMRF technology in additional countries for additional indications, including the U.S., is a key element of our future growth strategy. We currently do not have FDA clearance or approval to market the Viveve System in the U.S. for the treatment of vaginal laxity, sexual function, or SUI. We intend to seek clearance or approval for SUI from the FDA to expand our marketing efforts and have engaged with the FDA to help improve our likelihood of success. However, because the topline results from our VIVEVE II clinical trial did not meet the primary endpoint of demonstrating a statistically significant improvement in the mean change from baseline compared to sham treatment in total FSFI at 12 months, we no longer intend to pursue a sexual function or vaginal laxity label in the U.S. We cannot predict whether we will receive clearance or approval for SUI. The FDA has required us to conduct clinical trials to support regulatory clearance or approval, which trials are time-consuming and expensive, and may produce results that do not result in clearance or approval of our FDA marketing application. In the event that we do not obtain FDA clearance or approval of the Viveve System for the treatment of SUI, we will be unable to promote it in the U.S. for that indication, and the ability to grow our revenue may be adversely affected.

Our business is not currently profitable, and we may not be able to achieve profitability even if we are able to generate significant revenue.

As of December 31, 2021, we have incurred losses since inception of approximately $241.9 million. In 2021 and 2020, we incurred losses of $22.0 million and $21.9 million, respectively. Even though our revenue may increase, we expect to incur significant additional losses while we grow and expand our business. We cannot predict if and when we will achieve profitability. Our failure to achieve and sustain profitability could negatively impact the market price of our common stock and may require us to seek additional financing for our business. There are no assurances that we will be able to obtain any additional financing or that any such financing will be on terms that are favorable to us.

If there is not sufficient consumer demand for the procedures performed with our products, demand for our products could decline, which would adversely affect our operating results.

The medical device and aesthetic markets in which we operate are particularly vulnerable to economic trends. The procedures performed using the Viveve System are elective procedures that are not currently reimbursable through government or private health insurance. The cost of these elective procedures must be borne by the patient. As a result, the decision to undergo a procedure that uses our products may be influenced by the cost.

Consumer demand, and therefore our business, is sensitive to a number of factors that affect consumer spending, including political and macroeconomic conditions, health of credit markets, disposable consumer income levels, consumer debt levels, interest rates, consumer confidence and other factors. If there is not sufficient consumer demand for the procedures performed with our products, practitioner demand for our products would decline, and our business would suffer.

It is difficult to forecast future performance, which may cause our financial results to fluctuate unpredictably.

Our limited operating history makes it difficult to predict future performance. Additionally, the demand for the Viveve System may vary from quarter to quarter. A number of factors, over which we have limited or no control, may contribute to fluctuations in our financial results, such as:

- delays in receipt of anticipated purchase orders;
- performance of our independent distributors;
- positive or negative media coverage of the Viveve treatment or products of our competitors;
- our ability to obtain further regulatory clearances or approvals;
- delays in, or failure of, product and component deliveries by our subcontractors and suppliers;
- customer response to the introduction of new product offerings; and
- fluctuations in foreign currency.

Our limited operating history has limited our ability to determine an appropriate sales price for our products.

Our historical operating performance has limited our ability to determine the proper sales or lease prices for the Viveve System and the single-use treatment tips. Establishing appropriate pricing for our capital equipment and components has been challenging because there have not existed directly comparable competitive products. We may experience similar pricing challenges in the future as we enter new markets or introduce new products, which could have an unanticipated negative impact on our financial performance.

If there is not sufficient patient demand for our treatments, practitioner demand for the Viveve System could drop, resulting in lower revenue and unfavorable operating results.

All procedures performed using the Viveve System are elective procedures, the cost of which must be borne by the patient and are not currently reimbursable through government or private health insurance. The decision to undergo a Viveve treatment is thus driven by consumer demand, which may be influenced by a number of factors, such as:

- whether our marketing efforts directed toward increasing consumer awareness of the Viveve treatment, for which we have limited experience and resources and indications, are successful;
- the extent to which physicians recommend the Viveve treatment to their patients;
- the cost, safety and effectiveness of the Viveve procedure versus alternative treatments;
- general consumer sentiment about the benefits and risks of such procedures; and
- consumer confidence, which may be impacted by economic and political conditions.

Our financial performance could be materially harmed in the event that any of the above factors discourage patients from seeking the Viveve treatment.

The failure of the Viveve treatment to meet patient expectations or the occurrence of unpleasant side effects from a Viveve treatment could impair our financial performance.

Our future success depends upon patients having a positive experience with the Viveve treatment in order to increase physician demand for our products, as a result of positive feedback and word-of-mouth referrals. Patients may be dissatisfied if their expectations of the procedure, side effects and results, among other things, are not met. Despite what we believe to be the safety of the Viveve treatment, patients may experience undesirable side-effects such as temporary swelling or reddening of the treated tissue. Experiencing any of these side effects could discourage a patient from completing a Viveve treatment or discourage a patient from having future procedures or referring the Viveve procedure to others. In order to generate referral business, we believe that patients must be satisfied with the effectiveness of the Viveve treatment. Results obtained from the procedure are subjective and may be subtle. The Viveve treatment may produce results that may not meet patients' expectations. If patients are not satisfied with the procedure or feel that it is too expensive for the results obtained, our reputation and future sales will suffer.

Our success depends on growing physician adoption of the Viveve System and continued use of treatment tips.

Some of our target physician customers already own self-pay device products. Our ability to grow our business and convince physicians to purchase or rent a Viveve System depends on the success of our sales and marketing efforts. Our business model involves both an equipment rental or purchase and continued purchases by our customers of single-use treatment tips and ancillary consumables. This may be a novel business model for many potential customers who may be used to competing products that are exclusively capital equipment, such as many laser-based systems. We must be able to demonstrate that the cost of the Viveve System and the revenue that the physician can derive from performing procedures using it are compelling when compared to the cost and revenue associated with alternative products or therapies. When marketing to plastic surgeons, we must also, in some cases, overcome a bias against non-invasive procedures. If we are unable to increase physician adoption of our device and use of the treatment tips, our financial performance will be adversely affected.

Our revenue may suffer due to our transition of U.S. sales from a capital equipment sales model to a recurring revenue rental model.

In June 2019, in addition to a capital sales model, we began a new recurring revenue rental model for the U.S. sales of the Viveve System. The new U.S. commercial sales model is intended to lower up-front costs for customers and thus lower hurdles to adoption, increase placement rates, and improve profitability by reducing selling time per unit. The recurring revenue rental model has resulted in reduced revenue per unit placed, but it is projected to be offset by higher unit placements and improved revenue performance in the long term. While we believe physician adoption rates may be higher in the future utilizing this new recurring revenue rental model, the unit placements in the long term may not be sufficient to offset the reduced revenue per unit placed.

To successfully market and sell the Viveve System internationally, we must address many issues with which we have limited experience.

Sales outside the U.S. accounted for 42%, 54% and 44% of our revenue during the year ended December 31, 2021, 2020 and 2019, respectively. International sales are subject to a number of risks, including:

- difficulties in staffing and managing international operations;
- difficulties in penetrating markets in which our competitors' products may be more established;
- reduced or no protection for intellectual property rights in some countries;
- export restrictions, trade regulations and foreign tax laws;
- fluctuating foreign currency exchange rates;
- foreign certification and regulatory clearance or approval requirements;
- difficulties in developing effective marketing campaigns for unfamiliar, foreign countries;
- customs clearance and shipping delays;
- compliance with anti-bribery laws such as U.S. Foreign Corrupt Practices Act and its foreign counterparts;
- political and economic instability and global conflicts such as the war in Ukraine; and
- preference for locally produced products.

If one or more of these risks were realized, it could require us to dedicate significant resources to remedy the situation, and even if we are able to find a solution, our revenues may still decline.

If we violate the U.S. Foreign Corrupt Practices Act or applicable anti-bribery laws in other countries our business could be harmed.

We earn a significant portion of our total revenues from international sales. As a result, we are subject to the U.S. Foreign Corrupt Practices Act ("FCPA"), which generally prohibits U.S. companies and their intermediaries from making corrupt payments to foreign officials for the purpose of obtaining or keeping business or otherwise obtaining favorable treatment and requires companies to maintain appropriate record-keeping and internal accounting practices to accurately reflect the transactions of the Company. The FCPA applies to companies, individual directors, officers, employees and agents. Under the FCPA, U.S. companies may be held liable for actions taken by agents or local partners or representatives. In addition, the government may seek to hold us liable for successor liability FCPA violations committed by companies which we acquire. We are also subject to the U.K. Bribery Act and may be subject to certain anti-corruption laws of other countries in which we do business. If we or our intermediaries fail to comply with the requirements of the FCPA or the anti-corruption laws of other countries, governmental authorities in the U.S. or other countries could seek to impose civil and/or criminal penalties, which could have a material adverse effect on our business, results of operations, financial conditions and cash flows.

We depend on distributors to market and sell the Viveve System internationally. If they are not successful, our marketing and sales efforts will be harmed.

We currently depend exclusively on third-party distributors to sell and service the Viveve System internationally and to train our international customers, and if these distributors terminate their relationships with us or under-perform, we may be unable to maintain or increase our level of international revenue. We will also need to engage additional international distributors to grow our business and expand the territories in which we sell the Viveve System. Distributors may not commit the necessary resources to market, sell and service our device to the level of our expectations. If current or future distributors do not perform adequately, or if we are unable to engage distributors in particular geographic areas, our revenue from international operations will be adversely affected.

The ongoing pandemic of COVID-19 and the future outbreak of other highly infectious or contagious diseases, could seriously harm our research and development, manufacturing and commercialization efforts, increase our costs and expenses and have a material adverse effect on our business, financial condition and results of operations.

Broad-based business or economic disruptions caused by the COVID-19 pandemic could adversely affect our ongoing or planned research and development activities, our manufacturing operations and our commercialization efforts. COVID-19 originated in Wuhan, China, and has since spread globally. To date, the COVID-19 pandemic has caused significant disruptions to the U.S. and global economies and has contributed to significant volatility and negative pressure in financial markets. The global impact of the outbreak is continually evolving and, as additional cases of the virus are identified, many countries, including the U.S., have reacted by instituting quarantines, restrictions on travel and mandatory closures of businesses. Certain states and cities, including where we or the third parties with whom we engage operate, have also reacted by instituting quarantines, restrictions on travel, “shelter in place” rules, restrictions on types of business that may continue to operate, and/or restrictions on the types of projects that may continue. However, these government policies and directives are subject to change and many companies, including ours, maintain a work-from-home policy for office employees and sales representatives, and have implemented policies for our researchers and manufacturing workers designed to provide for a safe environment while maintaining progress on important laboratory research and commercial product supply.

The extent to which the COVID-19 pandemic, or the future outbreak of any other highly infectious or contagious diseases, impacts our product development, manufacturing capabilities, sales and marketing operations, future nonclinical studies and clinical trials and commercialization efforts will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the scope, severity and duration of such pandemic, the actions taken to contain the pandemic or mitigate its impact, and the direct and indirect economic effects of the pandemic and containment measures, among others. The rapid development and fluidity of this situation precludes any prediction as to the full adverse impact of the COVID-19 pandemic. Nevertheless, the COVID-19 pandemic may adversely affect our business, financial condition and results of operations, and it may have the effect of heightening many of the risks described herein, including the below.

● We are currently evaluating the Viveve System and Viveve treatment in a clinical trial. However, the COVID-19 pandemic may have an impact on the timing of conducting these trials, including initiation, opening of clinical trial sites and enrollment of patients and patient follow up. We are aware that some trial sponsors have encountered and may continue to encounter challenges in conducting clinical activities during the ongoing COVID-19 pandemic, including site closures and restrictions on site visits, and we may similarly experience such challenges in our current or future clinical trials.

● We currently rely on third parties to, among other things, manufacture and repair key elements of the Viveve System. If any such third parties in our supply chain for materials are adversely impacted by restrictions resulting from the COVID-19 pandemic, including staffing shortages, production slowdowns and disruptions in delivery systems, our supply chain may be disrupted.

● Health regulatory agencies globally may experience disruptions in their operations as a result of the COVID-19 pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or be under-resourced to continue to monitor our clinical trials and, as a result, review, inspection, and other timelines may be materially delayed. For example, in April 2020, the FDA stated that its New Drug Program was continuing to meet program user fee performance goals, but due to many agency staff working on COVID-19 activities, it was possible that the FDA would not be able to sustain that level of performance indefinitely. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of the Viveve System.

● The trading prices for our common stock and other medical device companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the COVID-19 pandemic could materially and adversely affect our business and the value of our common stock.

As a result of the COVID-19 pandemic, our commercial activities, manufacturing operations and clinical development progress, data and timelines, and general business operations, could be delayed or materially harmed, and our business, prospects, financial condition, and results of operations would suffer as a result.

We currently have limited sales and marketing resources or experience and failure to build and manage a sales force or to market and distribute the Viveve System effectively could have a material adverse effect on our business.

Our sales and marketing organization is structured so that we rely on a direct sales force to sell the Viveve System in the United States. However, in the first quarter of 2019, we reorganized and reduced the number of direct sales reps selling our products. Additionally, in response to the COVID-19 crisis, the Company implemented a series of significant cost-cutting actions in the second quarter of 2020, including the furlough of 31 full-time employees throughout the entire organization, designed to reduce expenses and reposition resources to support the Company's current customers and its pivotal clinical development program for our CMRF technology in the treatment of SUI. These corporate actions included an approximate two-thirds reduction of the direct sales organization. We believe our reorganization in 2019 and the operational changes implemented in 2020 related to the COVID-19 crisis will help reduce our operating expenses. We do not currently anticipate making any significant changes to our international distribution network.

Our reorganization and other operational changes may not have the desired effect of reducing our operating expenses and may result in a disruption to our business, adversely affect our sales and marketing organization and make it more difficult to retain qualified personnel. In addition, our management may divert a disproportionate amount of time away from its day-to-day activities to devoting a substantial amount of time to managing the reorganization which may increase our expenses. Our future financial performance and ability to compete effectively will depend, in part, on our ability to effectively manage the reorganization and future growth. To that end, we must be able to:

- hire qualified individuals as needed;
- provide adequate training for the effective sale of our device; and
- retain and motivate sales employees.

We may not be able to accomplish these tasks, which could harm our financial results and have a material adverse effect on our business.

Competition among providers of devices for the medical device and aesthetics markets is characterized by rapid innovation, and we must continuously innovate technology and develop new products, or our revenue may decline.

While we attempt to protect our technology through patents and other intellectual property rights, there are few barriers to entry that would prevent new entrants or existing competitors from developing products that compete directly with our products. For example, while we believe our monopolar RF technology maintains a strong intellectual property position, there may be other companies employing competing technologies which claim to have a similar clinical effect to our technology. Additionally, there are others who may market monopolar RF technology for competing purposes in a direct challenge to our intellectual property position. As we continue to create market demand for a non-surgical, non-invasive way to treat vaginal laxity, sexual function, and SUI competitors may enter the market with other products making similar or superior claims. We expect that any competitive advantage we may enjoy from our current and future innovations may diminish over time, as companies successfully respond to our innovations, or create their own. Consequently, we believe that we will have to continuously innovate and improve our technology or develop new products to compete successfully. If we are unable to develop new products or innovate successfully, the Viveve System could become obsolete and our revenue will decline as our customers purchase competing products.

We outsource the manufacturing and repair of key elements of the Viveve System to manufacturing partners.

We outsource the manufacture and repair of our Viveve System to contract manufacturing partners including Stellartech and Spartronics. If any of their operations are interrupted or if they are unable to meet our delivery requirements due to capacity limitations or other constraints, we may be limited in our ability to fulfill new customer orders or to repair equipment at current customer sites, and we may be required to seek new manufacturing partners in the future. Our manufacturing partners have limited manufacturing capacity, are themselves dependent upon third-party suppliers and are dependent on trained technical labor to effectively repair components making up the Viveve System. In addition, they are medical device manufacturers and are required to demonstrate and maintain compliance with the FDA's Quality System Regulation ("QSR"). If they or any future manufacturing partner fails to comply with the FDA's QSR, their manufacturing and repair operations could be halted. In addition, both the availability of our product to support the fulfillment of new customer orders as well as our ability to repair those products installed at current customer sites would be impaired. Viveve and its manufacturing partners operate under manufacturing and supply agreements, however our manufacturing operations could be adversely impacted if we are unable to enforce their performance under these agreements, or enter into new agreements with them, or a potential new manufacturer, if necessary, upon favorable terms or at all.

We outsource the manufacture and repair of our single-use treatment tips to manufacturing partners including Cirtec. If their operations are interrupted or if they are unable to meet our delivery requirements due to capacity limitations or other constraints, we may be limited in our ability to fulfill new customer orders or to repair equipment at current customer sites, and we may be required to seek new manufacturing partners in the future. Our manufacturing partners have limited manufacturing capacity, are themselves dependent upon third-party suppliers and are dependent on trained technical labor to effectively manufacture the single-use treatment tips. In addition, they are medical device manufacturers and are required to demonstrate and maintain compliance with the FDA's QSR. If they or any future manufacturing partner fails to comply with the FDA's QSR, their manufacturing and repair operations could be halted. In addition, both the availability of our product to support the fulfillment of new customer orders as well as our ability to repair those products installed at current customer sites would be impaired. Viveve and its manufacturing partners operate under long term forecasts and purchase orders, however our single-use treatment tip manufacturing operations could be adversely impacted if we are unable to enforce their performance or enter into a new agreement with a potential new manufacturer, if necessary, upon favorable terms or at all.

Our manufacturing operations and those of our key manufacturing subcontractors are dependent upon third-party suppliers, making us vulnerable to supply shortages and price fluctuations, which could harm our business.

The single source supply of each generation of the Viveve System from Stellartech and Spartronics could not be replaced without significant effort and delay in production. Also, several other components and materials that comprise our device are currently manufactured by a single supplier or a limited number of suppliers. In many of these cases, we have not yet qualified alternate suppliers and we rely upon purchase orders, rather than long-term supply agreements. A supply interruption or an increase in demand beyond our current suppliers' capabilities could harm our ability to manufacture the Viveve System until new sources of supply are identified and qualified. Our reliance on these suppliers subjects us to a number of risks that could harm our business, including:

- interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's variation in a component;
- a lack of long-term supply arrangements for key components with our suppliers;
- inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;
- difficulty locating and qualifying alternative suppliers for our components in a timely manner;
- production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications;
- delay in delivery due to suppliers prioritizing other customer orders over our orders;
- damage to our brand reputation caused by defective components produced by our suppliers;
- increased cost of our warranty program due to product repair or replacement based upon defects in components produced by our suppliers; and
- fluctuation in delivery by our suppliers due to changes in demand from us or from their other customers.

Any interruption in the supply of components or materials, or our inability to obtain substitute components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers, which would have an adverse effect on our business.

If, in the future, we decide to perform additional manufacturing functions internally that we currently outsource, our business could be harmed by our limited manufacturing experience and related capabilities.

In the future, for financial or operational purposes, we may elect to perform component or system manufacturing functions internally. Our limited experience with manufacturing processes could lead to difficulties in producing sufficient quantities of manufactured items that meet our quality standards and that comply with applicable regulatory requirements in a timely and cost-effective manner. In addition, if we experience these types of manufacturing difficulties, it may be expensive and time consuming to engage a new or previous subcontractor or supplier to fulfill our replacement manufacturing needs. The occurrence of any of these events could harm our business.

Our business could be harmed by our limited repair experience and related capabilities because we have implemented certain internal repair functions and we may, in the future, decide to perform additional internal repair functions internally that we currently outsource.

Viveve has implemented in-house repair services for common field failure modes for the Viveve system. This is limited to component or board level replacement where the replacement components are supplied by the original manufacturer. This reduces the risk of being able to obtain repair service on a timely basis but adds additional risk related to training and competence of our internal personnel to perform such training.

If the Viveve System malfunctions or if we discover a manufacturing defect that could lead to a malfunction, we may have to initiate a product recall or replace components, which could adversely impact our business.

Problems in our manufacturing processes, or those of our manufacturers or subcontractors, which lead to an actual or possible malfunction in any of the components of our device, may require us to recall product from customers or replace components and could disrupt our operations. Our results of operations, reputation and market acceptance of our products could be harmed if we encounter difficulties in manufacturing that result in a more significant issue or significant patient injury and delays our ability to fill customer orders.

We may not be able to develop an alternative cooling module that will be in compliance with changing environmental regulations in a timely or cost-effective manner.

Our cooling module relies upon a HFC called R134a, to protect the outer layer of the tissue from over-heating while the device delivers RF energy to the submucosal tissue. New environmental regulations phasing out HFCs over the next decade have been adopted or are under consideration in a number of countries. Since 2007, European Union directives aimed at the automotive industry require the phase-out of HFCs and prohibit the introduction of new products incorporating HFCs and it is currently anticipated that such directives may impact the medical device industry. In anticipation of future restrictions, we have qualified a more environmentally friendly HFC (1234ZE) for use in our generators. We do not anticipate that we will have to incur costs in the near future to develop an alternative cooling module for our device which is not dependent on HFCs. However, the impending restrictions on HFCs have reduced their current availability, as suppliers have less of an incentive to expand production capacity or maintain existing capacity. This change in supply could expose us to supply shortages or increased prices for R134a and 1234ZE, which could impair our ability to manufacture our device and adversely affect our results or operations. HFCs may also be classified by some countries as a hazardous substance and, therefore, subject to significant shipping surcharges that may negatively impact profit margins.

As a result, if we are unable to develop an alternative cooling module for our device which is not dependent on HFCs in a timely or cost-effective manner, the Viveve System may not be in compliance with environmental regulations, which could result in fines, civil penalties and the inability to sell our products in certain major international markets.

We rely on a limited number of suppliers and third-party manufacturers, and if they are unable or unwilling to continue to work with us, our business could be materially adversely affected.

We rely on a limited number of suppliers and third-party manufacturers. Our reliance on them increases our risk since in the event of an interruption from one or more of them, we may not be able to develop alternative resources without incurring additional costs or delays.

We forecast sales to determine requirements for components and materials used in Viveve procedures, and if our forecasts are incorrect, we may experience delays in shipments or increased inventory costs.

We keep limited materials, components and finished product on hand. To manage our manufacturing operations with our suppliers, we forecast anticipated product orders and material requirements to predict our inventory needs up to twelve months in advance and enter into purchase orders on the basis of these requirements. Our limited historical experience may not provide us with enough data to accurately predict future demand. If our business expands, our demand for components and materials would increase and our suppliers may be unable to meet our demand. If we overestimate our component and material requirements, we will have excess inventory, which would increase our expenses. If we underestimate our component and material requirements, we may have inadequate inventory, which could interrupt, delay or prevent delivery of the Viveve System to our customers. Any of these occurrences would negatively affect our financial performance and the level of satisfaction that our customers have with our business.

Even though we require training for users of the Viveve System, there exists a potential for misuse, which could harm our reputation and our business.

Outside of the U.S., our independent distributors sell in many jurisdictions that do not require specific qualifications or training for purchasers or operators of the Viveve System. We do not supervise the procedures performed with the device, nor can we be assured that direct physician supervision of our equipment occurs according to our recommendations. We and our distributors require purchasers of our device to undergo an initial training session as a condition of purchase, but do not require ongoing training. In addition, we prohibit the sale of the device to companies that rent it to third parties, but we cannot prevent an otherwise qualified physician from contracting with a rental company in violation of his or her purchase agreement with us.

In the U.S., current federal regulations allow us to sell our device to "licensed practitioners." The definition of "licensed practitioners" varies from state to state. As a result, the Viveve System may be operated by licensed practitioners with varying levels of training, and in many states by non-physicians, including physician assistants, registered nurses and nurse practitioners. Thus, in some states, the definition of "licensed practitioner" may result in the legal use of the Viveve System by non-physicians. In all instances, training of sites is performed by highly qualified Viveve Medical and Science Liaisons.

The use of our device by non-physicians, as well as noncompliance with the operating guidelines set forth in our training programs, may result in product misuse and adverse treatment outcomes, which could harm our reputation and expose us to costly product liability litigation.

Product liability suits could be brought against us due to defective design, labeling, material or workmanship, or misuse of the Viveve System, and could result in expensive and time-consuming litigation, payment of substantial damages and an increase in our insurance rates.

If the Viveve System is defectively designed, manufactured or labeled, contains defective components or is misused, we may become subject to substantial and costly litigation by our customers or their patients. Misusing the device or failing to adhere to operating guidelines could cause serious adverse events. In addition, if our operating guidelines are found to be inadequate, we may be subject to liability. We may, in the future, be involved in litigation related to the use of the device. Product liability claims could divert management's attention from our business, be expensive to defend and result in sizable damage awards against us. We may not have sufficient insurance coverage for all future claims. We may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, could harm our reputation in the industry and reduce product sales. Product liability claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and adversely affecting our operating results.

After-market modifications to treatment tips by third parties and the development of counterfeit products could reduce our sales, expose us to product liability litigation and dilute our brand quality.

Third parties may introduce adulterated after-market modifications to our treatment tips, which enable re-use of treatment tips in multiple procedures. Because the treatment tips are designed to withstand a finite number of pulses, modifications intended to increase the number of pulses could result in patient injuries caused by the use of worn-out or damaged treatment tips. In addition, third parties may seek to develop counterfeit products that are compatible with the Viveve System and available to practitioners at lower prices. If security features incorporated into the design of the device are unable to prevent after-market modifications to the treatment tips or the introduction of counterfeit products, we could be subject to reduced sales, product liability lawsuits resulting from the use of damaged or defective goods and damage to our reputation.

Third parties may also try to sell the Viveve System and its consumable products on a secondary market, which would remove Viveve's ability to track the products. If prior to or after being sold on the secondary market, the Viveve System or its consumable products are misused or modified by a third party, Viveve could be subject to liability. If this happens, we could be subject to reduced sales, product liability claims, inability to obtain sufficient insurance coverage in the future and damage to our reputation.

A data breach or cyberattack affecting our devices, information technology systems, or protected data could expose us to regulatory liability and litigation and dilute our brand quality.

Our information technology systems and the Viveve System, like other medical devices with software that may be accessible in some manner to users, are vulnerable to security breaches, cyberattacks, malicious intrusion, breakdown, destruction, loss of data privacy, or other significant disruption. We also collect, manage, and process protected personal information, including health information, in connection with our operations. A significant breach, attack, or other disruption could result in adverse consequences, including increased costs and expenses, regulatory inquiries, litigation, problems with product functionality, reputational damage, lost revenue, and fines or penalties. We invest in systems and technology and in the protection of our products and data to reduce the risk of an attack or other significant disruption. However, there can be no assurance that these measures and efforts will prevent future attacks or other significant disruptions to our information technology systems and the Viveve System. Additionally, Viveve products have no WiFi nor do they contain a receiver or transmitter, dramatically reducing the risk of a cyberattack. However, there can be no assurance that these measures and efforts will prevent future attacks or other significant disruptions to our information technology systems and the Viveve System.

We depend on skilled and experienced personnel to operate our business effectively. If we are unable to recruit, hire and retain these employees, our ability to manage and expand our business will be harmed, which would impair our future revenue and profitability.

Our success largely depends on the skills, experience and efforts of our officers and other key employees. While we have employment contracts with our Chief Executive Officer and our Senior Vice President of Finance and Administration (Principal Accounting and Financial Officer), these officers and other key employees may terminate their employment at any time. The loss of any senior management team members could weaken our management expertise and harm our business.

Our ability to retain our skilled labor force and our success in attracting and hiring new skilled employees will be a critical factor in determining whether we will be successful in the future. We may not be able to meet our future hiring needs or retain existing personnel. We will face particularly significant challenges and risks in hiring, training, managing and retaining engineering and sales and marketing employees, as well as independent distributors, most of whom are geographically dispersed and must be trained in the use of our device and benefits of the Viveve System and treatment. Failure to attract and retain personnel, particularly technical and sales and marketing personnel, would materially harm our ability to compete effectively and grow our business.

Any acquisitions or in-licenses that we make could disrupt our business and harm our financial condition.

We expect to evaluate potential strategic acquisitions of complementary businesses, products or technologies. We may also consider joint ventures and other collaborative projects, including in-license opportunities. We may not be able to identify appropriate acquisition candidates or strategic partners, or successfully negotiate, finance or integrate acquisitions of any businesses, products or technologies, as applicable, on favorable terms or at all. Furthermore, the integration of any acquisition or in-license and management of any collaborative project may divert management's time and resources from our business and disrupt our operations. We do not have any experience with acquiring companies or products or in-licensing of technologies. If we decide to expand our product offerings, we may spend time and money on projects that do not increase our revenues. Our inability to identify and secure such opportunities may harm our financial condition and our ability to compete and grow our business.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations which could affect our ability to realize tax benefits from our net operating losses.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations. As of December 31, 2021, we had federal and state net operating loss carryforwards ("NOLs") of approximately $194.0 million and $144.3 million, respectively, due to prior period losses. In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code") a corporation that undergoes an "ownership change" can be subject to limitations on its ability to utilize its NOLs to offset future taxable income. While the Company has not performed a formal study, we believe that the Company experienced a change in control in November 2019, which will result in expiration of $81.0 million and $109.6 million of federal and state NOLs, respectively, before utilization. Our existing NOLs may be subject to limitations arising from past ownership changes, including in connection with this offering. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code. In addition, under the Tax Cuts and Jobs Act (the "Tax Act"), the amount of future NOLs that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the NOL deduction itself. In addition, the Tax Act generally eliminates the ability to carry back any future NOL to prior taxable years, while allowing unused future NOLs to be carried forward indefinitely. There is a risk that due to changes under the Tax Act, regulatory changes, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities. For these reasons, we may not be able to realize a tax benefit from the use of our NOLs, whether or not we attain profitability.

We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

Developing our products is expensive, and we expect our research and development expenses to increase substantially in connection with our ongoing activities. We will continue to require substantial funds to support our clinical trials and fund our efforts to expand regulatory clearance or approval for our products, including in the U.S.

As of December 31, 2021, our cash and cash equivalents were $19.2 million. We expect that our cash and cash equivalents will be sufficient to fund our current operations for at least the next nine months through December 2022; however we will continue to require funds to fully implement our plan of operation. Additionally, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize, our product candidates. Raising funds in the current economic environment may present additional challenges. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidate or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidate or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Our historical operating results indicate substantial doubt exists related to the Company's ability to continue as a going concern.

Our financial statements have been prepared assuming that our Company will continue as a going concern. We have incurred net losses and used significant cash in operating activities since inception. We have an accumulated deficit of approximately $241.9 million, cash and cash equivalents of $19.2 million and working capital of $17.7 million as of December 31, 2021. Additionally, the Company used $12.9 million in cash for operations in the year ended December 31, 2021. These factors raise substantial doubts about our ability to continue as a going concern and satisfy our estimated liquidity needs 12 months from the issuance of the financial statements.

If we continue to experience operating losses, and we are not able to generate additional liquidity through a capital raise or other cash infusion, we might need to secure additional sources of funds, which may or may not be available to us. Additionally, a failure to generate additional liquidity could negatively impact our ability to operate our business.

Risks Related to Our Intellectual Property

Intellectual property rights may not provide adequate protection for the Viveve System, which may permit third parties to compete against us more effectively.

We rely on patent, copyright, trade secret and trademark laws and confidentiality agreements to protect our technology and Viveve treatment. We have an exclusive license (with a field of use limitation) to one issued U.S. patent and own 8 issued U.S. patents. Additionally, as of March 11, 2022, we have 7 pending U.S. patent applications; 74 issued foreign patents, including patents that may have lapsed; and 6 pending foreign patent applications. Some of the Viveve System's components are not, and in the future may not be, protected by patents. Additionally, our patent applications may not issue as patents or, if issued, may not issue in a form that will be advantageous to us. Any patents we obtain may be challenged, invalidated or legally circumvented by third parties. Consequently, competitors could market products and use manufacturing processes that are substantially similar to, or superior to, ours. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors, former employees or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. Moreover, we do not have patent rights in all foreign countries in which a market may exist, and where we have applied for foreign patent rights, the laws of many foreign countries may not protect our intellectual property rights to the same extent as the laws of the U.S.

In addition, competitors could purchase the Viveve System and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If our intellectual property is not adequately protected so as to defend our market against competitors' products and methods, our competitive position and business could be adversely affected.

We have been involved in and may be involved in future costly intellectual property litigation, which could impact our future business and financial performance.

Our industry has been characterized by frequent intellectual property litigation. Our competitors or other patent holders may assert that our device and the methods we employ are covered by their patents. If our device or methods are found to infringe, we could be prevented from marketing the Viveve System. In addition, we do not know whether our competitors or potential competitors have applied for, or will apply for or obtain, patents that will prevent, limit or interfere with our ability to make, use, sell, import or export the Viveve System. We may also initiate litigation against third parties to protect our intellectual property that may be expensive, protracted or unsuccessful. In the future there may be companies that market products for competing purposes in direct challenge to our intellectual property position, and we may be required to initiate litigation in order to stop them. For example, in October 2016 we filed a patent infringement lawsuit against ThermiGen, LLC, ThermiAesthetics, LLC and Dr. Red Alinsod alleging unauthorized use of certain of our patented technologies. based on Viveve's U.S. Patent Number 8,961,511 (the "'511 patent"). *Viveve, Inc. v. ThermiGen, LLC et al.,* No. 2:16-cv-1189-JRG (E.D. Tx.), filed October 16, 2016. On October 20, 2017, ThermiGen and ThermiAesthetics filed two petitions for *inter partes* review (IPR) of the '511 patent at the U.S. Patent Trial and Appeal Board (PTAB) challenging the validity of the '511 patent claims. *ThermiGen, LLC et al. v. Viveve, Inc.*, No. IPR2018-00088 (October 20, 2017) and *ThermiGen, LLC et al. v. Viveve, Inc.*, No. IPR2018-00089 (October 20, 2017). On June 4, 2018, we entered into a Settlement and License Agreement (the "Settlement Agreement") with ThermiGen LLC and ThermiAesthetics LLC ("ThermiGen," collectively) as well as Red Alinsod, M.D. resolving our patent litigation against ThermiGen and Dr. Alinsod. The Settlement Agreement also resolved ThermiGen's IPR proceedings against the Viveve.

Litigation related to infringement and other intellectual property claims, with or without merit, is unpredictable, can be expensive and time-consuming and could divert management's attention from our business. If we lose this kind of litigation, a court could require us to pay substantial damages, and prohibit us from using technologies essential to the Viveve System and Viveve treatment, any of which would have a material adverse effect on our business, results of operations and financial condition. In that event, we do not know whether necessary licenses would be available to us on satisfactory terms, or whether we could redesign the Viveve System or processes to avoid infringement.

Competing products may also appear in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, we could be prevented from marketing the Viveve System in one or more countries.

In addition, we may hereafter become involved in litigation to protect our trademark rights associated with our device name or treatment name. Names used may be claimed to infringe names held by others or to be ineligible for proprietary protection. If we have to change the name of the Company, device or treatment, we may experience a loss in goodwill associated with our brand name, customer confusion and a loss of sales.

Risks Related to Our Securities

Public company compliance may make it more difficult to attract and retain officers and directors.

The Sarbanes-Oxley Act and rules implemented by the SEC have required changes in corporate governance practices of public companies. As a public company, these rules and regulations increase our compliance costs and make certain activities more time consuming and costly. These rules and regulations may also make it more difficult and expensive for us to maintain our director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors or as executive officers, and to maintain insurance at reasonable rates, or at all.

Concentration of ownership of our common stock may have the effect of delaying or preventing a change in control.

As of March 11, 2022, our officers, directors and principal stockholders, i.e., stockholders who beneficially own greater than 10% of our outstanding common stock, collectively beneficially own approximately 5.6% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to control the management and affairs of our company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of our other stockholders.

We are a holding company with no business operations of our own and we depend on cash flow from Viveve, Inc. to meet our obligations.

We are a holding company with no business operations of our own or material assets other than the stock we own in Viveve, Inc. All of our operations are conducted by Viveve, Inc. As a holding company, we will require dividends and other payments from our subsidiary to meet cash requirements. The terms of any agreements governing indebtedness that we may enter into may restrict our subsidiary from paying dividends and otherwise transferring cash or other assets to us. If there is an insolvency, liquidation or other reorganization of our subsidiary, our stockholders likely will have no right to proceed against its assets. Creditors of our subsidiary will be entitled to payment in full from the sale or other disposal of the assets of our subsidiary before we, as an equity holder, would be entitled to receive any distribution from that sale or disposal. If Viveve, Inc. is unable to pay dividends or make other payments to us when needed, we will be unable to satisfy our obligations.

Our stock price may be volatile.

The market price of our common stock is likely to be highly volatile and could fluctuate widely in price in response to various factors, many of which are beyond our control, including the following:

- actual or anticipated fluctuations in our quarterly financial results or the quarterly financial results of companies perceived to be similar to us;
- changes in the market's expectations about our operating results;
- success of competitors;
- our operating results failing to meet the expectations of securities analysts or investors in a particular period;
- changes in financial estimates and recommendations by securities analysts concerning our business, the market for our products, the health services industry, or the healthcare and health insurance industries in general;
- operating and stock price performance of other companies that investors deem comparable to us;
- our ability to market new and enhanced products on a timely basis;
- changes in laws and regulations affecting our business;
- commencement of, or involvement in, litigation involving us;
- changes in our capital structure, such as future issuances of securities or the incurrence of debt;
- the volume of shares of our common stock available for public sale;
- any major change in our board of directors or management;
- sales of substantial amounts of common stock by our directors, executive officers or significant stockholders or the perception that such sales could occur; and
- general economic and political conditions such as recessions, fluctuations in interest rates and international currencies, and global conflicts such as the war in Ukraine.

In addition, the securities markets have from time-to-time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock.

Our shares of common stock are thinly traded, the price may not reflect our value, and there can be no assurance that there will be an active market for our shares of common stock either now or in the future.

Our shares of common stock are thinly traded, our common stock is held by a small number of holders, and the price may not reflect our actual or perceived value. There can be no assurance that there will be an active market for our shares of common stock either now or in the future. The market liquidity will be dependent on the perception of our operating business, among other things. We will take certain steps including utilizing investor awareness campaigns, investor relations firms, press releases, road shows and conferences to increase awareness of our business. Any steps that we might take to bring us to the awareness of investors may require that we compensate consultants with cash and/or stock. There can be no assurance that there will be any awareness generated or the results of any efforts will result in any impact on our trading volume. Consequently, investors may not be able to liquidate their investment or liquidate it at a price that reflects the value of the business, and trading may be at a depressed price relative to the performance of the Company due to, among other things, the availability of sellers of our shares. If an active market should develop, the price may be highly volatile. Because there is currently a relatively low per-share price for our common stock, many brokerage firms or clearing firms are not willing to effect transactions in the securities or accept our shares for deposit in an account. Many lending institutions will not permit the use of low-priced shares of common stock as collateral for any loans.

Offers or availability for sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

If our stockholders sell substantial amounts of our common stock in the public market upon the expiration of any statutory holding period under Rule 144, or shares issued upon the exercise of outstanding options or warrants, it could create a circumstance commonly referred to as an "overhang" and, in anticipation of which, the market price of our common stock could fall. The existence of an overhang, whether or not sales have occurred or are occurring, also could make more difficult our ability to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

In general, under Rule 144, a non-affiliated person who has held restricted shares of our common stock for a period of six months may sell into the market all of their shares, subject to the Company being current in our periodic reports filed with the SEC.

We do not expect to declare or pay dividends in the foreseeable future.

We have never paid cash dividends on our common stock and have no plans to do so in the foreseeable future, except the cumulative dividend payable on our Series B Preferred Stock, which could reduce a return in your investment in us. We intend to retain any earnings to develop, carry on, and expand our business. In addition, the terms of the indebtedness of our existing credit facility also restrict us from paying cash dividends to stockholders under some circumstances. The terms of our Series B Preferred Stock also provide that we may not pay dividends on our common stock without concurrently declaring dividends on each. If we do not pay dividends, our stock may be less valuable because a return on your investment will only occur if you sell our common stock after our stock price appreciates.

CRG has the right to acquire a significant percentage of our stock upon conversion of its Series B Preferred Stock and exercise of its warrants and is able to exert significant control over matters pursuant to the protective provisions therein as well as the covenants and other restrictions in the Loan Agreement.

Affiliates of CRG LP (collectively "CRG") have the right to acquire approximately 14% of our outstanding common stock on a fully diluted basis, subject to stockholder approval to authorize a sufficient number of common stock, Nasdaq stockholder approval requirements and beneficial ownership restrictions contained in the Series B Certificate of Designation and warrants held by CRG. Even though Series B Preferred Stock is non-voting stock, and has beneficial ownership restrictions, the Series B Certificate of Designation has protective provisions that will require CRG's consent to perform certain significant company events. For example, CRG's consent would be necessary to amend our organizational documents, or approve any merger, sale of assets, or other major corporate transaction. This consent requirement could delay or prevent any acquisition of our company on terms that other stockholders may desire and may adversely affect the market price of our common stock. CRG may have interests different than yours. For example, CRG may want us to pursue strategies that deviate from the interests of other stockholders.

The Series B Preferred Stock has a liquidation preference to our common stock.

Series B Preferred Stock has a liquidation preference that gets paid prior to any payment on our common stock (including shares issuable upon the exercise of the warrants). As a result, if we were to dissolve, liquidate, merge with another company or sell our assets, the holders of our Series B Preferred Stock would have the right to receive up to approximately $35.82 million plus any unpaid dividend from any such transaction before any amount is paid to the holders of our common stock or pursuant to the redemption rights in the warrants for fundamental transactions. The payment of the liquidation preferences could result in common stockholders and warrant holders not receiving any consideration if we were to liquidate, dissolve or wind up, either voluntarily or involuntarily.

The existence of the liquidation preferences may reduce the value of our common stock, make it harder for us to sell shares of common stock in offerings in the future, or prevent or delay a change of control. Furthermore, any conversion of Series B Preferred Stock into common stock will cause substantial dilution to our common stockholders.

If we fail to comply with ongoing Nasdaq listing standards and corporate governance requirements, we could be subject to delisting. Nasdaq delisting could materially adversely affect the market for our shares.

Our common stock is currently listed on The Nasdaq Capital Market. In order to maintain this listing, we are required to comply with various continued listing standards, including corporate governance requirements, set forth in the Nasdaq Listing Rules. These standards and requirements include, among other things, (1) an obligation to maintain a Board of Directors, a majority of whom are deemed to be independent and that we maintain an Audit Committee consisting of at least three independent Board Members, (2) an obligation that our listed securities maintain a minimum bid price of $1.00 per share, and (3) an obligation to maintain Nasdaq's threshold market value of listed securities (or comply with its alternative stockholders' equity requirement).

In the past, we have been in non-compliance with Nasdaq's minimum bid price requirement, Audit Committee independence requirement and market value of listed securities requirement, but we cured our deficiencies and regained compliance with Nasdaq's continued listing standards. Furthermore, as of March 16, 2022, the bid price of our common stock has closed below $1.00 per share for 22 consecutive trading days. In the event that the bid price of our common stock remains below such threshold for 30 consecutive trading days, we may receive a notice of non-compliance with Nasdaq's minimum bid price requirement and grace period to regain compliance. In such an event, we may need to effect a reverse stock split to regain compliance. Nasdaq may also decline to continue our listing on account of multiple reverse stock splits for compliance with its minimum bid price requirement. There can be no assurance that we will continue to be in compliance with Nasdaq's continued listing standards in the future.

In the event that our common stock is not eligible for continued listing on Nasdaq or another national securities exchange, trading of our common stock could be conducted in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by security analysts and the news media, which could cause the price of our common stock to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on a major exchange.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

On February 1, 2017, we entered into a Sublease for approximately 12,400 square feet of building space for the Company's corporate headquarters in Englewood, Colorado, which was effective as of January 26, 2017. The lease term was 36 months. The lease term commenced on June 1, 2017 and was to terminate in May 2020. In November 2019, we exercised the option to extend the lease for one year through May 2021. In March 2021, we amended our lease extending the lease term 34 months. The term of the lease agreement, as amended, will terminate on March 31, 2024. We believe that this facility is adequate for our current business operations.

The office operating lease expense for the years ended December 31, 2021 and 2020 was $256,000 and $268,000, respectively. Future minimum payments under the office operating lease are approximately as follows:

Year Ending December 31,		
2022	–	$257,000
2023	–	$264,000
2024	–	$67,000

Item 3. Legal Proceedings

The Company currently has no pending or open legal proceedings.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

As of March 11, 2022, our common stock is trading on The Nasdaq Capital Market under the symbol “VIVE”.

Holders of Common Stock

As of March 11, 2022, there were approximately 92 holders of record of our common stock.

Dividends

Our Series B Preferred Stock carries a cumulative dividend at a rate of 12.5% of $1,000 per annum, compounded annually. This cumulative dividend is payable in arrears on quarterly basis, commencing with December 31, 2021, and at our option is payable in additional shares of Series B Preferred Stock. Additionally, the terms of our Series A Preferred Stock and Series B Preferred Stock provide that we may not declare dividends on the common stock without concurrently declaring dividends on such series of preferred stock in an amount equal to that payable had they been converted to common stock prior to the dividend. We have paid $16,694 in cash and issued a total of 9,204 shares of Series B Preferred Stock as preferred dividend to the holders of Series B Preferred Stock through December 31, 2021.

Other than the preferred dividend on Series B Preferred Stock, we have not declared or paid any cash dividends on our common stock, and we currently intend to retain future earnings, if any, to finance the expansion of our business; we do not expect to pay any cash dividends in the foreseeable future. The decision whether to pay cash dividends on our common stock will be made by our board of directors, in their discretion, and will depend on our financial condition, results of operations, capital requirements and other factors that our board of directors considers significant.

Securities Authorized For Issuance Under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Issuances of Unregistered Securities

Pursuant to the Certificate of Designation of Series B Preferred Stock, we issued 1,118 shares of Series B Preferred Stock in lieu of $1,118,000 in cash dividend to holders of Series B Preferred Stock, exempt from registration pursuant to Section 4(a)(2) of the Securities Act, on March 31, 2021.

Pursuant to the Certificate of Designation of Series B Preferred Stock, we issued 1,153 shares of Series B Preferred Stock in lieu of $1,153,000 in cash dividend to holders of Series B Preferred Stock, exempt from registration pursuant to Section 4(a)(2) of the Securities Act, on June 30, 2021.

Pursuant to the Certificate of Designation of Series B Preferred Stock, we issued 1,189 shares of Series B Preferred Stock in lieu of $1,189,000 in cash dividend to holders of Series B Preferred Stock, exempt from registration pursuant to Section 4(a)(2) of the Securities Act, on September 30, 2021.

Pursuant to the Certificate of Designation of Series B Preferred Stock, we issued 1,225 shares of Series B Preferred Stock in lieu of $1,225,000 in cash dividend to holders of Series B Preferred Stock, exempt from registration pursuant to Section 4(a)(2) of the Securities Act, on December 31, 2021.

The shares of Series B Preferred Stock and warrants to purchase shares of common stock issued to affiliates of CRG will only be convertible or exercisable into common stock, as applicable, following such time as we have filed an amendment to the certificate of incorporation that authorizes at least 125,000,000 shares of common stock. The conversion or exercise of securities issued to affiliates of CRG are also further subject to certain beneficial ownership restrictions. If the Series B Preferred Stock becomes convertible into common stock, it will be convertible into that number of shares of common stock determined by dividing $1,000 by the conversion price of $15.30.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. Selected Financial Data

Not applicable.

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

Forward-Looking Statements

This report contains forward-looking statements that involve risks and uncertainties. These statements relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology including, "could" "may", "will", "should", "expect", "plan", "anticipate", "believe", "estimate", "predict", "potential" and the negative of these terms or other comparable terminology. These statements are only predictions. Actual events or results may differ materially.

While these forward-looking statements, and any assumptions upon which they are based, are made in good faith and reflect our current judgment regarding the direction of our business, actual results will almost always vary, sometimes materially, from any estimates, predictions, projections, assumptions or other future performance suggested in this Annual Report.

The following discussion should be read in conjunction with the consolidated financial statements and the related notes contained elsewhere in this Annual Report. In addition to historical information, the following discussion contains forward looking statements based upon current expectations that are subject to risks and uncertainties. Actual results may differ substantially from those referred to herein due to a number of factors, including, but not limited to, risks described in the section entitled "***Risk Factors***".

Overview of Our Business

In the discussion below, when we use the terms "we", "us" and "our", we are referring to Viveve Medical, Inc. and our wholly-owned subsidiaries, Viveve, Inc. and Viveve BV.

We design, develop, manufacture and market a platform medical technology, which we refer to as *Cryogen-cooled Monopolar Radiofrequency* ("CMRF"). Our proprietary CMRF technology is delivered through an RF generator, handpiece and treatment tip that, collectively, we refer to as the Viveve® System. The Viveve System is currently marketed and sold for a number of indications, depending on the relevant country-specific clearance or approval. Currently, the Viveve System is cleared for marketing in 50 countries throughout the world under the following indications for use:

Indication for Use:	**No. of Countries:**
General surgical procedures for electrocoagulation and hemostasis	4 (including the U.S.)
General surgical procedures for electrocoagulation and hemostasis of vaginal tissue and the treatment of vaginal laxity	29
For treatment of vaginal laxity	5
For treatment of the vaginal introitus, after vaginal childbirth, to improve sexual function	9
General surgical procedures for electrocoagulation and hemostasis as well as for the treatment of vaginal laxity	1
For vaginal rejuvenation	1
For treatment of vaginal laxity and to improve mild urinary incontinence and sexual function	1

In the U.S., the Viveve System is indicated for use in general surgical procedures for electrocoagulation and hemostasis and we market and sell primarily through a direct sales force. Outside the U.S., we primarily market and sell through distribution partners. As of December 31, 2021, we have a global installed base of 884 Viveve Systems and we have sold approximately 61,000 single-use treatment tips worldwide.

Because the revenue we have earned to date have not been sufficient to support our operations, we have relied on sales of our securities, bank term loans and loans from related parties to fund our operations.

We are subject to risks, expenses and uncertainties frequently encountered by companies in the medical device industry. These risks include, but are not limited to, intense competition, whether we can be successful in obtaining FDA and other governmental clearance or approval for the sale of our product for all desired indications and whether there will be a demand for the Viveve System, given that the cost of the procedure will likely not be reimbursed by the government or private health insurers. In addition, we will continue to require substantial funds to support our clinical trials and fund our efforts to expand regulatory clearance or approval for our products, including in the U.S. We cannot be certain that any additional required financing will be available when needed or on terms which are favorable to us. Our operations to date have been primarily funded through the sales of our securities, bank term loans and loans from related parties. Various factors, including our limited operating history with limited revenue to date and our limited ability to market and sell our products have resulted in limited working capital available to fund our operations. There are no assurances that we will be successful in securing additional financing in the future to fund our operations going forward. Failure to generate sufficient cash flows from operations, raise additional capital or reduce certain discretionary spending could have a material adverse effect on our ability to achieve our intended business objectives.

On December 1, 2020, the Company effected a 1-for-10 reverse stock split of all outstanding common stock of the Company. All share numbers, exercise prices for options and warrants, conversion price of preferred stock and other capitalization information in this Annual Report on Form 10-K is represented on a post-split basis, unless as otherwise indicated.

Recent Events

Effective Shelf Registration Statement

On July 2, 2021, we filed a universal shelf registration statement with the SEC on Form S-3 for the proposed offering from time to time of up to $75,000,000 of our securities, including common stock, preferred stock, and/or warrants. This registration statement currently has a capacity of $75,000,000. However, as a result of the limitations of General Instruction I.B.6. of Form S-3, or the so-called "baby shelf rules", the amount of shares of our common stock available for sale under a registration statement on Form S-3 is limited to one-third of the aggregate market value of our common equity held by non-affiliates of the Company over any rolling 12-month period. As of December 31, 2021, we have not issued any shares or received any proceeds pursuant to the universal shelf registration statement.

Reduction of Common Warrant Exercise Price

On January 19, 2021, the Company closed a public offering at an effective price of $3.40 per share of its common stock. As a result, the per share exercise price of our previously issued Series B, A-2 and B-2 common stock warrants was automatically reduced pursuant to the terms of the warrants. The exercise price for Series B warrants was reduced from $6.10 per share to $3.40 per share. The exercise price for Series A-2 and B-2 warrants was reduced from $6.371 per share to $3.40 per share. There was no change to the quantity of warrant shares.

In February and March 2021, a total of 40,000 shares of common stock were issued in connection with the exercise of Series B warrants for gross proceeds of approximately $136,000 and a total of 12,760 shares of common stock were issued in connection with the exercise of January 2021 warrants for gross proceeds of approximately $43,000.

On May 4, 2021, pursuant to the provisions under the Purchase Agreement as amended, LPC (as defined below) purchased 250,000 shares at $2.817 per share of the Company's common stock. As a result, the per share exercise price of our previously issued Series B, A-2 and B-2 common stock warrants was automatically reduced from $3.40 to $2.817 pursuant to the terms of the warrants. There was no change to the quantity of warrant shares.

As of December 31, 2021, there were Series B warrants to purchase a total of 285,632 shares of common stock, Series A-2 warrants to purchase a total of 392,830 shares of common stock, and Series B-2 warrants to purchase a total of 20,380 shares of common stock still remaining and outstanding.

2021 Public Offering

On January 19, 2021, the Company closed an upsized underwritten public offering of units (the "January 2021 Offering") for gross proceeds of approximately $27,600,000, which included the exercise of the underwriter's over-allotment option to purchase additional shares and warrants, prior to deducting underwriting discounts and commissions and offering expenses payable by Viveve.

The offering comprised of: (1) 4,607,940 Class A Units, priced at a public offering price of $3.40 per Class A Unit, with each unit consisting of one share of common stock and one warrant to purchase one share of common stock, at an exercise price of $3.40 per share that expires on the fifth anniversary of the date of issuance; and (2) 2,450,880 Class B Units, priced at a public offering price of $3.40 per Class B Unit, with each unit consisting of one share of Series C convertible preferred stock and one warrant to purchase one share of common stock, at an exercise price of $3.40 per share that expires on the fifth anniversary of the date of issuance. The underwriter exercised an over-allotment option to purchase an additional 1,058,820 shares of common stock and warrants to purchase 1,058,820 shares of common stock in the offering. The net proceeds to the Company, after deducting underwriting discounts and commissions and offering expenses payable by the Company, were approximately $25,122,000.

A total of 2,450,880 shares of Series C convertible preferred stock were issued in the January 2021 Offering. In January 2021, all Series C convertible preferred stock were converted into common stock and there are no remaining shares of Series C convertible preferred stock outstanding.

Warrants to purchase a total of 8,117,640 shares of common stock were issued in the January 2021 Offering. In February and March 2021, holders exercised January 2021 warrants to purchase 12,760 shares of common stock for aggregate exercise proceeds to the Company of approximately $43,000. As of December 31, 2021, there were January 2021 warrants to purchase a total of 8,104,880 shares of common stock still remaining and outstanding.

Purchase Agreement with Lincoln Park Capital, LLC

The Company previously entered into a purchase agreement on June 8, 2020, as amended on March 31, 2021 (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("LPC"), which provided that the Company had the right, in its sole discretion, to sell to LPC, and LPC has committed to purchase from us, up to $10,000,000 of our common stock, subject to certain limitations, from time to time over a 30-month period pursuant to the terms of the Purchase Agreement.

On May 4, 2021, LPC purchased 250,000 shares of common stock at price per share of $2.817 under the Purchase Agreement for gross proceeds of approximately $704,000.

As of December 31, 2021, the equity facility with LPC has a remaining financing commitment of approximately $9,000,000.

Paycheck Protection Program Loan

The Paycheck Protection Program ("PPP") was established under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") and is administered by the U.S. Small Business Administration. On April 24, 2020, Viveve, Inc. ("Viveve"), a wholly-owned subsidiary of the Company, entered into a promissory note evidencing an unsecured loan in the aggregate amount of approximately $1,343,000 made to Viveve under the PPP (the "PPP Loan"). The PPP Loan to Viveve was made through Western Alliance Bank. The interest rate on the PPP Loan was 1.00% and the term was two years.

On May 25, 2021, the entire amount of the PPP Loan in the aggregate amount of $1,358,000, including the total principal amount and the accrued interest through the forgiveness payment date of May 21, 2021, was forgiven.

PURSUIT – U.S. Pivotal SUI Trial

The Company received FDA approval of its IDE application to conduct its U.S. pivotal, multicenter PURSUIT trial for improvement of SUI in women in July 2020, as well as FDA approval of requested amendments to the IDE protocol in December 2020. Initiation of the PURSUIT trial was announced by the Company on January 21, 2021 and completion of subject enrollment was reported on December 14, 2021. Topline results are anticipated at the end of 2022.

PURSUIT is a randomized, double-blinded, sham-controlled trial with an intended enrollment of approximately 390 subjects with moderate SUI (≥ 10ml – 50ml urine leakage on the 1-hour Pad Weight Test) at up to 30 study sites in the U.S. Randomized in a 2:1 ratio for active and sham treatments, subjects in the active treatment arm (260 subjects) will receive CMRF treatment (90J/cm2 RF and cryogen-cooling), while subjects in the control arm (130 subjects) will receive an inert sham treatment.

The primary efficacy endpoint of the PURSUIT trial is a comparison of the proportion of patients who experience greater than 50% reduction in urine leakage compared to baseline on the standardized 1-hour Pad Weight Test at 12 months post-treatment versus the new sham procedure. The study also includes several secondary endpoints, including: proportion of patients who experience greater than 50% reduction in urine leakage on the standardized 1-hour Pad Weight Test at three and six months post-treatment, percentage change from baseline in the 1-hour Pad Weight Test at three, six and 12 months, percent of subjects with no incontinence episodes at three, six and 12 months post treatment as assessed with the three-day bladder voiding diary, and change from baseline in the MESA Questionnaire (Medical, Epidemiologic and Social Aspects of Aging), Incontinence Quality of Life (I-QOL), Patient Global Impression of Improvement (PGI-1) Questionnaire, and International Consultation on Incontinence Modular Questionnaire-Urinary Incontinence Short Form (ICIQ-UI-SF) at three, six, and nine months post-treatment. Subject safety will be monitored throughout the study.

Three-Arm SUI Feasibility Study

In December 2019, the Company received approval of an ITA from the Canadian Ministry of Health and in January 2020 initiated a three-arm, three-month feasibility study to compare Viveve's CMRF treatment and a cryogen-only sham to an inert sham treatment for the improvement of SUI in women. Completion of subject enrollment in the study was reported in March 2020. Study subjects were randomized in a 1:1:1 ratio to the three arms and were assessed using the 1-hour Pad Weight Test, 3-day Voiding Diary, the 24-hour Pad Weight Test and I-QOL at five months post treatment. Due to patient, provider and medical facility health and safety concerns caused by the COVID-19 pandemic, the final subject follow-up visit was changed to five months versus three months.

Final results were reported in August 2020, indicating the primary efficacy endpoint (i.e., change from baseline in the standardized 1-hour Pad Weight Test at five months post treatment) was positively achieved. The median change from baseline in the active CMRF treatment group (N=13) and the cryogen-only sham treatment group (N=12) was -9.5 grams and -6.8 grams respectively, as compared to -4.4 grams in the inert sham treatment group (N=11). The study also assessed several secondary endpoints but showed no differentiation between groups. No device-related safety issues were reported. The meaningful separation demonstrated between the CMRF treatment arm and the inert sham arm in the feasibility study is believed to help provide confidence in the potential to achieve positive separation between the two treatment arms in the underway U.S. pivotal PURSUIT trial.

In-vivo Preclinical Study and Results for New Sham Treatment Tip

In response to the inconclusive results in which the treated arm showed no separation versus the sham control arm reported in July 2019 from the Company's LIBERATE-International SUI trial conducted in Canada (aimed at supporting SUI indications in Canada, the European Union and several other international countries), Viveve conducted an in-vivo preclinical temperature and immunohistochemistry study to evaluate a new inert sham treatment tip. The Good Laboratory Practices study was initiated in June of this year following several months of engineering, validation, and development work. The study assessed both in-vivo tissue temperature changes during treatment, and histopathology at 30 days post-treatment compared to baseline, in three parous ewes using Viveve's CMRF treatment tip (Active), cryogen-cooling only tip ("Old" sham treatment used in previous LIBERATE-International SUI study), and a new inert sham treatment tip. Histopathology of vaginal biopsies were performed and included use of α-SMA staining for fibroblast activation and formation. All tissue samples were evaluated by an independent and blinded pathologist.

The positive preclinical findings demonstrated, as reported in August 2020, that both temperature and immunohistochemistry results support the validity of the new inert sham tip to provide a true inert or placebo treatment. Only minor tissue temperature change (less than 2 degrees centigrade) was generated by the new inert sham tip and no fibroblast activation was shown through elevated a-SMA staining. In contrast, both the Active and cryogen-cooling sham tips demonstrated meaningful tissue temperature changes during treatment and increased fibroblast activation 30 days post-treatment. We believe that the positive in-vivo preclinical study validates our new inert sham tip for use in the U.S. pivotal PURSUIT trial that is currently underway.

New Category III CPT Code for SUI Procedure

In early July 2021, the Company announced that the American Medical Association ("AMA") had issued a new Category III Current Procedural Terminology ("CPT"®) code for the Company's dual-energy procedure effective January 1, 2022. The new code establishes a long-term pathway for potential reimbursement for Viveve's noninvasive treatment under evaluation in the PURSUIT trial to improve SUI in women if approved by the FDA for this indication. The new Category III CPT code for Viveve's SUI procedure is defined as: endovaginal cryogen-cooled, monopolar radiofrequency remodeling of the tissue surrounding the female bladder neck and proximal urethra for urinary incontinence.

U.S. Commercial Sales Transition to Recurring Revenue Rental Model

In June 2019, in addition to a capital sales model, we began a new recurring revenue rental model for the U.S. sales of the Viveve System. The new U.S. commercial sales model is intended to lower up-front costs for customers and thus lower hurdles to adoption, increase placement rates, and improve profitability by significantly reducing selling time per unit.

Under the recurring revenue rental model, customers may lease the Viveve System for a set initial term. After the initial term, the customer may purchase the Viveve System, continue to pay a monthly rental amount or terminate the contract.

The rental program is accounted for under the Financial Standards Board's ("FASB") Accounting Standards Codification ("ASC") No. 2016-02, Leases (Topic 842) and meets the classification criteria for an operating lease. Revenue from the rental program is included in total revenue. For the years ended December 31, 2021 and 2020, rental revenue recognized during the period was $1,214,000 and $1,337,000, respectively. The Viveve Systems that are being leased are included in property and equipment, net and depreciated over their expected useful lives of five years. When other products ("non-lease components"), such as single-use treatment tips or ancillary consumables, are included in the offering, the Company follows the relevant guidance in ASC Topic 606, Revenue from Contracts with Customers, to determine how to allocate contractual consideration between the lease and non-lease components.

Impact of the Coronavirus

As of the filing of this Annual Report on Form 10-K, the United States and many other countries continue to face outbreaks or resurgences of the highly transmissible pathogenic coronavirus and its variants, which has resulted in an increasingly widespread global health crisis, adversely affected general commercial activity and the economies and financial markets of many countries and is likely to continue to adversely affect our business, financial condition and results of operations. The extent to which the coronavirus impacts us will depend on future developments, which are highly uncertain and cannot be accurately predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

Plan of Operation

We intend to increase our sales both internationally and in the U.S. market by seeking additional regulatory clearances or approvals for the sale and distribution of our products, identifying and training qualified distributors and expanding the scope of physicians who offer the Viveve System.

In June 2019, in addition to a capital sales model, we began a new recurring revenue rental model for the U.S. sales of the Viveve System. Sale of Viveve products outside of the U.S. will continue to be supported by our international distributors.

In addition, we intend to use the strategic relationships that we have developed with outside contractors and medical experts to improve our products by focusing our research and development efforts on various areas including, but not limited to:

- designing new treatment tips optimized for both ease-of-use and to reduce procedure times for patients and physicians; and
- developing new RF consoles.

The net proceeds received from sales of our securities and the term loans have been used to support commercialization of our product in existing and new markets, for our research and development efforts and for protection of our intellectual property, as well as for working capital and other general corporate purposes. We expect that our cash will be sufficient to fund our current operations for at least the next nine months through December 2022; however, we will continue to require funds to fully implement our plan of operation. Our operating costs include employee salaries and benefits, compensation paid to consultants, professional fees and expenses, costs associated with our clinical trials, capital costs for research and other equipment, costs associated with research and development activities including travel and administration, legal expenses, sales and marketing costs, general and administrative expenses, and other costs associated with an early stage public company subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We also expect to incur expenses related to obtaining regulatory clearance and approvals in the U.S. and internationally as well as legal and related expenses to protect our intellectual property. We expect capital expenditures, for the foreseeable future, to be less than $1,000,000 annually.

We intend to continue to meet our operating cash flow requirements through the sales of our products and by raising additional capital from the sale of equity or debt securities. If we sell our equity securities, or securities convertible into equity, to raise capital, our current stockholders will likely be substantially diluted. We may also consider the sale of certain assets, or entering into a strategic transaction, such as a merger, with a business complimentary to ours, although we do not currently have plans for any such transaction. While we have been successful in raising capital to fund our operations since inception, other than as discussed in this Annual Report on Form 10-K, we do not have any committed sources of financing and there are no assurances that we will be able to secure additional funding, or if we do secure additional financing that it will be on terms that are favorable to us. If we cannot obtain financing, then we may be forced to curtail our operations or consider other strategic alternatives.

Results of Operations

Comparison of the Year Ended December 31, 2021 and 2020

Revenue

	Year Ended December 31,		Change	
	2021	2020	$	%
	(in thousands, except percentages)			
Revenue	$ 6,426	$ 5,479	$ 947	17%

We recorded revenue of $6,426,000 for the year ended December 31, 2021, compared to revenue of $5,479,000 for the year ended December 31, 2020, an increase of $947,000, or approximately 17%. The increase in revenue was primarily due to higher sales volume of Viveve Systems and treatment tips sold during the year. Revenue in 2021 included sales of 46 Viveve Systems and approximately 10,750 disposable treatment tips sold globally. Revenue in 2020 included sales of 31 Viveve Systems and approximately 8,900 disposable treatment tips sold globally.

Under the recurring revenue rental program, we placed 24 Viveve Systems in the U.S. market in 2021; however, these new placements were offset by the negative impact of the COVID-19 crisis on our sales activity in the year which resulted in the non-renewal of subscriptions for 36 Viveve Systems during the year. In 2020, we placed 29 Viveve Systems under the subscription offering program in the U.S. market, but these new placements were offset by the negative impact of the COVID-19 crisis on our sales activity in the year which resulted in the non-renewal of subscriptions for 42 Viveve Systems during the year. Rental revenue on these leases is recognized on a straight-line basis over the term of the lease. For the years ended December 31, 2021 and 2020, rental revenue recognized during the period was $1,214,000 and $1,337,000, respectively. As of December 31, 2021 and 2020, the Company had deferred revenue in the amount of $452,000 and $345,000 related to its rental program.

Late in the first quarter of 2020 and through the end of the year 2021, the COVID-19 pandemic was in full effect adversely impacting commercial activity and the economies in the United States and most other countries and is likely to continue to adversely affect businesses and results of operations. Government and public health agencies issued directives halting performance of non-essential medical treatments and elective procedures in an effort to combat the spread of the coronavirus and protect public health and safety. As a result, Viveve's customers either temporarily closed their medical practices or dramatically reduced services and staff. The consequence has been both a public health and economic crisis that continues for existing and prospective Viveve customers. In a supportive partnership response, in the second quarter of 2020 Viveve contacted all of its subscription customers and provided them with a three-month deferral of their rental payment. Although clinics in various regions continue to re-open and gradually increase their limited services, we anticipate that until the COVID-19 pandemic abates, more practices re-open and elective patient's safety concerns are reduced that we will continue to experience reduced revenue from existing customers, as well as a greatly reduced number of new and prospective customers.

Gross Profit

	Year Ended December 31,		Change	
	2021	2020	$	%
	(in thousands, except percentages)			
Gross profit	$ 620	$ 296	$ 324	109%

Gross profit was $620,000 or 10% of revenue, for the year ended December 31, 2021 compared to gross profit of $296,000, or 5% of revenue, for the year ended December 31, 2020, an increase of $324,000, or approximately 109%. The increase in gross profit was primarily due to the higher sales volume of Viveve Systems and treatment tips sold during the year. Additionally, fixed manufacturing costs in 2020 were spread over a lower sales volume thereby lowering gross margins for the year.

Research and development expenses

	Year EndedDecember 31,		Change	
	2021	2020	$	%
	(in thousands, except percentages)			
Research and development	$ 9,665	$ 5,125	$ 4,540	189%

Research and development expenses totaled $9,665,000 for the year ended December 31, 2021, compared to research and development expenses of $5,125,000 for the year ended December 31, 2020, an increase of $4,540,000, or approximately 89%.

Spending on research and development increased primarily due to higher clinical study costs related to the initiation of the pivotal U.S. PURSUIT clinical trial for the treatment of SUI in the first quarter of 2021 with subject enrollment advancing in the year. The subject enrollment in the trial was completed in December 2021. Furthermore, spending on research and development in 2021 also included increased engineering and development work related to our products.

Selling, general and administrative expenses

	Year EndedDecember 31,		Change	
	2021	2020	$	%
	(in thousands, except percentages)			
Selling, general and administrative	$ 12,508	$ 13,666	$ (1,158)	(8)%

Selling, general and administrative expenses totaled $12,508,000 for the year ended December 31, 2021, compared to $13,666,000 for the year ended December 31, 2020, a decrease of $1,158,000, or approximately 8%. The decrease in selling, general and administrative expenses was primarily due to reduced spending as a result of the Company's organizational realignment to advance our SUI clinical development program and operational measures to lower costs and reduce cash burn in response to the continuing economic conditions caused by the COVID-19 crisis, partially offset by higher personnel costs for existing employees in 2021.

Gain on forgiveness of Paycheck Protection Program loan

	Year Ended December 31,		Change	
	2021	2020	$	%
	(in thousands, except percentages)			
Gain on forgiveness of Paycheck Protection Program loan	$ 1,358	$ -	$ 1,358	NM

In May 2021, the Company's request for forgiveness of the PPP Loan was approved in full. The total principal amount and the accrued interest through the forgiveness payment date was forgiven. The Company recognized a gain on the extinguishment of debt in the amount of $1,358,000.

Modification of Series A and B Warrants

	Year Ended December 31,		Change	
	2021	2020	$	%
	(in thousands, except percentages)			
Modification of warrants	$ 373	$ 1,838	$ (1,465)	(80)%

In January 2021, the Company reduced the exercise price of the outstanding Series B, A-2 and B-2 warrants pursuant to the terms of the warrants. The exercise price for Series B warrants was reduced from $6.10 per share to $3.40 per share. The exercise price for Series A-2 and B-2 warrants was reduced from $6.371 per share to $3.40 per share. The Series B, A-2 and B-2 warrant exercise price reduction resulted in the recognition of a modification expense of $287,000.

In May 2021, the Company reduced the exercise price of the outstanding Series B, A-2 and B-2 warrants from $3.40 per share to $2.817 per share pursuant to the terms of the warrants. The Series B, A-2 and B-2 warrant exercise price reduction resulted in the recognition of a modification expense of $86,000.

In April 2020, the Company reduced the exercise price of the outstanding Series A warrants and Series B warrants from $15.50 per share to $6.10 per share. The Series A and B warrant exercise price reduction resulted in the recognition of a modification expense of $1,838,000.

Interest expense

	Year Ended December 31,		Change	
	2021	2020	$	%
	(in thousands, except percentages)			
Interest expense, net	$ 1,000	$ 910	$ 90	10%

During the year ended December 31, 2021, we had interest expense, net, of $1,000,000 as compared to $910,000 for the year ended December 31, 2020, an increase of $90,000 or approximately 10%. The increase resulted primarily from a higher term loan balance in 2021 compared to 2020 due to the interest in-kind which was added to the total outstanding principal loan amount.

Other expense, net

	Year Ended December 31,		Change	
	2021	2020	$	%
	(in thousands, except percentages)			
Other expense, net	$ 203	$ 289	$ (86)	(30)%

During the year ended December 31, 2021, we had other expense, net, of $203,000 as compared to $289,000 for the year ended December 31, 2020.

Loss from minority interest in limited liability company

	Year Ended December 31,		Change	
	2021	2020	$	%
	(in thousands, except percentages)			
Loss from minority interest in limited liability company	$ 256	$ 383	$ (127)	(33)%

The Company uses the equity method to account for its investment in InControl Medical, LLC ("ICM"). For the years ended December 31, 2021 and 2020, the allocated net loss from ICM's operations was $256,000 and $383,000, respectively.

Liquidity and Capital Resources

Comparison of the Year Ended December 31, 2021 and 2020

Since inception, the Company has sustained significant operating losses and such losses are expected to continue for the foreseeable future. At December 31, 2021, we had accumulated deficit of $241,853,000, cash and cash equivalents of $19,162,000 and working capital of $17,705,000. The Company's financing activities provided cash of $25,973,000 during the year ended December 31, 2021, which was primarily due to the net proceeds from the January 2021 Offering. However, we used $12,878,000 in cash for operations during the year ended December 31, 2021. As of the date our financial statements for the year ended December 31, 2021 are issued, we did not have sufficient cash to fund our operations through March 31, 2023, without additional financing and, therefore, we concluded there was substantial doubt about our ability to continue as a going concern within one year after the date the financial statements are issued.

Management currently believes that it will be necessary for us to raise additional funding. We may obtain additional funding in the future through the issuance of our common stock, or through other equity or debt financing. The failure to raise additional funding when needed could have a material adverse effect on our business and financial condition. We may not be able to obtain additional financing as needed on acceptable terms, or at all, which may require us to reduce our operating costs and other expenditures, including reductions of personnel, salaries and capital expenditures. Alternatively, or in addition to such potential measures, we may elect to implement additional cost reduction actions as we may determine are necessary and in our best interests. Any such actions undertaken might limit the Company's ability to achieve its strategic objectives.

The following table summarizes the primary sources and uses of cash for the periods presented below (in thousands):

	Year Ended December 31,	
	2021	2020
Net cash used in operating activities	$ (12,878)	$ (15,234)
Net cash used in investing activities	(456)	(781)
Net cash provided by financing activities	25,973	9,230
Net increase (decrease) in cash and cash equivalents	$ 12,639	$ (6,785)

Operating Activities

We have incurred, and expect to continue to incur, significant expenses in the areas of research and development, regulatory and clinical study costs associated with the Viveve System.

Operating activities used $12,878,000 of cash for the year ended December 31, 2021 compared to $15,234,000 used for the year ended December 31, 2020. The primary use of our cash was to fund selling, general and administrative expenses and research and development expenses associated with the Viveve System. Net cash used during the year ended December 31, 2021 consisted of a net loss of $22,027,000 adjusted for noncash expenses including provision for doubtful accounts of $125,000, depreciation and amortization of $1,123,000, stock-based compensation of $3,779,000, non-cash interest expense of $606,000, amortization of operating lease right-of-use assets and accretion of operating lease liabilities of $16,000, a loss from minority interest in limited liability company of $256,000, a loss on disposal of property and equipment of $113,000, a noncash charge for the modification of Series B, A-2 and B-2 warrants of $373,000, a gain on the extinguishment of debt of $1,358,000 related to forgiveness of the PPP Loan and cash inflows from changes in operating assets and liabilities of $4,116,000. The change in operating assets and liabilities was primarily due to a decrease in accounts receivable of $96,000, a decrease in inventory of $2,207,000, an increase in prepaid expenses and other current assets of $24,000, a decrease in other noncurrent assets of $320,000, an increase in accounts payable $599,000, an increase in accrued and other liabilities of $553,000, and an increase of other noncurrent liabilities of $365,000.

Net cash used during the year ended December 31, 2020 consisted of a net loss of $21,915,000 adjusted for noncash expenses including provision for doubtful accounts and the write-off of accounts receivable of $454,000, depreciation and amortization of $1,295,000, stock-based compensation of $2,651,000, non-cash interest expense of $535,000, amortization of operating lease right-of-use assets and accretion of operating lease liabilities of $2,000, a loss from minority interest in limited liability company of $383,000, a loss on disposal of property and equipment of $20,000, a noncash charge for the modification of Series A and B warrants of $1,838,000, and cash outflows from changes in operating assets and liabilities of $497,000. The change in operating assets and liabilities was primarily due to a decrease in accounts receivable of $349,000, a decrease in inventory of $1,360,000, a decrease in prepaid expenses and other current assets of $151,000, a decrease in other noncurrent assets of $461,000, a decrease in accounts payable $727,000, a decrease in accrued and other liabilities of $2,422,000, and an increase of other noncurrent liabilities of $331,000.

Investing Activities

Net cash used in investing activities during the years ended December 31, 2021 and 2020 was $456,000 and $781,000, respectively. Net cash used in investing activities during 2021 and 2020 was used for the purchase of property and equipment. The purchase of property and equipment primarily consisted of rental equipment in connection with our recurring revenue rental program, which was launched in June 2019. We expect to continue to purchase property and equipment in the normal course of our business. The amount and timing of these purchases and the related cash outflows in future periods is difficult to predict and is dependent on a number of factors including, but not limited to, any increase in the number of our employees and any changes to the capital equipment requirements related to our development programs and clinical trials.

Financing Activities

Net cash provided by financing activities during year ended December 31, 2021 was $25,973,000, which was the result of proceeds of $25,122,000 from the January 2021 Offering net of issuance costs, proceeds of $704,000 from purchase of common shares in connection with the Purchase Agreement with LPC, proceeds of $179,000 from exercises of common warrants and $38,000 of proceeds from issuance of common shares from employee stock purchase plan, partially offset by transaction costs of $70,000 in connection with the Purchase Agreement with LPC. As of December 31, 2021, the equity facility with LPC has a remaining financing commitment of approximately $9,000,000.

Net cash provided by financing activities during year ended December 31, 2020 was $9,230,000, which was the result of net proceeds of $8,407,000 from exercises of common warrants, proceeds of $1,343,000 from the PPP Loan and proceeds of $341,000 from the initial purchase of common shares under the Purchase agreement from LPC, partially offset by transaction costs of $334,000 in connection with the 2020 Warrant Offering, transaction costs of $494,000 in connection with the Purchase Agreement with LPC, and additional transaction costs of $33,000 in connection with our November 2019 Offering.

On July 2, 2021, we filed a universal shelf registration statement with the SEC on Form S-3 for the proposed offering from time to time of up to $75,000,000 of our securities, including common stock, preferred stock, and/or warrants. This registration statement currently has a capacity of $75,000,000. However, as a result of the limitations of General Instruction I.B.6. of Form S-3, or the so-called “baby shelf rules”, the amount of shares of our common stock available for sale under a registration statement on Form S-3 is limited to one-third of the aggregate market value of our common equity held by non-affiliates of the Company over any rolling 12-month period. As of December 31, 2021, we have not issued any shares or received any proceeds pursuant to the universal shelf registration statement.

Contractual Payment Obligations

In February 2017, we entered into a sublease for approximately 12,400 square feet of building space for the relocation of the Company’s corporate headquarters to Englewood, Colorado. The lease term was 36 months and the monthly base rent for the first, second and third years was $20.50, $21.12 and $21.75 per rentable square foot, respectively. In connection with the execution of the sublease, the Company paid a security deposit of approximately $22,000. The Company was also entitled to an allowance of approximately $88,000 for certain tenant improvements relating to the engineering, design and construction of the sublease premises. The lease term commenced in June 2017 and was to terminate in May 2021. In March 2021, the Company amended the sublease for its office building space. The lease term was extended for a period of 34 months and will terminate on March 31, 2024. The monthly gross rent for the first, second and third years of the lease extension is $21,028, $21,643 and $22,258 per month, respectively. The Company was also provided a rent abatement for the month of June 2021. Additionally, the sublandlord agreed to perform certain construction, repair, maintenance or other tenant improvements to the subleased premises with estimated costs of approximately $19,000.

In May 2017, the Company entered into the 2017 Loan Agreement with affiliates of CRG LP (“CRG”). The credit facility consists of $20,000,000 that was drawn at closing and the ability to access additional funding of up to an aggregate of $10,000,000 for a total of $30,000,000 under the credit facility. In December 2017, the Company accessed the remaining $10,000,000 available under the CRG credit facility. The term of the loan is six years with the first four years being interest only. In November 2019, the Company and CRG amended the 2017 Loan Agreement concurrent with the conversion of approximately $29,000,000 of the principal amount under the term loan with CRG (plus accrued interest, the prepayment premium and the back-end fee applicable thereto), for an aggregate amount of converted debt obligations of approximately $31,300,000. The amounts converted into 31,300 shares of the newly authorized Series B convertible preferred stock and warrants to purchase up to 989,379 shares of common stock were also issued. The outstanding principal balance under the 2017 Loan Agreement was $5,124,000 as of December 31, 2021.

In October 2020, the Company entered into a 36-month noncancelable operating lease agreement for office equipment. The lease commenced in December 2020 and will terminate in December 2023. The monthly payment is approximately $2,000.

Critical Accounting Policies and Estimates

The discussion and analysis of financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in conformity with accounting principles generally accepted in the United States of America. 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 our management or can be materially affected by changes from period to period in economic factors or conditions that are outside of our control. As a result, they are subject to an inherent degree of uncertainty. In applying these policies, management uses their judgment to determine the appropriate assumptions to be used in the determination of certain estimates. Those estimates are based on our historical operations, our future business plans and projected financial results, the terms of existing contracts, observance of trends in the industry, information provided by our customers and information available from other outside sources, as appropriate. Please see Note 2 to our consolidated financial statements for a more complete description of our significant accounting policies.

Inventory

Inventory is stated at the lower of cost or net realizable value. Cost is determined on an actual cost basis on a first-in, first-out method. Inventory as of December 31, 2021 and 2020 is mainly finished goods but also includes a small quantity of raw materials. Lower of cost or net realizable value is evaluated by considering obsolescence, excessive levels of inventory, deterioration and other factors. Adjustments to reduce the cost of inventory to its net realizable value, if required, are made for estimated excess, obsolescence or impaired inventory. Excess and obsolete inventory is charged to cost of revenue and a new lower-cost basis for that inventory is established and subsequent changes in facts and circumstances do not result in the restoration or increase in that newly established cost basis.

As part of the Company's recurring revenue rental model, the Company utilizes Viveve Systems transferred from finished goods inventory. The Company is amortizing these units over an estimated useful life of five years. The amortization of these Viveve Systems is charged to cost of sales and these units are included in the property and equipment, net balance on the consolidated balance sheets as of December 31, 2021 and 2020.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable. When such an event occurs, management determines whether there has been an impairment by comparing the anticipated undiscounted future net cash flows to the related asset's carrying value. If an asset is considered impaired, the asset is written down to fair value, which is determined based either on discounted cash flows or appraised value, depending on the nature of the asset. The Company has not identified any such impairment losses to date.

Revenue from Contracts with Customers

Revenue consists primarily of the sale of the Viveve System, single-use treatment tips and ancillary consumables. The Company applies the following five steps: (1) identify the contract with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract, and (5) recognize revenue when a performance obligation is satisfied. The Company considers customer purchase orders to be the contracts with a customer. Revenue, net of expected discounts, is recognized when the performance obligations of the contract with the customer are satisfied and when control of the promised goods are transferred to the customer, typically when products, which have been determined to be the only distinct performance obligations, are shipped to the customer. Expected costs of assurance warranties and claims are recognized as expense. Revenue is recognized net of any sales taxes from the sale of the products.

Rental revenue is generated through the lease of the Viveve System. The Company's operating leases for the Viveve System have a rental period of 6s to 12 months and can be extended or terminated by the customer after that time or the Viveve System can be purchased by the customer. Rental revenue on those operating leases is recognized on a straight-line basis over the terms of the underlying leases. For the years ended December 31, 2021 and 2020, rental revenue recognized was $1,214,000 and $1,337,000. As of December 31, 2021 and 2020, the Company had deferred revenue in the amount of $452,000 and $345,000 related to its rental program.

In connection with the lease of the Viveve System, the Company offers single-use treatment tips and ancillary consumables that are considered non-lease components. In the contracts with lease and non-lease components, the Company follows the relevant guidance in ASC 606, Revenue from Contracts with Customers, to determine how to allocate contractual consideration between the lease and non-lease components.

Sales of our products are subject to regulatory requirements that vary from country to country. The Company has regulatory clearance for differing indications, or can sell its products without a clearance, in many countries throughout the world, including countries within the following regions: North America, Latin America, Europe, the Middle East and Asia Pacific. In the United States, we market and sell primarily through a direct sales force. Outside of the United States, we market and sell primarily through distribution partners.

The Company does not provide its customers with a right of return.

Allowance for Doubtful Accounts

We make ongoing assumptions relating to the collectability of our accounts receivable in our calculation of the allowance for doubtful accounts. In determining the amount of the allowance, we make judgements about the creditworthiness of customers based on ongoing credit evaluations and assess current economic trends affecting our customers that might impact the level of credit losses in the future and result in different rates of bad debts than previously seen. We also consider our historical level of credit losses. As of December 31, 2021 and 2020, the allowance for doubtful accounts was $66,000 and $124,000, respectively.

Product Warranty

The Company's products are generally subject to a one-year warranty, which provides for the repair, rework or replacement of products (at the Company's option) that fail to perform within stated specification. The Company has assessed the historical claims and, to date, product warranty claims have not been significant.

Research and Development

Research and development costs are charged to operations as incurred. Research and development costs include, but are not limited to, payroll and personnel expenses, prototype materials, laboratory supplies, consulting costs, and allocated overhead, including rent, equipment depreciation, and utilities.

Income Taxes

Accounting for income taxes requires that deferred tax assets and liabilities be recognized using enacted tax rates for the effect of temporary differences between the book and tax bases of recorded assets and liabilities. The liability method is used in accounting for income taxes. Deferred tax assets and liabilities are determined based on the differences between financial reporting and the tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Deferred tax assets may be reduced by a valuation allowance if it is more likely than not that some or all of the deferred tax asset will not be realized. We evaluate annually the realizability of our deferred tax assets by assessing our valuation allowance and by adjusting the amount of such allowance, if necessary. The factors used to assess the likelihood of realization include our forecast of future taxable income and available tax planning strategies that could be implemented to realize the net deferred tax assets. As of December 31, 2021 and 2020, the Company has recorded a full valuation allowance for our deferred tax assets based on our historical losses and the uncertainty regarding our ability to project future taxable income. In future periods if we are able to generate income, we may reduce or eliminate the valuation allowance.

Accounting for Uncertainty in Income Taxes

We consider many factors when evaluating and estimating our tax positions and tax benefits, which may require periodic adjustments, and which may not accurately anticipate actual outcomes. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement. Whether the more-likely-than-not recognition threshold is met for a tax position is a matter of judgment based on the individual facts and circumstances of that position evaluated in light of all available evidence.

Accounting for Stock-Based Compensation

Stock-based compensation cost is measured at grant date, based on the fair value of the award, and is recognized as expense over the employee's service period. The Company recognizes compensation expense on a straight-line basis over the requisite service period of the award.

We determined that the Black-Scholes option pricing model is the most appropriate method for determining the estimated fair value for stock options and purchase rights under the Company's employee stock purchase plan. The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions which determine the fair value of share-based awards, including the option's expected term and the price volatility of the underlying stock.

Equity instruments issued to nonemployees are recorded in the same manner as similar instruments issued to employees.

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, as amended, which revises the measurement of credit losses for most financial instruments measured at amortized cost, including trade receivables, from an incurred loss methodology to an expected loss methodology which results in earlier recognition of credit losses. Under the incurred loss model, a loss is not recognized until it is probable that the loss-causing event has already occurred. The new standard introduces a forward-looking expected credit loss model that requires an estimate of the expected credit losses over the life of the instrument by considering all relevant information including historical experience, current conditions, and reasonable and supportable forecasts that affect collectability. The guidance in ASU 2016-13 is effective for the Company for financial statements issued for fiscal years beginning after December 15, 2022 and interim periods within those fiscal years, with early adoption permitted. The Company is still evaluating the impact of the adoption of this standard.

In December 2019, the FASB issued ASU 2019-12, "Income Taxes (Topic 740). The amendments in this Update provide further simplification of accounting standards for the accounting for income taxes. Certain exceptions for are removed and requirements regarding the accounting for franchise taxes, tax basis of goodwill, and tax law rate changes are made. This guidance is effective for annual reporting periods beginning after December 15, 2020, including interim periods within that reporting period, with early adoption permitted. We adopted this guidance as of January 1, 2021 and the adoption of the guidance did not have a significant impact on the consolidated financial statements.

We have reviewed other recent accounting pronouncements and concluded they are either not applicable to the business, or no material effect is expected on the consolidated financial statements as a result of future adoption.

Trends, Events and Uncertainties

Research, development and commercialization of new technologies and products is, by its nature, unpredictable. Although we will undertake development efforts, including efforts, with commercially reasonable diligence, there can be no assurance that we will have adequate capital to develop or commercialize our technology to the extent needed to create future sales to sustain our operations.

We cannot assure you that our technology will be adopted, that we will ever earn revenue sufficient to support our operations, or that we will ever be profitable. Furthermore, since we have no committed source of financing, we cannot assure you that we will be able to raise money as and when we need it to continue our operations. If we cannot raise funds as and when we need them, we may be required to severely curtail, or even to cease, our operations.

Other than as discussed above and elsewhere in this Annual Report on Form 10-K, we are not aware of any trends, events or uncertainties that are likely to have a material effect on our financial condition.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, the Company is not required to provide information required by this Item.

Item 8. Financial Statements and Supplementary Data

See pages beginning with page F-1.

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

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal accounting and financial officer, as appropriate, to allow timely decisions regarding required disclosure.

We carried out an evaluation under the supervision and with the participation of management, including our principal executive officer and our principal accounting and financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2021, the end of the period covered by this Annual Report on Form 10-K. Based upon the evaluation of our disclosure controls and procedures as of December 31, 2021, our Chief Executive Officer (principal executive officer) and our Senior Vice President of Finance and Administration (principal accounting and financial officer) concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level. In addition, our ability to maintain an effective internal control environment has not been impacted by the COVID-19 pandemic.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive officer and principal accounting and financial officer and effected by our board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of our inherent limitations, our internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2021. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control – Integrated Framework (2013 Framework).* Based on this assessment, our management, with the participation of our Chief Executive Officer (principal executive officer) and our Senior Vice President of Finance and Administration (principal accounting and financial officer), has concluded that, as of December 31, 2021, our internal control over financial reporting was effective based on those criteria.

Changes in Internal Control over Financial Reporting

There were no changes during the last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

On March 14, 2022, the Company filed a Certificate of Elimination (the "Series C Certificate of Elimination") with the Delaware Secretary of State with respect to 2,450,880 authorized shares of Series C Convertible Preferred Stock, par value $0.0001 per share (the "Series C Preferred Stock"). The Series C Preferred Stock had been designated pursuant to the Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock filed with the Delaware Secretary of State on January 15, 2021. As of the date of the filing of the Series C Certificate of Elimination, no shares of Series C Preferred Stock were outstanding. Upon filing the Series C Certificate of Elimination, the 2,450,880 shares of Series C Preferred Stock were returned to the status of authorized but unissued shares of preferred stock of the Company, without designation as to series or rights, preferences, privileges or limitations.

The foregoing summary of the Series C Certificate of Elimination is qualified in its entirety by reference to the full text of the Series C Certificate of Elimination, which is filed as an exhibit to this Annual Report on Form 10-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

Our independent public accounting firm is BPM LLP, San Jose, CA, PCAOB Auditor ID 207.

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

Financial Statements

See Index to Consolidated Financial Statements at Item 8 herein.

Financial Statement Schedules have been omitted as they are either not required, not applicable, or the information is otherwise included.

Exhibit Index

Exhibit No.	Description
2.1	Agreement and Plan of Merger dated May 9, 2014 by and among Viveve, Inc., PLC Systems, Inc. and PLC Systems Acquisition Corporation (1)
2.1.1	Amendment to Agreement and Plan of Merger (1)
2.2	RenalGuard Reorganization Agreement (2)
3.1	Certificate of Conversion for Delaware (3)
3.2	Amended and Restated Certificate of Incorporation (4)
3.3	Articles of Amendment to the Articles of Continuance of Viveve Medical, Inc. (5)
3.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation (6)
3.5	Certificate of Amendment to the Amended and Restated Certificate of Incorporation dated November 30, 2020 (33)
3.6	Certificate of Elimination of Series A Preferred Stock (34)
3.7	Certificate of Designation of Preferences, Rights and Limitations of Series B Preferred Stock (7)
3.8	Form of Certificate of Designation of Preferences, Rights and Limitations of Series C Preferred Stock (36)
3.9	Certificate of Elimination of Series C Preferred Stock*
3.10	Amended and Restated Bylaws (4)
3.11	Amendment to the Amended and Restated Bylaws (38)
4.1	Common Stock Purchase Warrant issued on February 17, 2015 to Scott Durbin (8) +
4.2	Common Stock Purchase Warrant issued on February 17, 2015 to Jim Robbins (8) +
4.3	Common Stock Purchase Warrant issued on February 17, 2015 to Patricia Scheller (8) +
4.4	Common Stock Purchase Warrant issued on May 12, 2015 to James Atkinson (8) +
4.5	Common Stock Purchase Warrant issued on December 16, 2015 to James Atkinson (8) +
4.6	Common Stock Purchase Warrant issued on December 16, 2015 to Jim Robbins (8) +
4.7	Common Stock Purchase Warrant issued on April 1, 2016 to Dynamic Medical Technologies (Hong Kong) Limited (3)
4.8	Common Stock Purchase Warrant issued on May 11, 2016 to Theresa Stern (9)
4.9	Common Stock Purchase Warrant issued on May 11, 2016 to Chris Rowan (9)
4.10	Common Stock Purchase Warrant issued on June 20, 2016 to Western Alliance Bank (10)
4.11	Common Stock Purchase Warrant, dated May 25, 2017, by and between the Registrant and CRG Partners III - Parallel Fund "A" L.P. (11)
4.12	Common Stock Purchase Warrant, dated May 25, 2017, by and between the Registrant and CRG Partners III L.P. (11)
4.13	Form of Series A/B Common Stock Purchase Warrant issued on November 26, 2019 (7)
4.14	Form of Series A-2/B-2 Common Stock Purchase Warrant issued on April 20, 2020 (30)
4.15	Form of Common Stock Purchase Warrant issued to affiliates of CRG LP on November 26, 2019 (7)
4.16	Form of Common Stock Purchase Warrant for the 2021 Warrants (35)
4.17	Warrant Agent Agreement by and between VStock Transfer LLC and the Registrant (7)
4.18	Form of Warrant Agent Agreement by and between VStock Transfer LLC and the Registrant, effective January 2021 (35)
4.19	Specimen Common Stock Certificate (12)
4.20	Description of Securities*
10.1	Intellectual Property Assignment and License Agreement dated February 10, 2006, as amended, between Dr. Edward Knowlton and TivaMed, Inc (13)
10.2	Amended and Restated Development and Manufacturing Agreement dated October 4, 2007 between TivaMed, Inc. and Stellartech Research Corporation (13)
10.3	Sublease Agreement, entered into on February 1, 2017 and effective as of January 26, 2017, between the Registrant and Ingredion Incorporated (16)
10.4	Settlement and License Agreement by and among the Registrant, ThermiGen LLC and ThermiAesthetics LLC, dated June 3, 2018. (24)†

10.5	Membership Subscription Agreement, dated August 1, 2017, by and between the Registrant and InControl Medical, LLC (18)
10.6	Employment Agreement by and between the Registrant and James G. Atkinson, dated February 27, 2018 (14)+
10.7	Amended and Restated Employment Agreement by and between the Registrant and Scott C. Durbin, dated May 11, 2018. (23) +
10.8	Amended and Restated Employment Agreement by and between the Registrant and Jim Robbins, dated May 11, 2018. (23) +
10.10	Amended and Restated 2013 Stock Option and Incentive Plan and amendment thereto (20) +
10.11	2017 Employee Stock Purchase Plan (21) +
10.12	Forms of Indemnification Agreement (28) +
10.13	Security Agreement, dated May 25, 2017, by and among the Registrant, Viveve, Inc. and CRG Servicing LLC (11)
10.14	Patent and Trademark Security Agreement, dated May 25, 2017, by and among the Registrant, Viveve, Inc. and CRG Servicing LLC (11)
10.15	Term Loan Agreement, dated May 22, 2017, among the Registrant, Viveve, Inc., CRG Servicing LLC, as administrative agent, and certain lenders (17)
10.16	Waiver No. 2 to Loan Agreement, dated December 12, 2017, among the Registrant, CRG Servicing LLC and the lenders party thereto (19)
10.17	Amendment No. 2 to Loan Agreement, dated November 29, 2018, among the Registrant, CRG Servicing LLC, as administrative agent and collateral agent, the lenders from time to time party thereto and Viveve, Inc., as subsidiary guarantor (25)
10.18	Amendment No. 3 to the Loan Agreement, dated as of November 12, 2019, by and between the Registrant and CRG LP (26)
10.19	Form of Registration Rights Agreement by and between the Registrant and CRG LP entered into on November 26, 2019 (26)
10.20	Series B Preferred Stock and Warrant Purchase Agreement, dated as of November 12, 2019, by and between the Registrant and affiliates of CRG LP (26)
10.21	Amendment No. 1 to the Series B Preferred Stock and Warrant Purchase Agreement, dated as of November 20, 2019, by and between the Registrant and affiliates of CRG LP (7)
10.22	Lock-Up Agreement between affiliates of CRG LP and Ladenburg Thalmann & Co. Inc., dated as of November 12, 2019 (26)
10.23	Form of Inducement Letter (29)
10.24	Purchase Agreement between the Registrant and Lincoln Park Capital, LLC dated June 8, 2020 (31)
10.25	Registration Rights Agreement between the Registrant and Lincoln Park Capital, LLC dated June 8, 2020 (31)
10.26	First Amendment to Purchase Agreement, dated March 31, 2021, by and between Viveve Medical, Inc. and Lincoln Park Capital Fund, LLC (37).
10.27	Form of Retention Bonus Agreement (39) +
14.1	Code of Conduct, adopted September 23, 2014 (27)
21	List of the Registrants Subsidiaries (22)
23.1	Consent of BPM LLP, independent registered public accounting firm*
24.1	Power of Attorney* (included on signature page hereto)
31.1	Certification of the Company's Principal Executive Officer pursuant to 15d-15(e), under the Securities and Exchange Act of 1934*
31.2	Certification of the Company's Principal Accounting and Financial Officer pursuant to 15d-15(e), under the Securities and Exchange Act of 1934*
32.1	Certification of the Company's Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
32.2	Certification of the Company's Principal Accounting and Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema Document*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document*
104	Cover Page Interactive Data File (embedded within the Inline XBRL document) *

* Filed herewith.

** This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended (the "Exchange Act"), except to the extent specifically incorporated by reference into such filing.

\+ Management contract or compensation plan, contract or arrangement.

† Certain provisions of this exhibit have been omitted pursuant to a request for confidential treatment.

(1) Incorporated by reference to Annex A to the Registrant's Definitive Proxy Statement on Schedule 14A filed with the SEC on August 11, 2014.
(2) Incorporated by reference to Annex B to the Registrant's Definitive Proxy Statement on Schedule 14A filed with the SEC on August 11, 2014.
(3) Incorporated by reference from the Form 10-Q filed with the SEC on May 13, 2016.
(4) Incorporated by reference from the Form 8-K filed with the SEC on August 17, 2017.
(5) Incorporated by reference from the Form 8-K filed with the SEC on April 14, 2016.
(6) Incorporated by reference from the Form 8-K filed with the SEC on September 18, 2019.
(7) Incorporated by reference from the Form S-1/A filed with the SEC on November 21, 2019.
(8) Incorporated by reference from the Form 10-K filed with the SEC on March 24, 2016.
(9) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 11, 2016.
(10) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on June 21, 2016.
(11) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on June 1, 2017.
(12) Incorporated by reference to the Registrant's Registration Statement on Form S-8 filed with the SEC on October 5, 2017.
(13) Incorporated by reference to the Registrant's on Form S-1 filed with the SEC on November 21, 2014.
(14) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on March 1, 2018.
(16) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on February 3, 2017.
(17) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on May 24, 2017.
(18) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 8, 2017.
(19) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on December 14, 2017.
(20) Incorporated by reference to the Registrant's Proxy Statement on Schedule 14A filed with the SEC on August 19, 2019.
(21) Incorporated by reference to the Registrant's Proxy Statement on Schedule 14A filed with the SEC on July 7, 2017.
(22) Incorporated by reference to the Registrant's Annual Report on Form 10-K filed with the SEC on February 16, 2017.
(23) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on May 17, 2018.
(24) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2018.
(25) Incorporated by reference to the Registrant's Quarterly Report on Form 8-K filed with the SEC on December 4, 2018.
(26) Incorporated by reference from the Form S-1/A filed with the SEC on November 13, 2019.
(27) Incorporated by reference to the Registrant's Annual Report on Form 10-K filed with the SEC on March 16, 2015.
(28) Incorporated by reference to the Registrant's Annual Report on Form 10-K filed with the SEC on March 16, 2018.
(29) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on April 17, 2020.
(30) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on April 24, 2020.
(31) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on June 10, 2020.
(32) Incorporated by reference from the Form 10-K filed with the SEC on March 19, 2020.
(33) Incorporated by reference from the Form 8-K filed with the SEC on December 1, 2020.
(34) Incorporated by reference from the Form 8-K filed with the SEC on December 17, 2020.
(35) Incorporated by reference to the Registrant's Registration Statement on Form S-1 filed with the SEC on January 12, 2021.
(36) Incorporated by reference from the Form 8-K filed with the SEC on January 19, 2021.
(37) Incorporated by reference from the Form 8-K filed with the SEC on March 31, 2021.
(38) Incorporated by reference from the Form 8-K filed with the SEC on June 16, 2021.
(39) Incorporated by reference from the Form 8-K filed with the SEC on January 21, 2022.

Item 16. Form 10-K Summary.

Not applicable.

SIGNATURES

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

VIVEVE MEDICAL, INC.
(Registrant)

March 17, 2022

By: /s/ Scott Durbin
Scott Durbin
Chief Executive Officer

POWER OF ATTORNEY

We, the undersigned officers and directors of Viveve Medical, Inc., hereby severally constitute and appoint Scott Durbin and Jim Robbins, and each of them singly (with full power to each of them to act alone), our true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution in each of them for him or her and, place and stead, and in any and all capacities, to sign conformed for us and in our names in the capacities indicated below any and all signatures and amendments to this report, and to file the same, with all exhibits thereto filing date and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as full to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitute or substitutes, may lawfully 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/Scott Durbin Scott Durbin	Chief Executive Officer and Director (Principal Executive Officer)	March 17, 2022
/s/Jim Robbins Jim Robbins	Senior Vice President of Finance and Administration (Principal Accounting and Financial Officer)	March 17, 2022
/s/Steven Basta Steven Basta	Chairman of the Board of Directors	March 17, 2022
/s/Debora Jorn Debora Jorn	Director	March 17, 2022
/s/Arlene Morris Arlene Morris	Director	March 17, 2022
/s/Sharon Collins Presnell Sharon Collins Presnell	Director	March 17, 2022

VIVEVE MEDICAL, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report Of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of
Viveve Medical, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Viveve Medical, Inc. and its 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 two years in the period ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the 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 two years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that Viveve Medical, Inc. and its subsidiaries will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company's recurring losses from operations, available cash and accumulated deficit 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 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our 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 consolidated 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 consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our 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 consolidated 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 consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Inventory Valuation - Adjustments for Excess or Obsolete Inventory

As described in Note 2 to the consolidated financial statements, the Company's consolidated inventory balance was $1.5 million as of December 31, 2021. The Company's inventory is stated at the lower of cost, which is determined on an actual cost basis on a first-in, first-out method, or net realizable value. The Company evaluates the net realizable value by considering obsolescence, excessive levels of inventory, deterioration and other factors. Adjustments to reduce the cost of inventory to its net realizable value, if required, are made for estimated excess, obsolescence or impaired inventory. If actual demand were to be substantially lower than estimated, there could be a significant adverse impact on the carrying value of the inventory and results of operations.

The principal considerations for our determination that performing procedures relating to adjustments for excess or obsolete inventory is a critical audit matter are the significant amount of judgement by management in developing the assumptions of the forecasted product demand, which in turn led to significant auditor judgement, subjectivity, and effort in performing audit procedures and evaluating audit evidence relating to the forecasted product demand. Additionally, for certain new product launches or sales channels there may be limited historical data with which to evaluate forecasts.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others, testing management's process for developing the estimate of the adjustments for excess or obsolete inventory, testing the completeness and accuracy of the underlying data used in the estimate, and evaluating management's assumptions of forecasted product demand. Evaluating management's demand forecast for reasonableness involved considering historical sales of its products, comparing prior period estimates to actual results of the same period, and determining whether the demand forecast used was consistent with evidence obtained in other areas of the audit.

/s/ BPM LLP

We have served as the Company's auditor since 2013.

San Jose, California
March 17, 2022

VIVEVE MEDICAL, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,162	$ 6,523
Accounts receivable, net of allowance for doubtful accounts of $66 and $124 as of December 31, 2021 and 2020, respectively	549	770
Inventory	1,472	3,254
Prepaid expenses and other current assets	1,055	1,031
Total current assets	22,238	11,578
Property and equipment, net	1,554	2,759
Investment in limited liability company	577	833
Other assets	1,544	1,460
Total assets	$ 25,913	$ 16,630
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,480	$ 881
Accrued liabilities	3,053	2,416
Paycheck Protection Program loan, current portion	-	918
Total current liabilities	4,533	4,215
Note payable, noncurrent portion	5,124	4,518
Paycheck Protection Program loan, noncurrent portion	-	425
Other noncurrent liabilities	1,190	498
Total liabilities	10,847	9,656
Commitments and contingences (Note 10)		
Stockholders' equity:		
Convertible preferred stock;		
10,000,000 shares authorized as of December 31, 2021 and 2020;		
Series B preferred stock, $0.0001 par value; 40,504 and 35,819 shares issued and outstanding as of December 31, 2021 and 2020, respectively	-	-
Series C preferred stock, $0.0001 par value; 0 shares issued and outstanding as of December 31, 2021	-	-
Common stock, $0.0001 par value;		
75,000,000 shares authorized as of December 31, 2021 and 2020;		
10,619,846 and 2,171,316 shares issued and outstanding as of December 31, 2021 and 2020, respectively	1	-
Additional paid-in capital	256,918	226,800
Accumulated deficit	(241,853)	(219,826)
Total stockholders' equity	15,066	6,974
Total liabilities and stockholders' equity	$ 25,913	$ 16,630

The accompanying notes are an integral part of these consolidated financial statements.

VIVEVE MEDICAL, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	Year Ended December 31,	
	2021	**2020**
Revenue	$ 6,426	$ 5,479
Cost of revenue	5,806	5,183
Gross profit	620	296
Operating expenses:		
Research and development	9,665	5,125
Selling, general and administrative	12,508	13,666
Total operating expenses	22,173	18,791
Loss from operations	(21,553)	(18,495)
Gain on forgiveness of Paycheck Protection Program loan	1,358	-
Modification of warrants	(373)	(1,838)
Interest expense, net	(1,000)	(910)
Other expense, net	(203)	(289)
Net loss from consolidated companies	(21,771)	(21,532)
Loss from minority interest in limited liability company	(256)	(383)
Comprehensive and net loss	(22,027)	(21,915)
Series B convertible preferred stock dividends	(4,691)	(4,149)
Net loss attributable to common stockholders	$ (26,718)	$ (26,064)
Net loss per share of common stock:		
Basic and diluted	$ (2.65)	$ (16.56)
Weighted average shares used in computing net loss per common share:		
Basic and diluted	10,089,722	1,573,528

Note: All share and per share data has been adjusted to reflect the 1-for-10 reverse stock split which became effective after market close on December 1, 2020, as discussed in Note 2.

The accompanying notes are an integral part of these consolidated financial statements.

VIVEVE MEDICAL, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For each of the two years in the period ended December 31, 2021
(in thousands, except share data)

	Serie A Convertible Preferred Stock, $0.0001 par value		Serie B Convertible Preferred Stock, $0.0001 par value		Series C Convertible Preferred Stock, $0.0001 par value		Common Stock, $0.0001 par value		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balances as of January 1, 2020	**185,218**	**$ -**	**31,678**	**$ -**	**-**	**$ -**	**707,571**	**$ -**	**$ 214,432**	**$ (197,911)**	**$ 16,521**
Issuance costs in connection with November 2019 Offering	-	-	-	-	-	-	-	-	(33)	-	(33)
Conversion of Series A convertible preferred stock into common stock	(185,218)	-	-	-	-	-	185,218	-	-	-	-
Issuance of common shares in connection with Series A and B common warrant exercises	-	-	-	-	-	-	1,115,863	-	7,814	-	7,814
Issuance of common shares in connection with Series A-2 and B-2 common warrant exercises	-	-	-	-	-	-	93,129	-	593	-	593
Modification of Series A and B warrants in connection with 2020 Warrant Offering	-	-	-	-	-	-	-	-	1,838	-	1,838
Issuance of Series A-2 and B-2 warrants in connection with 2020 Warrant Offering	-	-	-	-	-	-	-	-	1,838	-	1,838
Issuance costs for Series A-2 and B-2 warrants in connection with 2020 Warrant Offering	-	-	-	-	-	-	-	-	(1,838)	-	(1,838)
Transaction costs in connection with 2020 Warrant Offering	-	-	-	-	-	-	-	-	(334)	-	(334)
Issuance of initial purchase common shares under the Purchase Agreement with LPC	-	-	-	-	-	-	52,500	-	341	-	341
Issuance costs in connection with Purchase Agreement with LPC	-	-	-	-	-	-	-	-	(494)	-	(494)
Series B convertible preferred stock dividends	-	-	-	-	-	-	-	-	(4,149)	-	(4,149)
Series B convertible preferred stock dividends paid in PIK shares	-	-	4,141	-	-	-	-	-	4,141	-	4,141
Stock-based compensation expense	-	-	-	-	-	-	-	-	2,577	-	2,577
Issuance of common shares from employee stock purchase plan	-	-	-	-	-	-	84	-	-	-	-
Issuance of common shares for vesting of restricted stock award granted to consultant	-	-	-	-	-	-	25	-	-	-	-
Issuance of restricted common shares in connection with consulting agreement	-	-	-	-	-	-	10,995	-	74	-	74
Reverse stock split - rounding adjustment	-	-	-	-	-	-	5,931	-	-	-	-
Net loss	-	-	-	-	-	-	-	-	-	(21,915)	(21,915)
Balances as of December 31, 2020	**-**	**-**	**35,819**	**-**	**-**	**-**	**2,171,316**	**-**	**226,800**	**(219,826)**	**6,974**
January 2021 Offering, net of issuance costs	-	-	-	-	2,450,880	-	5,666,760	1	25,121	-	25,122
Conversion of Series C convertible preferred stock into common stock	-	-	-	-	(2,450,880)	-	2,450,880	-	-	-	-

Issuance of purchased common shares under the Purchase Agreement with LPC	-	-	-	-	-	-	250,000	-	704	-	704
Transaction costs in connection with First Amendment to Purchase Agreement with LPC	-	-	-	-	-	-	-	-	(70)	-	(70)
Issuance of common shares in connection with common warrant exercises	-	-	-	-	-	-	52,760	-	179	-	179
Modification of exercise price of common warrants	-	-	-	-	-	-	-	-	373	-	373
Dividend on Series B convertible preferred stock	-	-	-	-	-	-	-	-	(4,691)	-	(4,691)
Dividend on Series B convertible preferred stock paid in PIK shares	-	-	4,685	-	-	-	-	-	4,685	-	4,685
Stock-based compensation expense	-	-	-	-	-	-	-	-	3,779	-	3,779
Issuance of common shares from employee stock purchase plan	-	-	-	-	-	-	28,130	-	38	-	38
Net loss	-	-	-	-	-	-	-	-	-	(22,027)	(22,027)
Balances as of December 31, 2021	**-**	**$ -**	**40,504**	**$ -**	**-**	**$ -**	**10,619,846**	**$ 1**	**$ 256,918**	**$ (241,853)**	**$ 15,066**

Note: All share and per share data has been adjusted to reflect the 1-for-10 reverse stock split which became effective after market close on December 1, 2020, as discussed in Note 2.

The accompanying notes are an integral part of these consolidated financial statements.

VIVEVE MEDICAL, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (22,027)	$ (21,915)
Adjustments to reconcile net loss to net cash used in operating activities:		
Provision for doubtful accounts	125	454
Depreciation and amortization	1,123	1,295
Stock-based compensation	3,779	2,651
Non-cash interest expense	606	535
Amortization of operating lease right-of-use assets and accretion of operating lease liabilities		
Loss from minority interest in limited liability company	256	383
Loss on disposal of property and equipment	113	20
Modification of warrants	373	1,838
Forgiveness of Paycheck Protection Program loan	(1,358)	-
Changes in assets and liabilities:		
Accounts receivable	96	349
Inventory	2,207	1,360
Prepaid expenses and other current assets	(24)	151
Other noncurrent assets	320	461
Accounts payable	599	(727)
Accrued and other liabilities	553	(2,422)
Other noncurrent liabilities	365	331
Net cash used in operating activities	(12,878)	(15,234)
Cash flows from investing activities:		
Purchase of property and equipment	(456)	(781)
Net cash used in investing activities	(456)	(781)
Cash flows from financing activities:		
Proceeds from January 2021 Offering, net of issuance costs	25,122	-
Proceeds from exercise of common warrants	179	8,407
Transaction costs in connection with 2020 Warrant Offering	-	(334)
Proceeds from purchase of common shares under Purchase Agreement with LPC	704	341
Transaction costs in connection with Purchase Agreement with LPC	(70)	(494)
Proceeds from Paycheck Protection Program loan	-	1,343
Transaction costs in connection with November 2019 Offering	-	(33)
Proceeds from issuance of common shares from employee stock purchase plan	38	-
Net cash provided by financing activities	25,973	9,230
Net increase (decrease) in cash and cash equivalents	12,639	(6,785)
Cash and cash equivalents - beginning of period	6,523	13,308
Cash and cash equivalents - end of period	$ 19,162	$ 6,523
Supplemental disclosure:		
Cash paid for interest	$ -	$ -
Cash paid for income taxes	$ -	$ -
Supplemental disclosure of cash flow information as of end of period:		
Forgiveness of Paycheck Protection Program loan	$ 1,358	$ -
Issuance of Series B convertible preferred stock in settlement of dividends	$ 4,685	$ 4,141
Issuance of note payable in settlement of accrued interest	$ 602	$ 532
Net transfer of equipment between inventory and property and equipment	$ (425)	$ 247
Supplemental cash flow information related to leases was as follows:		
Operating cash outflows from operating leases	$ 195	$ 303

The accompanying notes are an integral part of these consolidated financial statements.

1. The Company and Basis of Presentation

Viveve Medical, Inc. ("Viveve Medical", the "Company", "we", "our", or "us") designs, develops, manufactures and markets a platform medical technology, which we refer to as *Cryogen-cooled Monopolar RadioFrequency* ("CMRF"). Our proprietary CMRF technology is delivered through a radiofrequency generator, handpiece and treatment tip, which collectively, we refer to as the Viveve® System. Viveve Medical competes in the women's intimate health industry in some countries by marketing the Viveve System as a way to improve the overall well-being and quality of life of women suffering from vaginal introital laxity, for improved sexual function, or stress urinary incontinence, depending on the relevant country-specific clearance or approval. In the United States, the Viveve System is currently indicated for use in general surgical procedures for electrocoagulation and hemostasis.

Effective Shelf Registration Statement

On July 2, 2021, we filed a universal shelf registration statement with the Securities and Exchange Commission (the "SEC") on Form S-3 for the proposed offering from time to time of up to $75,000,000 of our securities, including common stock, preferred stock, and/or warrants. This registration statement currently has a capacity of $75,000,000. However, as a result of the limitations of General Instruction I.B.6. of Form S-3, or the so-called "baby shelf rules", the amount of shares of our common stock available for sale under a registration statement on Form S-3 is limited to one-third of the aggregate market value of our common equity held by non-affiliates of the Company over any rolling 12-month period. As of December 31, 2021, we have not issued any shares or received any proceeds pursuant to the universal shelf registration statement.

Reduction of Common Warrant Exercise Price

On January 19, 2021, the Company closed a public offering at an effective price of $3.40 per share of its common stock. As a result, the per share exercise price of our previously issued Series B, A-2 and B-2 common stock warrants was automatically reduced pursuant to the terms of the warrants. The exercise price for Series B warrants was reduced from $6.10 per share to $3.40 per share. The exercise price for Series A-2 and B-2 warrants was reduced from $6.371 per share to $3.40 per share. There was no change to the quantity of warrant shares. As a result of this reduction of warrant exercise price, the Company recognized a modification charge of $287,000.

In February and March 2021, a total of 40,000 shares of common stock were issued in connection with the exercise of Series B warrants for gross proceeds of approximately $136,000 and a total of 12,760 shares of common stock were issued in connection with the exercise of January 2021 warrants for gross proceeds of approximately $43,000.

On May 4, 2021, pursuant to the provisions under the Purchase Agreement as amended, LPC purchased 250,000 shares at $2.817 per share of the Company's common stock. As a result, the per share exercise price of our previously issued Series B, A-2 and B-2 common stock warrants was automatically reduced from $3.40 to $2.817 pursuant to the terms of the warrants. There was no change to the quantity of warrant shares. As a result of this reduction of warrant exercise price, the Company recognized a modification charge of $86,000.

As of December 31, 2021, there were Series B warrants to purchase a total of 285,632 shares of common stock, Series A-2 warrants to purchase a total of 392,830 shares of common stock, and Series B-2 warrants to purchase a total of 20,380 shares of common stock still remaining and outstanding.

2021 Public Offering

On January 19, 2021, the Company closed an underwritten public offering of units (the "January 2021 Offering") for gross proceeds of approximately $27,600,000, which included the exercise of the underwriter's over-allotment option to purchase additional shares and warrants, prior to deducting underwriting discounts and commissions and offering expenses payable by Viveve.

The offering comprised of: (1) 4,607,940 Class A Units, priced at a public offering price of $3.40 per Class A Unit, with each unit consisting of one share of common stock and one warrant to purchase one share of common stock, at an exercise price of $3.40 per share that expires on the fifth anniversary of the date of issuance; and (2) 2,450,880 Class B Units, priced at a public offering price of $3.40 per Class B Unit, with each unit consisting of one share of Series C convertible preferred stock and one warrant to purchase one share of common stock, at an exercise price of $3.40 per share that expires on the fifth anniversary of the date of issuance. The underwriter exercised an over-allotment option to purchase an additional 1,058,820 shares of common stock and warrants to purchase 1,058,820 shares of common stock in the offering. The net proceeds to the Company, after deducting underwriting discounts and commissions and offering expenses payable by the Company, were approximately $25,122,000.

A total of 2,450,880 shares of Series C convertible preferred stock were issued in the January 2021 Offering. In January 2021, all Series C convertible preferred stock were converted into common stock and there are no remaining shares of Series C convertible preferred stock outstanding.

Warrants to purchase a total of 8,117,640 shares of common stock were issued in the January 2021 Offering. In February and March 2021, holders exercised January 2021 warrants to purchase 12,760 shares of common stock for aggregate exercise proceeds to the Company of approximately $43,000. As of December 31, 2021, there were January 2021 warrants to purchase a total of 8,104,880 shares of common stock still remaining and outstanding.

Series C Convertible Preferred Stock

In connection with the closing of the January 2021 Offering, the Company filed the Certificate of Designation of Preferences, Rights and Limitations of Series C convertible preferred stock (the "Series C Certificate of Designation") with the Secretary of State of the State of Delaware. The Series C Certificate of Designation provides for the issuance of the shares of Series C convertible preferred stock. The shares of Series C convertible preferred stock rank on par with the shares of the common stock, in each case, as to dividend rights and distributions of assets upon liquidation, dissolution or winding up of the Company.

With certain exceptions, as described in the Series C Certificate of Designation, the shares of Series C convertible preferred stock have no voting rights.

Each share of Series C convertible preferred stock is convertible at any time at the holder's option into one share of common stock, which conversion ratio will be subject to adjustment for stock splits, stock dividends, distributions, subdivisions and combinations and other similar transactions as specified in the Series C Certificate of Designation.

All Series C convertible preferred stock have been converted into common stock and there are no remaining shares outstanding.

Elimination of Series A Convertible Preferred Stock

On December 16, 2020, the Company filed a Certificate of Elimination (the "Certificate of Elimination") with the Delaware Secretary of State with respect to 547,345 authorized shares of Series A convertible preferred stock, par value $0.0001 per share. The Series A convertible preferred stock had been designated pursuant to the Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock filed with the Delaware Secretary of State on November 25, 2019. As of the date of the filing of the Certificate of Elimination, no shares of Series A convertible preferred stock were outstanding. Upon filing the Certificate of Elimination, the 547,345 authorized shares of Series A convertible preferred stock were returned to the status of authorized but unissued shares of preferred stock of the Company, without designation as to series or rights, preferences, privileges or limitations.

Purchase Agreement with Lincoln Park Capital, LLC

The Company previously entered into a purchase agreement on June 8, 2020 (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("LPC"), which provided that the Company had the right, in its sole discretion, to sell to LPC, and LPC has committed to purchase from us up to $10,000,000 of our common stock, subject to certain limitations, from time to time over a 30-month term of the Purchase Agreement.

The Purchase Agreement limited the Company's sale of shares of common stock to LPC to 301,762 shares of common stock, representing 19.99% of the shares of the common stock outstanding on the date of the Purchase Agreement unless (i) shareholder approval was obtained to issue more than such amount or (ii) the average price of all applicable sales of common stock to LPC under the Purchase Agreement equaled or exceeded $6.46 per share. On June 9, 2020, LPC purchased 52,500 shares of common stock at a price per share of $6.50 (the "Initial Purchase Shares") under the Purchase Agreement for gross proceeds of approximately $341,000. Transaction costs in connection with the Purchase Agreement with LPC totaled approximately $494,000.

On March 31, 2021, the Company and LPC entered into a First Amendment to the Purchase Agreement. The amendment limited the Company's sale of shares of common stock to LPC from the date there of to 2,068,342 shares of shares of common stock, representing19.99% of the shares of the common stock outstanding on the date of amendment unless (i) shareholder approval is obtained to issue more than such amount or (ii) the average price of all applicable sales of common stock to LPC under the Purchase Agreement, as amended equals or exceeds $2.99 per share. Transaction costs in connection with the amendment to Purchase Agreement with LPC totaled approximately $70,000.

On May 4, 2021, LPC purchased 250,000 shares of common stock at price per share of $2.817 under the Purchase Agreement for gross proceeds of approximately $704,000.

On June 23, 2021, the Company's stockholders approved the proposal for the potential issuance of 20% or more of the Company's outstanding common stock to LPC pursuant to the provisions under the Purchase Agreement, as amended.

As of December 31, 2021, the equity facility with LPC has a remaining financing commitment of approximately $9,000,000.

2020 Warrant Offering

On April 15, 2020, the Company reduced the exercise price of the outstanding Series A warrants and Series B warrants from $15.50 per share to $6.10 per share. On April 16, 2020, the Company entered into inducement letter agreements with certain institutional and accredited holders of Series A warrants and Series B warrants pursuant to which such holders agreed to exercise Series A warrants to purchase 482,059 shares of common stock and Series B warrants to purchase 24,279 shares of common stock for aggregate exercise proceeds to the Company of approximately $3,089,000. In conjunction, the Company also agreed to issue new Series A-2 warrants to purchase up to 482,059 shares of common stock as an inducement for the exercise of Series A warrants, and new Series B-2 warrants to purchase up to 24,279 shares of common stock as an inducement for the exercise of Series B warrants, in each case at an exercise price of $6.371 per share and for a term of five years. The transaction closed on April 20, 2020. Transaction costs in connection with the 2020 Warrant Offering totaled approximately $334,000. (See Note 12 – Common Stock for the calculation of the modification expense for the Series A and B warrants and the issuance of Series A-2 and B-2 warrants.) As of December 31, 2021, there were Series A-2 warrants to purchase a total of 392,830 shares of common stock and Series B-2 warrants to purchase a total of 20,380 shares of common stock still remaining and outstanding.

Liquidity and Management Plans

The Company has adopted the Financial Accounting Standards Board's ("FASB") Accounting Standard Codification ("ASC") Topic 205-40, Presentation of Financial Statements – Going Concern, which requires that management evaluate whether there are relevant conditions and events that, in the aggregate, raise substantial doubt about the entity's ability to continue as a going concern and to meet its obligations as they become due within one year after the date that the financial statements are issued.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. However, since inception, the Company has sustained significant operating losses and such losses are expected to continue for the foreseeable future. As of December 31, 2021, the Company had accumulated deficit of $241,853,000, cash and cash equivalents of $19,162,000 and working capital of $17,705,000. The Company's financing activities provided cash of $25,973,000 during the year ended December 31, 2021, which was primarily due to the net proceeds from the January 2021 Offering. However, the Company used $12,878,000 in cash for operations in the year ended December 31, 2021. As of the date our financial statements for the year ended December 31, 2021 are issued, the Company did not have sufficient cash to fund its operations through March 31, 2023, without additional financing and, therefore, the Company concluded there was substantial doubt about its ability to continue as a going concern within one year after the date the financial statements are issued.

To fund further operations, the Company will need to raise additional capital. The Company may obtain additional financing in the future through the issuance of its common stock, or through other equity or debt financings. The Company's ability to continue as a going concern or meet the minimum liquidity requirements in the future is dependent on its ability to raise significant additional capital, of which there can be no assurance. If the necessary financing is not obtained or achieved, the Company will likely be required to reduce its planned expenditures, which could have an adverse impact on the results of operations, financial condition and the Company's ability to achieve its strategic objective. There can be no assurance that financing will be available on acceptable terms, or at all.

2. Summary of Significant Accounting Policies

Financial Statement Presentation

The consolidated financial statements include the accounts of the Company and our wholly-owned subsidiaries, Viveve, Inc. and Viveve BV. All significant intercompany accounts and transactions have been eliminated in consolidation.

Reclassification of Prior Year Presentation

Certain prior year amounts have been reclassified for consistency with the current period presentation. These reclassifications had no effect on the reported results of operations. An adjustment has been made to the Consolidated Balance Sheet for the year ended December 31, 2020 to reclassify certain prepaid inventory amounts from current assets to noncurrent assets.

Reverse Stock Split - December 2020

The Company effected a 1-for-10 reverse stock split of its common stock that became effective after market close on December 1, 2020. The reverse stock split uniformly affected all issued and outstanding shares of the Company's common stock. The reverse stock split provided that every ten shares of the Company's issued and outstanding common stock was automatically combined into one issued and outstanding share of common stock, without any change in par value per share. The number of authorized shares of common stock remained at 75,000,000 shares.

As a result of the reverse stock split, proportionate adjustments were made to the per share exercise price and/or the number of shares issuable upon the exercise or vesting of all then outstanding stock options, deferred restricted stock awards and warrants, which will result in a proportional decrease in the number of shares of the Company's common stock reserved for issuance upon exercise or vesting of such stock options, deferred restricted stock awards and warrants, and, in the case of stock options and warrants, a proportional increase in the exercise price of all such stock options and warrants. In addition, the number of shares reserved for issuance under the Company's equity compensation plans immediately prior to the effective date will be reduced proportionately.

No fractional shares were issued as a result of the reverse stock split. Stockholders of record who would otherwise have been entitled to receive a fractional share were rounded up to the nearest whole number. The Company issued 5,931 shares of common stock as a result of this rounding adjustment.

All of the share numbers, share prices, and exercise prices have been adjusted, on a retroactive basis, to reflect this 1-for-10 reverse stock split.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, and expenses and the related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates. In addition, any change in these estimates or their related assumptions could have an adverse effect on our operating results.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less, at the time of purchase, to be cash equivalents. The Company's cash and cash equivalents are deposited in demand accounts primarily at one financial institution. Deposits in this institution may, from time to time, exceed the federally insured amounts.

Concentration of Credit Risk and Other Risks and Uncertainties

To achieve profitable operations, the Company must successfully develop, manufacture, and market its products. There can be no assurance that any such products can be developed or manufactured at an acceptable cost and with appropriate performance characteristics, or that such products will be successfully marketed. These factors could have a material adverse effect upon the Company's financial results, financial position, and future cash flows.

Most of the Company's products to date require clearance or approvals from the U.S. Food and Drug Administration ("FDA") or other international regulatory agencies prior to commencing commercial sales. There can be no assurance that the Company's products will receive any of these required clearances or approvals or for the indications requested. If the Company was denied such clearances or approvals or if such clearances or approvals were delayed, it would have a material adverse effect on the Company's financial results, financial position and future cash flows.

The Company is subject to risks common to companies in the medical device industry including, butnot limited to, new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, uncertainty of market acceptance of products, product liability, and the need to obtain additional financing. The Company's ultimate success is dependent upon its ability to raise additional capital and to successfully develop and market its products.

The Company designs, develops, manufactures and markets a medical device that it refers to as the Viveve System, which is intended for the non-invasive treatment of vaginal introital laxity, for improved sexual function, for vaginal rejuvenation, for use in general surgical procedures for electrocoagulation and hemostasis, and stress urinary incontinence, depending on the relevant country-specific clearance or approval. The Viveve System consists of three main components: a radiofrequency generator housed in a table-top console, a reusable handpiece and a single-use treatment tip. Included with the system are single-use accessories (e.g. return pad, coupling fluid), as well as a cryogen canister that can be used for approximately four to five procedures, and a foot pedal. The Company outsources the manufacture and repair of the Viveve System to a contract manufacturing partners. Also, certain other components and materials that comprise the device are currently manufactured by a single supplier or a limited number of suppliers. A significant supply interruption or disruption in the operations of the contract manufacturer or these third-party suppliers would adversely impact the production of our products for a substantial period of time, which could have a material adverse effect on our business, financial condition, operating results and cash flows.

In the United States, the Company sells its products primarily through a direct sales force to health care practitioners. Outside the United States, the Company sells through an extensive network of distribution partners. During the year ended December 31, 2021, one distributor accounted for 30% of the Company's revenue. During the year ended December 31, 2020, one distributor accounted for 36% of the Company's revenue. There were no direct sales to customers that accounted for 10% or more of the Company's revenue during the years endedDecember 31, 2021 and 2020.

As of December 31, 2021, one direct customer, accounted for 10% of total accounts receivable, net. As ofDecember 31, 2020, one distributor, collectively, accounted for 37% of total accounts receivable, net. No additional customers accounted for 10% or more of the Company's total accounts receivable, net.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are recorded at the invoiced amount and arenot interest bearing. Our typical payment terms vary by region and type of customer (distributor or physician). Occasionally, payment terms of up to six months may be granted to customers with an established history of collections without concessions. Should we grant payment terms greater than six months or terms that are not in accordance with established history for similar arrangements, revenue would be recognized as payments become due and payable assuming all other criteria for revenue recognition have been met. The Company maintains an allowance for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. The Company makes ongoing assumptions relating to the collectability of its accounts receivable in its calculation of the allowance for doubtful accounts. In determining the amount of the allowance, the Company makes judgments about the creditworthiness of customers based on ongoing credit evaluations and assesses current economic trends affecting its customers that might impact the level of credit losses in the future and result in different rates of bad debts than previously seen. The Company also considers its historical level of credit losses. The allowance for doubtful accounts was $66,000 and $124,000 as of December 31, 2021 and 2020, respectively.

During the year ended December 31, 2021, the Company wrote-off previously reserved accounts receivable totaling $183,000 primarily related to U.S. customers. During the year ended December 31, 2020, the Company wrote-off previously reserved accounts receivable totaling $736,000 primarily related to Middle Eastern and Latin American distributors in connection with the Company's shift in its international business model to a strategic focus on the Asia Pacific geographic territory.

Inventory

Inventory is stated at the lower of cost or net realizable value. Inventory as ofDecember 31, 2021 consisted of $979,000 of finished goods and $493.000 of raw materials. Inventory as of December 31, 2020 consisted of $2,818,000 of finished goods and $436,000 of raw materials. Cost is determined on an actual cost basis on a first-in, first-out method. Lower of cost or net realizable value is evaluated by considering obsolescence, excessive levels of inventory, deterioration and other factors. Adjustments to reduce the cost of inventory to its net realizable value, if required, are made for estimated excess, obsolescence or impaired inventory. Excess and obsolete inventory is charged to cost of revenue and a new lower-cost basis for that inventory is established and subsequent changes in facts and circumstances do not result in the restoration or increase in that newly established cost basis.

As part of the Company's recurring revenue rental model, the Company utilizes Viveve Systems transferred from finished goods inventory. The Company is amortizing these units over an estimated useful life of five years. The amortization of these Viveve Systems is charged to cost of sales and these units are included in the property and equipment, net balance on the consolidated balance sheets as of December 31, 2021 and 2020.

Property and Equipment, net

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation of property and equipment is computed using the straight-line method over their estimated useful lives of three to seven years. Leasehold improvements are amortized on a straight-line basis over the lesser of their useful lives or the life of the lease. Upon sale or retirement of assets, the cost and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is reflected in operations. Maintenance and repairs are charged to operations as incurred.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable. When such an event occurs, management determines whether there has been an impairment by comparing the anticipated undiscounted future net cash flows to the related asset's carrying value. If an asset is considered impaired, the asset is written down to fair value, which is determined based either on discounted cash flows or appraised value, depending on the nature of the asset. The Company has not identified any such impairment losses to date.

Revenue from Contracts with Customers

Revenue consists primarily of the sale of the Viveve System, single-use treatment tips and ancillary consumables. The Company applies the following five steps: (1) identify the contract with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract, and (5) recognize revenue when a performance obligation is satisfied. The Company considers customer purchase orders to be the contracts with a customer. Revenue, net of expected discounts, are recognized when the performance obligations of the contract with the customer are satisfied and when control of the promised goods are transferred to the customer, typically when products, which have been determined to be the only distinct performance obligations, are shipped to the customer. Expected costs of assurance warranties and claims are recognized as expense. Revenue is recognized net of any sales taxes from the sale of the products.

Rental revenue is generated through the lease of the Viveve System. The Company's operating leases for the Viveve System generally have a rental period of 6 to 12 months and can be extended or terminated by the customer after that time or the Viveve System could be purchased by the customer. Rental revenue on those operating leases is recognized on a straight-line basis over the terms of the underlying leases. For the years ended December 31, 2021 and 2020, rental revenue recognized was $1,214,000 and $1,337,000. As of December 31, 2021 and 2020, the Company had deferred revenue in the amount of $452,000 and $345,000 related to its rental program, which is included in accrued liabilities. During the year ended December 31, 2021, the Company recognized $318,000 of rental revenue, which was deferred as of December 31, 2020. During the year ended December 31, 2020, the Company recognized $594,000 of rental revenue, which was deferred as of December 31, 2019.

Late in the first quarter of 2020 and through the year ended December 31, 2021, the negative impact of the COVID-19 pandemic on medical facilities and practitioners was in full effect in the United States. Federal, regional, and local government and public health agencies issued directives halting performance of non-essential medical treatments and elective procedures in an effort to combat the spread of the coronavirus and protect public health and safety. As a result, a large percentage of Viveve's U.S. customers either temporarily closed their medical practices or dramatically reduced services and staff. The consequence has been both a public health and economic crisis that is continuing for existing and prospective Viveve customers. In a supportive partnership response, in the second quarter of 2020 Viveve contacted all of its subscription customers and provided them with a three-month deferral of the rental payment. Although clinics in various regions continue to re-open and gradually increase their limited services, we anticipate that until the COVID-19 pandemic abates, more practices re-open and elective patient's safety concerns are reduced, that we will continue to experience reduced revenue from existing subscription customers, as well as a greatly reduced number of new and prospective customers.

In connection with the lease of the Viveve System, the Company offers single-use treatment tips and ancillary consumables that are considered non-lease components. In the contracts with lease and non-lease components, the Company follows the relevant guidance in ASC 606, Revenue from Contracts with Customers, to determine how to allocate contractual consideration between the lease and non-lease components.

Sales of our products are subject to regulatory requirements that vary from country to country. The Company has regulatory clearance for differing indications, or can sell its products without a clearance, in many countries throughout the world, including countries within the following regions: North America, Asia Pacific, Europe, the Middle East and Latin America. In the United States, we market and sell primarily through a direct sales force. Outside of the United States, we market and sell primarily through distribution partners.

The Company does not provide its customers with a right of return.

Customer Advance Payments

From time to time, customers will pay for a portion of the products ordered in advance. Upon receipt of such payments, the Company records the customer advance payment as a component of accrued liabilities. The Company will remove the customer advance payment from accrued liabilities when revenue is recognized upon shipment of the products.

Contract Assets and Liabilities

The Company continually evaluates whether the revenue generating activities and advanced payment arrangements with customers result in the recognition of contract assets or liabilities. No such assets existed as of December 31, 2021 or 2020. The Company had customer contract liabilities in the amount of $7,000 and $17,000 that performance had not yet been delivered to its customers as of December 31, 2021 and December 31, 2020, respectively. Contract liabilities are recorded in accrued liabilities on the consolidated balance sheets.

The following table reflects the changes in our customer contract liabilities for the year ended December 31, 2021:

	December 31,		
	2021	**2020**	**Change**
Customer contracts liabilities:			
Marketing programs	$ 7	$ 17	$ (10)
Total	$ 7	$ 17	$ (10)

Separately, accounts receivable, net represents receivables from contracts with customers.

Significant Financing Component

The Company applies the practical expedient to not make any adjustment for a significant financing component if, at contract inception, the Company does not expect the period between customer payment and transfer of control of the promised goods or services to the customer to exceed one year. During the years ended December 31, 2021 and 2020, the Company did not have any contracts for the sale of its products with its customers with a significant financing component.

Contract Costs

The Company expects that commissions paid to obtain subscriptions are recoverable and has therefore capitalized them as a contract cost in the amount of $84,000 and $132,000 at December 31, 2021 and 2020, respectively. Capitalized commissions are amortized based on the subscription periods to which the assets relate and are included in selling, general and administrative expenses. For the year ended December 31, 2021 and 2020, the amount of amortization was $66,000 and $417,000, respectively. There was no impairment loss in relation to the costs capitalized.

Shipping and Handling

Shipping costs billed to customers are recorded as revenue. Shipping and handling expense related to costs incurred to deliver product are recognized within cost of goods sold. The Company accounts for shipping and handling activities that occur after control has transferred as a fulfillment cost as opposed to a separate performance obligation, and the costs of shipping and handling are recognized concurrently with the related revenue.

Revenue by Geographic Area:

Management has determined that the sales by geography is a key indicator for understanding the Company's financials because of the different sales and business models that are required in the various regions of the world (including regulatory, selling channels, pricing, customers and marketing efforts). The following table presents the revenue from unaffiliated customers disaggregated by geographic area for the year ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,	
	2021	2020
United States	$ 3,701	$ 2,537
Asia Pacific	2,647	2,732
Canada	66	110
Europe and Middle East	12	86
Latin America	-	14
Total	$ 6,426	$ 5,479

The Company determines geographic location of its revenue based upon the destination of the shipments of its products.

Investments in Unconsolidated Affiliates

The Company uses the equity method to account for its investments in entities that it does not control but have the ability to exercise significant influence over the investee. Equity method investments are recorded at original cost and adjusted periodically to recognize (1) the proportionate share of the investees' net income or losses after the date of investment, (2) additional contributions made and dividends or distributions received, and (3) impairment losses resulting from adjustments to net realizable value. The Company eliminates all intercompany transactions in accounting for equity method investments. The Company records the proportionate share of the investees' net income or losses in equity in earnings of unconsolidated affiliates on the consolidated statements of operations. The Company utilizes a three-month lag in reporting equity income from its investments, adjusted for known amounts and events, when the investee's financial information is not available timely or when the investee's reporting period differs from our reporting period.

The Company assesses the potential impairment of the equity method investments when indicators such as a history of operating losses, a negative earnings and cash flow outlook, and the financial condition and prospects for the investee's business segment might indicate a loss in value. The carrying value of the investments is reviewed annually for changes in circumstances or the occurrence of events that suggest the investment may not be recoverable. During the years ended December 31, 2021 and 2020, no impairment charges have been recorded in the consolidated statements of operations.

Product Warranty

The Company's products sold to customers are generally subject to warranties between one and three years, which provides for the repair, rework or replacement of products (at the Company's option) that fail to perform within stated specifications. The Company has assessed the historical claims and, to date, product warranty claims have not been significant.

Advertising Costs

Advertising costs are charged to selling, general and administrative expenses as incurred. Advertising expenses, which are recorded in selling, general and administrative expenses, were immaterial for the years ended December 31, 2021 and 2020.

Research and Development

Research and development costs are charged to operations as incurred. Research and development costs include, but are not limited to, payroll and personnel expenses, prototype materials, laboratory supplies, consulting costs, and allocated overhead, including rent, equipment depreciation, and utilities.

Income Taxes

The provision for income taxes is determined using the asset and liability approach of accounting for income taxes. Under this approach, deferred taxes represent the future tax consequences expected to occur when the reported amounts of assets and liabilities are recovered or paid. The provision for income taxes represents income taxes paid or payable for the current year plus the change in deferred taxes during the year. Deferred taxes result from differences between the financial and tax basis of the Company's assets and liabilities and are adjusted for changes in tax rates and tax laws when changes are enacted. Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized.

The Company must assess the likelihood that the Company's deferred tax assets will be recovered from future taxable income, and to the extent the Company believes that recovery is not likely, the Company establishes a valuation allowance. Management judgment is required in determining the Company's provision for income taxes, deferred tax assets and liabilities, and any valuation allowance recorded against the net deferred tax assets. The Company recorded a full valuation allowance as of December 31, 2021 and 2020. Based on the available evidence, the Company believes it is more likely than not that it will not be able to utilize its deferred tax assets in the future. The Company intends to maintain valuation allowances until sufficient evidence exists to support the reversal of such valuation allowances. The Company makes estimates and judgments about its future taxable income that are based on assumptions that are consistent with its plans. Should the actual amounts differ from the Company's estimates, the carrying value of the Company's deferred tax assets could be materially impacted.

The Company recognizes in the financial statements the impact of a tax position, if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The Company's policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. The Company does not believe there are any tax positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within 12 months of the reporting date.

Accounting for Stock-Based Compensation

Share-based compensation cost is measured at grant date, based on the fair value of the award, and is recognized as expense over the employee's service period. The Company recognizes compensation expense on a straight-line basis over the requisite service period of the award.

The Company determined that the Black-Scholes option pricing model is the most appropriate method for determining the estimated fair value for stock options and purchase rights under the employee stock purchase plan. The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions which determine the fair value of share-based awards, including the option's expected term and the price volatility of the underlying stock.

Equity instruments issued to nonemployees are recorded in the same manner as similar instruments issued to employees.

Comprehensive Loss

Comprehensive loss represents the changes in equity of an enterprise, other than those resulting from stockholder transactions. Accordingly, comprehensive loss may include certain changes in equity that are excluded from net loss. For the years ended December 31, 2021 and 2020, the Company's comprehensive loss is the same as its net loss.

Net Loss per Share

The Company's basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. The diluted net loss per share is computed by giving effect to all potentially dilutive common stock equivalents outstanding during the period. For purposes of this calculation, stock options and warrants to purchase common stock and restricted common stock awards are considered common stock equivalents. For periods in which the Company has reported net losses, diluted net loss per share is the same as basic net loss per share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

The following securities were excluded from the calculation of net loss per share because the inclusion would be anti-dilutive.

		Year Ended December 31,	
		2021	2020
Convertible preferred stock:			
Series A convertible preferred stock	(a)	-	-
Series B convertible preferred stock	(b)	2,647,320	2,341,111
Series C convertible preferred stock	(c)	-	-
Warrants to purchase common stock		9,793,599	1,728,725
Stock options to purchase common stock		3,173,103	986,399
Deferred restricted common stock units		674,000	-
Deferred restricted common stock awards		228	234

(a) Each share of Series A convertible preferred stock was convertible at any time at the holder's option intoone share of common stock. In December 2020, the Company filed a Certificate of Elimination with the Delaware Secretary of State with respect to the authorized shares of Series A convertible preferred stock. As of December 31, 2021, all Series A convertible preferred stock had been converted into common stock and there were no remaining shares outstanding.

(b) As of December 31, 2021 and 2020, a total of 40,504 and 35,819 shares of Series B convertible preferred stock were outstanding and convertible into 2,647,320 and 2,341,111 shares of common stock, respectively. Each share of Series B convertible preferred stock is convertible at the holder's option into shares of common stock at a conversion ratio of 1-for-65.36 per share determined by dividing the Series B liquidation amount of $1,000 per share by the Series B conversion price of $15.30 per share. However, under the terms of the Series B Preferred Stock and Warrant Purchase Agreement, as amended, CRG will not convert the Series B preferred stock or exercise the CRG warrants until the Company's stockholders act to authorize additional number of shares of common stock sufficient to cover the conversion shares.

(c) Each share of Series C preferred stock is convertible at any time at the holder's option intoone share of common stock. As of December 31, 2021, all Series C convertible preferred stock had been converted into common stock and there areno remaining shares of Series C convertible preferred stock outstanding.

Recently Issued Accounting Standards

In June 2016, the FASB issued ASU 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, as amended, which revises the measurement of credit losses for most financial instruments measured at amortized cost, including trade receivables, from an incurred loss methodology to an expected loss methodology which results in earlier recognition of credit losses. Under the incurred loss model, a loss is not recognized until it is probable that the loss-causing event has already occurred. The new standard introduces a forward-looking expected credit loss model that requires an estimate of the expected credit losses over the life of the instrument by considering all relevant information including historical experience, current conditions, and reasonable and supportable forecasts that affect collectability. The guidance in ASU 2016-13 is effective for the Company for financial statements issued for fiscal years beginning after December 15, 2022 and interim periods within those fiscal years, with early adoption permitted. The Company is still evaluating the impact of the adoption of this standard.

In December 2019, the FASB issued ASU 2019-12, "Income Taxes (Topic 740). The amendments in this Update provide further simplification of accounting standards for the accounting for income taxes. Certain exceptions for are removed and requirements regarding the accounting for franchise taxes, tax basis of goodwill, and tax law rate changes are made. This guidance is effective for annual reporting periods beginning after December 15, 2020, including interim periods within that reporting period, with early adoption permitted. We adopted this guidance as of January 1, 2021 and the adoption of the guidance did not have a significant impact on the consolidated financial statements.

We have reviewed other recent accounting pronouncements and concluded they are either not applicable to the business, orno material effect is expected on the consolidated financial statements as a result of future adoption.

3. Fair Value Measurements

The Company recognizes and discloses the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to valuations based upon unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to valuations based upon unobservable inputs that are significant to the valuation (Level3 measurements). Each level of input has different levels of subjectivity and difficulty involved in determining fair value.

Level 1	Inputs used to measure fair value are unadjusted quoted prices that are available in active markets for the identical assets or liabilities as of the reporting date. Therefore, determining fair value for Level 1 investments generally does not require significant judgment, and the estimation is not difficult.
Level 2	Pricing is provided by third party sources of market information obtained through investment advisors. The Company does not adjust for or apply any additional assumptions or estimates to the pricing information received from its advisors.
Level 3	Inputs used to measure fair value are unobservable inputs that are supported by little omo market activity and reflect the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management's estimates of market participant assumptions. The determination of fair value for Level 3 instruments involves the most management judgment and subjectivity.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

There were no financial instruments that were measured at fair value on a recurring basis as of December 31, 2021 and 2020.

The carrying amounts of the Company's financial assets and liabilities, including cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses as of December 31, 2021 and 2020 approximate fair value because of the short maturity of these instruments. Based on borrowing rates currently available to the Company for loans with similar terms, the carrying value of the note payable approximates fair value.

There were no changes in valuation techniques from prior periods.

4. Property and Equipment, Net

Property and equipment, net, consisted of the following as of December 31, 2021 and 2020 (in thousands):

	Life (in years)	December 31, 2021	December 31, 2020
Medical equipment	5	$ 2,628	$ 3,111
Rental equipment	5	1,118	1,812
Computer equipment	3	157	242
Leasehold Improvements	3	122	122
Furniture and fixtures	7	244	386
Software	3	35	25
		4,304	5,698
Less: Accumulated depreciation and amortization		(2,750)	(2,939)
Property and equipment, net		$ 1,554	$ 2,759

Depreciation and amortization expense for the years ended December 31, 2021 and 2020 was $1,123,000 and $1,295,000, respectively.

5. Investment in Limited Liability Company

On August 8, 2017, the Company entered into an exclusive Distributorship Agreement (the "Distributorship Agreement") with InControl Medical, LLC ("ICM"), a Wisconsin limited liability company focused on women's health, pursuant to which the Company will directly market, promote, distribute and sell ICM's products to licensed medical professional offices and hospitals in North America.

In connection with the Distributorship Agreement, the Company also entered into a Membership Unit Subscription Agreement with ICM and the associated limited liability company operating agreement of ICM, pursuant to which the Company invested $2,500,000 in, and acquired membership units of, ICM. This investment has been recorded in investment in a limited liability company in the consolidated balance sheets. The Company used the equity method to account for the investment in ICM because the Company does not control it but has the ability to exercise significant influence over it. As of December 31, 2021, the Company owns approximately 7% ownership interest in ICM. The Company recognizes its allocated portion of ICM's results of operations on a three-month lag due to the timing of financial information. For the years ended December 31, 2021 and 2020, the allocated net loss from ICM's operations was $256,000 and $383,000 respectively. The allocated net loss from ICM's operations was recorded as a loss from minority interest in limited liability company in the consolidated statements of operations.

In February 2019, the Company executed a mutual termination of the Distributorship Agreement with ICM. As a result, the Company no longer has a minimum purchase requirement to purchase a certain quantity of ICM products per month.

During the years ended December 31, 2021 and 2020, the Company purchased 140 and 485 units of ICM products for approximately $17,000 and $51,000, respectively. The Company paid ICM approximately $17,000 and $52,000 for product related costs during the years ended December 31, 2021 and 2020, respectively. There were no amounts due to ICM for accounts payable as of December 31, 2021 and 2020.

6. Accrued Liabilities

Accrued liabilities consisted of the following as of December 31, 2021 and 2020 (in thousands):

	December 31,	
	2021	2020
Accrued bonuses	$ 1,209	$ 744
Accrued payroll and other related expenses	495	473
Deferred revenue - subscription rental program	448	345
Accrued clinical trial costs	337	91
Current operating lease liabilities	225	132
Accrued professional fees	120	290
Other accruals	219	341
Total accrued liabilities	$ 3,053	$ 2,416

7. Note Payable

On May 22, 2017, the Company entered into a Term Loan Agreement, as amended on December 12, 2017 and November 29, 2018 (collectively, the "2017 Loan Agreement") with affiliates of CRG LP ("CRG"). The credit facility consists of $20,000,000 drawn at closing and access to additional funding of up to an aggregate of $10,000,000 for a total of $30,000,000 available under the credit facility. On December 29, 2017, the Company accessed the remaining $10,000,000 available under the credit facility.

In connection with the 2017 Loan Agreement, the Company issued two 10-year warrants to CRG to purchase a total of 223 shares of the Company's common stock at an exercise price of $9,500.00 per share. (See Note 12 – Common Stock.)

Under the 2017 Loan Agreement, as in effect prior to the November 12, 2019 amendment, the credit facility had a six-year term with four years of interest-only payments after which quarterly principal and interest payments were to be due through the maturity date. Amounts borrowed under the 2017 Loan Agreement accrued interest at an annual fixed rate of 12.5%, 4.0% of which may, at the election of the Company, could be paid in-kind during the interest-only period by adding such accrued amount to the principal loan amount each quarter. The Company was also required to pay CRG a final payment fee upon repayment of the loans in full equal to 5.0% of the sum of the aggregate principal amount plus the deferred interest added to the principal loan amount during the interest-only period.

As security for its obligations under the 2017 Loan Agreement, the Company entered into security agreements with CRG whereby the Company granted CRG a lien on substantially all of the Company's assets, including intellectual property.

The terms of the 2017 Loan Agreement also required the Company to meet certain financial and other covenants. The 2017 Loan Agreement also contained customary affirmative and negative covenants for a credit facility of this size and type.

On November 12, 2019, the Company and CRG amended the 2017 Loan Agreement (the "Amendment No. 3"). In connection with the amendment, the Company converted approximately $28,981,000 of the outstanding principal amount under the term loan plus accrued interest, the prepayment premium and the back-end facility fee for an aggregate amount of converted debt obligations of approximately $31,300,000. The debt obligations converted into 31,300 shares of the newly authorized Series B convertible preferred stock and warrants to purchase up to 989,379 shares of common stock were also issued. The warrants have a term of 5 years and an exercise price equal to 120% of the Series convertible B preferred stock conversion price of $15.30 or $18.36 per share. (See Note 12 – Common Stock.) CRG entered into a one year lock up agreement on all securities that it holds.

The Amendment No. 3 to the 2017 Loan Agreement addressed, among other things:

- repayment provisions were amended such that repayment is permitted only with, or after, the redemption in full of the Series B convertible preferred stock issued to CRG;
- the interest only payment period and the period during which the Company may elect to pay the full interest in Paid In-Kind ("PIK") interest payments was extended through the 23rd date after the first payment date. Pursuant to the amendment, CRG shall consent to the payment of such interest in the form of PIK loans, provided that (i) as of such payment date, no default shall have occurred and be continuing, and (ii) the principal amount of each PIK loan shall accrue interest in accordance with the provisions of the 2017 Loan Agreement;
- modified certain of the covenants, including (i) to permit issuance of the Series B convertible preferred stock and any preferred stock issued in the equity financing and the exercise and performance by the Company of its rights and obligations in connection with such CRG preferred stock and any preferred stock issued in the equity financing, (ii) eliminate the Company's ability to enter into permitted acquisitions, (iii) further restrict the incurrence of additional indebtedness and removal of the equity cure right, and (iv) eliminate the minimum revenue requirement; and
- the back-end facility fee on the aggregate remaining principal balance on the term loan shall be increased from 5% to 25%.

Pursuant to the amendment, the Company paid interest in-kind of $602,000 and $532,000 during the years ended December 31, 2021 and 2020, respectively, which was added to the total outstanding principal loan amount.

As of December 31, 2021, the Company was in compliance with all covenants.

As of December 31, 2021 and 2020, $5,124,000 and $4,518,000 was recorded on the consolidated balance sheets as note payable, noncurrent portion, which is net of the remaining unamortized debt discount. The term loan has a maturity date of March 31, 2023.

As of December 31, 2021, future minimum payments under the note payable were as follows (in thousands):

Year Ending December 31,	
2022	$ -
2023	5,992
Total Payments	5,992
Less: Amount representing interest	(863)
Present value of obligations	5,129
Less: Unamortized debt discount	(5)
Note payable, noncurrent portion	$ 5,124

8. Paycheck Protection Program Loan

The Paycheck Protection Program ("PPP") was established under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") and is administered by the U.S. Small Business Administration ("SBA"). On April 24, 2020, Viveve, Inc. ("Viveve"), a wholly-owned subsidiary of the Company, entered into a promissory note evidencing an unsecured loan in the aggregate amount of approximately $1,343,000 made to Viveve under the PPP (the "PPP Loan"). The PPP Loan to Viveve was made through Western Alliance Bank ("WAB"). The interest rate on the PPP Loan is 1.00% and the term was two years. In accordance with the updated Small Business guidance, the PPP Loan was modified so that, beginning ten months from the date of the PPP Loan, Viveve was required to make monthly payments of principal and interest. The promissory note evidencing the PPP Loan contained customary events of default relating to, among other things, payment defaults or breaching the terms of the PPP Loan documents. The occurrence of an event of default would result in the repayment of all amounts outstanding, collection of all amounts owing from Viveve, or filing suit and obtaining judgment against Viveve. Under the terms of the CARES Act, PPP Loan recipients could apply for and be granted forgiveness for all or a portion of the loan granted under the PPP. Such forgiveness would be determined, subject to limitations, based on the use of loan proceeds for payment of payroll costs and any payments of mortgage interest, rent, and utilities. No assurance was provided that Viveve would obtain forgiveness of the PPP Loan in whole or in part.

In October 2020, the Company was notified that the terms of its PPP Loan with WAB were modified. The amount of time that the Company had to spend the proceeds of the PPP Loan (the "covered period") was extended from 8 weeks to 24 weeks. The date to begin repaying unforgiven portions of the PPP Loan was also extended from six months after the funding date to up to 10 months after the end of the covered period (approximately 16 months from the funding date) depending on when the Company applies for forgiveness. The SBA would also cover interest on the forgiveness portion of the loan during this period. There was no change to the maturity date of the loan. All PPP Loans must be repaid or forgiven within two years after the funding date. The Company submitted its PPP Loan forgiveness application to the SBA in October 2020.

In May 2021, the Company was notified by WAB that its request for forgiveness of the PPP Loan had been approved in full. The total principal amount and the accrued interest through the forgiveness payment date was forgiven. The Company has recognized a gain on the extinguishment of debt in the consolidated statements of operations during the year ended December 31, 2021 in the amount of $1,358,000.

9. Leases

Lessee:

The following information pertains to those operating lease agreements where the Company is the lessee.

On February 1, 2017, the Company entered into a sublease agreement (the "Sublease") for approximately 12,400 square feet of building space for the relocation of the Company's corporate headquarters to Englewood, Colorado (the "Sublease Premises"), which was effective as of January 26, 2017. The lease term commenced on June 1, 2017 and was to terminate in May 2020. In November 2019, the Company exercised the option to extend the lease for one year through May 2021. The Company relocated its corporate headquarters from Sunnyvale, California to Englewood, Colorado in June 2017.

The monthly base rent under the Sublease was equal to $20.50 per rentable square foot of the Sublease Premises during the first year. The monthly base rent was equal to $21.12 and $21.75 per rentable square foot during the second and third years, respectively. In connection with the execution of the Sublease, the Company also agreed to pay a security deposit of approximately $22,000. The Company was also provided an allowance of approximately $88,000 for certain tenant improvements relating to the engineering, design and construction of the Sublease Premises which has been reimbursed.

In March 2021, the Company amended the Sublease for its office building space. The lease term was extended for a period of 34 months and will terminate on March 31, 2024. The monthly gross rent for the first, second and third years of the lease extension is $21,028, $21,643 and $22,258 per month, respectively. The Company was also provided a rent abatement for the month of June 2021. Additionally, the sublandlord agreed to perform certain construction, repair, maintenance or other tenant improvements to the Subleased Premises with estimated costs of approximately $19,000.

In September 2018, the Company entered into a 36-month noncancelable operating lease agreement for office equipment. The lease commenced in September 2018 and it was terminated in November 2020. The monthly lease payment was approximately $3,000.

In October 2020, the Company entered into a new 36-month noncancelable operating lease agreement for office equipment. The lease term commenced in December 2020 and will terminate in December 2023. The monthly lease payment is approximately $2,000.

Operating lease rentals are expensed on a straight-line basis over the life of the lease beginning on the date the Company takes possession of the property. At lease inception, the Company determines the lease term by assuming the exercise of those renewal options that are reasonably assured. The lease term is used to determine whether a lease is financing or operating and is used to calculate straight-line rent expense. Additionally, the depreciable life of leasehold improvements is limited by the expected lease term. Leases with an initial term of 12 months or less are not recorded on the balance sheet; the Company recognizes lease expense for these leases on a straight-line basis over the lease term.

The following table reflects the Company's lease assets and lease liabilities at December 31, 2021 and 2020 (in thousands):

	December 31,	
	2021	2020
Assets:		
Operating lease right-of-use assets	$ 534	$ 130
Liabilities:		
Current operating lease liabilities	$ 225	$ 132
Noncurrent operating lease liabilities	327	-
	$ 552	$ 132

The operating lease right-of-use assets are included in other assets on the consolidated balance sheets. The operating lease liabilities are included in accrued liabilities and other noncurrent liabilities on the consolidated balance sheets.

The operating lease expense for the years ended December 31, 2021 and 2020 was $280,000 and $300,000, respectively.

As of December 31, 2021, the maturity of operating lease liabilities was as follows (in thousands):

Year Ending December 31,	
2022	$ 282
2023	287
2024	67
Total lease payments	636
Less: Amount representing interest	(84)
Present value of lease liabilities	$ 552

The weighted average remaining lease term was approximately 27 months as of December 31, 2021. The weighted average discount rate for the year ended December 31, 2021 was 12.5%.

Lessor:

The following information pertains to those operating lease agreements where the Company is the lessor.

As of December 31, 2021, minimum future rentals from customers on non-cancellable operating leases of Viveve Systems are as follows (in thousands):

Year Ending December 31,	
2022	$ 448
2023	4
Total	$ 452

As of December 31, 2021, the Company included rental program equipment related to these operating leases agreements with a net value of $464,000 in property and equipment, net. The depreciation expense for rental program equipment for the years ended December 31, 2021 and 2020 is $325,000 and $462,000, respectively.

10. Commitments and Contingencies

Indemnification Agreements

The Company enters into standard indemnification arrangements in the ordinary course of business. Pursuant to these arrangements, the Company indemnifies, holds harmless and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, in connection with performance of services within the scope of the agreement, breach of the agreement by the Company, or noncompliance of regulations or laws by the Company, in all cases provided the indemnified party has not breached the agreement and/or the loss is not attributable to the indemnified party's negligence or willful malfeasance. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The maximum potential amounts of future payments the Company could be required to make under these arrangements is not determinable. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the Company believes the estimated fair value of these agreements is minimal.

Loss Contingencies

The Company is or has been subject to proceedings, lawsuits and other claims arising in the ordinary course of business. The Company evaluates contingent liabilities, including threatened or pending litigation, for potential losses. If the potential loss from any claim or legal proceeding is considered probable and the amount can be estimated, the Company accrues a liability for the estimated loss. Because of uncertainties related to these matters, accruals are based upon the best information available. For potential losses for which there is a reasonable possibility (meaning the likelihood is more than remote but less than probable) that a loss exists, the Company will disclose an estimate of the potential loss or range of such potential loss or include a statement that an estimate of the potential loss cannot be made. As additional information becomes available, the Company reassesses the potential liability related to pending claims and litigation and may revise its estimates, which could materially impact the consolidated financial statements. Management doesnot believe that the outcome of any outstanding legal matters will have a material adverse effect on the Company's consolidated financial position, results of operations and cash flows.

11. Preferred Stock

Series A Convertible Preferred Stock

On December 16, 2020, the Company filed a Certificate of Elimination with the Delaware Secretary of State with respect to the authorized shares of Series A convertible preferred stock. As of the date of the filing of the Certificate of Elimination, no shares of Series A convertible preferred stock were outstanding. Upon filing the Certificate of Elimination, the 547,345 authorized shares of Series A convertible preferred stock were returned to the status of authorized but unissued shares of preferred stock of the Company, without designation as to series or rights, preferences, privileges or limitations.

Series B Convertible Preferred Stock

As previously reported (see Note 7 – Note Payable), the CRG debt obligations converted into 31,300 shares of the newly authorized Series B convertible preferred stock and warrants to purchase up to 989,379 shares of common stock were also issued.

In connection with the CRG debt conversion, on November 26, 2019, the Company filed the Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (the "Series B Certificate of Designation") with the Secretary of State of the State of Delaware. The Series B Certificate of Designation provides for the issuance of the shares of Series B convertible preferred stock. The holders of Series B convertible preferred stock are entitled to receive compounding dividends at a rate of 12.5% per annum payable quarterly at the Company's option through additional paid in-kind shares of Series B convertible preferred stock or in cash. During the year ended December 31, 2020, the Company paid dividend in-kind of an additional 4,141 shares of Series B convertible preferred stock and a cash dividend of approximately $8,000 for the remaining fractional shares. During the year ended December 31, 2021, the Company paid dividend in-kind of an additional 4,685 shares of Series B convertible preferred stock and a cash dividend of approximately $6,400 for the remaining fractional shares. As of December 31, 2021, there were 40,504 shares of Series B convertible preferred stock outstanding. We have paid approximately $17,000 in cash and issued a total of 9,204 shares of Series B convertible preferred stock as preferred dividend to the holders of Series B convertible preferred stock through December 31, 2021.

As of December 31, 2021 and December 31, 2020, there were 40,504 and 35,819 shares of Series B convertible preferred stock outstanding and convertible into 2,647,320 and 2,341,111 shares of common stock, respectively. Each share of Series B convertible preferred stock is convertible at the holder's option into shares of common stock at a conversion ratio of 1-for-65.36 per share determined by dividing the Series B liquidation amount of $1,000 per share by the Series B conversion price of $15.30 per share. However, under the terms of the Series B Preferred Stock and Warrant Purchase Agreement, as amended, CRG will not convert the Series B preferred stock or exercise the CRG warrants until the Company's stockholders act to authorize additional number of shares of common stock sufficient to cover the conversion shares.

The shares of Series B convertible preferred stock have no voting rights and rank senior to all other classes and series of our equity in terms of repayment and certain other rights.

The Series B convertible preferred stock also provides that for so long as any shares are outstanding, the consent of the holders of the Series B convertible preferred stockholders would be required to amend the Company's organizational documents, approve any merger, sale of assets, or other major corporate transaction, or incur additional indebtedness, among other items.

Series C Convertible Preferred Stock

In connection with the closing of the public offering on January 19, 2021, the Company filed the Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (the "Series C Certificate of Designation") with the Secretary of State of the State of Delaware. The Series C Certificate of Designation provides for the issuance of the shares of Series C convertible preferred stock. The shares of Series C convertible preferred stock rank on par with the shares of the common stock, in each case, as to dividend rights and distributions of assets upon liquidation, dissolution or winding up of the Company.

With certain exceptions, as described in the Series C Certificate of Designation, the shares of Series C convertible preferred stock have no voting rights.

Each share of Series C convertible preferred stock is convertible at any time at the holder's option into one share of common stock, which conversion ratio will be subject to adjustment for stock splits, stock dividends, distributions, subdivisions and combinations and other similar transactions as specified in the Series C Certificate of Designation.

A total of 2,450,880 shares of Series C convertible preferred stock were issued in the January 2021 Offering. In January 2021, all Series C convertible preferred stock were converted into common stock and there are no remaining shares of Series C convertible preferred stock outstanding.

12. Common Stock

Purchase Agreement with Lincoln Park Capital, LLC

On June 8, 2020, the Company entered into the Purchase Agreement with Lincoln Park LPC, pursuant to which provided that the Company had the right, in its sole discretion, to sell to LPC, and LPC has committed to purchase from us, up to $10,000,000 of our common stock, subject to certain limitations, from time to time over a 30 -month period pursuant to the terms of the Purchase Agreement.

The Purchase Agreement limited the Company's sale of shares of common stock to LPC to 301,762 shares of common stock, representing 19.99% of the shares of the common stock outstanding on the date of the Purchase Agreement unless (i) shareholder approval was obtained to issue more than such amount or (ii) the average price of all applicable sales of common stock to LPC under the Purchase Agreement equaled or exceeded $6.46 per share, which represented the lower of (a) the closing price of our common stock on the Nasdaq Capital Market immediately preceding the date of the Purchase Agreement or (b) the average of the closing price of the common stock on the Nasdaq Capital Market for the five business days immediately preceding the date of the Purchase Agreement, as calculated in accordance with Nasdaq Rules. On June 9, 2020, LPC purchased 52,500 shares of common stock at a price per share of $6.50 (the "Initial Purchase Shares") under the Purchase Agreement for gross proceeds of approximately $341,000. Transaction costs in connection with the Purchase Agreement with LPC totaled approximately $494,000. Included in these transaction costs was a commitment fee paid by the Company in the amount of $325,000. While this commitment fee relates to the entire offering and the purchases of common shares that will occur over time, the Company has recorded the entire commitment fee as issuance costs in additional paid-in capital at the time the commitment fee was paid because the offering has been consummated, and there is no guaranteed future economic benefit from this payment.

On March 31, 2021, the Company and LPC entered into the first amendment to the Purchase Agreement. The amendment limited the Company's sale shares of common stock to LPC from the date thereof to 2,068,342 shares of shares of common stock, representing 19.99% of the shares of the common stock outstanding on the date of amendment unless (i) shareholder approval is obtained to issue more than such amount or (ii) the average price of all applicable sales of common stock to LPC under the Purchase Agreement, as amended equals or exceeds $2.99 per share, which represents the lower of (a) the closing price of the common stock on the Nasdaq Capital Market immediately preceding the date of the Amendment or (b) the average of the closing prices of our common stock on the Nasdaq Capital Market for the five business days immediately preceding the date of the Amendment, as calculated in accordance with Nasdaq Rules. Transaction costs in connection with the amendment to Purchase Agreement with LPC totaled approximately $70,000.

On May 4, 2021, pursuant to the provisions under the Purchase Agreement as amended, LPC purchased 250,000 shares of common stock at price per share of $2.817 for gross proceeds of approximately $704,000.

On June 23, 2021, the Company's stockholders approved the proposal for the potential issuance of 20% or more of the Company's outstanding common stock to LPC pursuant to the provisions under the Purchase Agreement, as amended.

As of December 31, 2021, the equity facility with LPC has a remaining financing commitment of approximately $9,000,000.

2021 Public Offering

On January 19, 2021, the Company closed an underwritten public offering of units (the "January 2021 Offering") for gross proceeds of approximately $27,600,000, which included the exercise of the underwriter's over-allotment option to purchase additional shares and warrants, prior to deducting underwriting discounts and commissions and offering expenses payable by Viveve.

The offering comprised of: (1) 4,607,940 Class A Units, priced at a public offering price of $3.40 per Class A Unit, with each unit consisting of one share of common stock and one warrant to purchase one share of common stock, at an exercise price of $3.40 per share that expires on the fifth anniversary of the date of issuance; and (2) 2,450,880 Class B Units, priced at a public offering price of $3.40 per Class B Unit, with each unit consisting of one share of Series C convertible preferred stock and one warrant to purchase one share of common stock, at an exercise price of $3.40 per share that expires on the fifth anniversary of the date of issuance. The underwriter exercised an over-allotment option to purchase an additional 1,058,820 shares of common stock and warrants to purchase 1,058,820 shares of common stock in the offering. The net proceeds to the Company, after deducting underwriting discounts and commissions and offering expenses payable by the Company, were approximately $25,122,000.

A total of 2,450,880 shares of Series C convertible preferred stock were issued in the January 2021 Offering. In January 2021, all Series C convertible preferred stock were converted into common stock and there are no remaining shares of Series C convertible preferred stock outstanding.

Warrants to purchase a total of 8,117,640 shares of common stock were issued in the January 2021 Offering. In February and March 2021, holders exercised January 2021 warrants to purchase 12,760 shares of common stock for aggregate exercise proceeds to the Company of approximately $43,000. As of December 31, 2021, there were January 2021 warrants to purchase a total of 8,104,880 shares of common stock still remaining and outstanding.

Restricted Common Shares

There were no restricted common shares issued during the year ended December 31, 2021.

The activity of restricted common shares for the year ended December 31, 2020 is described as follows:

In March 2020, the Company issued 2,832 restricted shares of its common stock at an aggregate value of approximately $24,000.

In June 2020, the Company issued 3,453 restricted shares of its common stock at an aggregate value of approximately $25,000.

In September 2020, the Company issued 4,709 restricted shares of its common stock at an aggregate value of approximately $25,000.

Warrants for Common Stock

As of December 31, 2021, outstanding warrants to purchase shares of common stock were as follows:

Issuance Date	Exercisable for	Expiration Date	Exercise Price	Number of Shares Outstanding Under Warrants
February 2015	Common Shares	February 17, 2025	$ 4,000.00	79
March 2015	Common Shares	March 26, 2025	$ 2,720.00	2
May 2015	Common Shares	May 12, 2025	$ 4,240.00	37
December 2015	Common Shares	December 16, 2025	$ 5,600.00	31
April 2016	Common Shares	April 1, 2026	$ 6,080.00	25
June 2016	Common Shares	June 20, 2026	$ 4,980.00	101
May 2017	Common Shares	May 25, 2027	$ 9,500.00	223
November 2019	Common Shares	November 26, 2024	$ 18.36	989,379
November 2019	Common Shares	November 26, 2024	$ 2.82	285,632
April 2020	Common Shares	April 21, 2025	$ 2.82	413,210
January 2021	Common Shares	January 19, 2026	$ 3.40	8,104,880
				9,793,599

As of December 31, 2020, outstanding warrants to purchase shares of common stock were as follows:

Issuance Date	Exercisable for	Expiration Date	Exercise Price	Number of Shares Outstanding Under Warrants
February 2015	Common Shares	February 17, 2025	$ 4,000.00	79
March 2015	Common Shares	March 26, 2025	$ 2,720.00	2
May 2015	Common Shares	May 12, 2025	$ 4,240.00	37
December 2015	Common Shares	December 16, 2025	$ 5,600.00	31
April 2016	Common Shares	April 1, 2026	$ 6,080.00	25
May 2016	Common Shares	May 11, 2021	$ 7,740.00	6
June 2016	Common Shares	June 20, 2026	$ 4,980.00	101
May 2017	Common Shares	May 25, 2027	$ 9,500.00	223
November 2019	Common Shares	November 26, 2024	$ 6.10	325,632
November 2019	Common Shares	November 26, 2024	$ 18.36	989,379
April 2020	Common Shares	April 21, 2025	$ 6.37	413,210
				1,728,725

In connection with the 2017 Loan Agreement, the Company issued warrants to purchase a total of 223 shares of common stock at an exercise price of $9,500.00 per share. The warrants have a contractual life of ten years and are exercisable immediately in whole or in part. The fair value of the warrants, along with financing and legal fees, are recorded as debt issuance costs and presented in the condensed consolidated balance sheets as a deduction from the carrying amount of the note payable. The debt issuance costs are amortized to interest expense over the loan term. During the years ended December 31, 2021 and 2020, the Company recorded $4,000 and $3,000, respectively, of interest expense relating to the debt issuance costs using the effective interest method. As of December 31, 2021, the unamortized debt discount was $5,000.

In connection with the CRG Debt Conversion, CRG received warrants exercisable for 989,379 shares of common stock, an amount equal to 15% of our common stock on a fully diluted basis after taking the November 2019 Offering into account (the "CRG Warrants"). The CRG Warrants have a contractual term of five years and an exercise price equal to 120% of the Series B convertible preferred stock conversion price of $15.30 or $18.36 per share. The Company determined the fair value of the warrants on the date of issuance to be approximately $3,502,000 using the Black-Scholes option pricing model. Assumptions used were dividend yield of 0%, volatility of 68.8%, risk free interest rate of 1.58% and a contractual life of five years. The fair value of the CRG warrants is recorded as additional paid-in capital as part of the accounting for the debt conversion.

In February 2020, a total of 102,626 shares of common stock were issued in connection with the exercise of Series A warrants for gross proceeds of approximately $1,591,000, and a total of 4,548 shares of common stock were issued in connection with the exercise of Series B warrants for gross proceeds of approximately $70,000.

On April 15, 2020, the Company reduced the exercise price of the outstanding Series A warrants and Series B warrants from $15.50 per share to $6.10 per share. The Series A and B warrant exercise price adjustment to $6.10 per share from $15.50 per share resulted in the recognition of a modification expense on April 15, 2020, under the analogous guidance with respect to stock option modification under FASB ASC Topic 718, Stock-Based Compensation (ASC 718), wherein an exchange of warrants is deemed to be a modification of the initial warrant agreement by the replacement with a revised warrant agreement, requiring the incremental fair value, measured as the difference between the fair value immediately after the modification as compared to the fair value immediately before the modification, to the extent an increase, recognized as a modification expense. In this regard, the Series A warrants and Series B warrants exercise price adjustment resulted in the recognition of a current period modification expense of $1,838,000 included in other income (expense) in the consolidated statement of operations, with a corresponding increase to additional paid-in capital in the consolidated balance sheet. The modification expense incremental fair value was estimated using a Black-Scholes valuation model, using the following assumptions:

	Immediately before Modification	Immediately After Modification
Exercise price	$ 15.50	$ 6.10
Common stock price	$ 6.30	$ 6.30
Expected term (in years)	2.8	2.8
Average volatility	97%	97%
Risk-free interest rate	0.27%	0.27%
Dividend yield	0%	0%

On April 16, 2020, the Company entered into inducement letter agreements with certain institutional and accredited holders of Series A warrants and Series B warrants pursuant to which such holders agreed to exercise Series A warrants to purchase 482,059 shares of common stock and Series B warrants to purchase 24,279 shares of common stock for aggregate exercise proceeds to the Company of approximately $3,089,000.

In conjunction, the Company also agreed to issue new Series A-2 warrants to purchase up to 482,059 shares of common stock as an inducement for the exercise of Series A warrants, and new Series B-2 warrants to purchase up to 24,279 shares of common stock as an inducement for the exercise of Series B warrants, in each case at an exercise price of $6.371 per share and for a term of five years. The Company determined the fair value of the Series A-2 and the Series B-2 warrants on the date of issuance to be approximately $1,838,000 using the Black-Scholes option pricing model. Assumptions used were dividend yield of 0%, volatility of 84.1%, risk free interest rate of .35% and a contractual life of five years. The fair value of the Series A-2 and B-2 warrants is recorded as a cost of issuance of the offering and as additional paid-in capital. The transaction closed on April 20, 2020. Other transaction costs in connection with the 2020 Warrant Offering were approximately $334,000.

In May 2020, a total of 410 shares of common stock were issued in connection with the exercise of Series A warrants for gross proceeds of approximately $2,000.

In June 2020, a total of 2,761 shares of common stock were issued in connection with the exercise of Series A warrants for gross proceeds of approximately $17,000, and a total of 5,070 shares of common stock were issued in connection with the exercise of Series B warrants for gross proceeds of approximately $31,000.

In August 2020, a total of 111,704 shares of common stock were issued in connection with the exercise of Series A warrants for gross proceeds of approximately $681,000, and a total of 380,913 shares of common stock were issued in connection with the exercise of Series B warrants for gross proceeds of approximately $2,324,000.

In August 2020, a total of 89,230 shares of common stock were issued in connection with the exercise of Series A-2 warrants for gross proceeds of approximately $568,000, and a total of 3,899 shares of common stock were issued in connection with the exercise of Series B-2 warrants for gross proceeds of approximately $25,000.

In September 2020, a total of 1,500 shares of common stock were issued in connection with the exercise of Series B warrants for gross proceeds of approximately $9,000.

In connection with the January 2021 Offering, warrants to purchase up to 8,117,640 shares of common stock were issued in the offering. The warrants to purchase one share of common stock have an exercise price of $3.40 per share and expires on the fifth anniversary of the date of issuance.

As a result of the closing of the January 2021 Offering at an effective price of $3.40 per share of its common stock, the per share exercise price of our previously issued Series B, A-2 and B-2 common stock warrants was automatically reduced pursuant to the terms of the warrants. The exercise price for Series B warrants was reduced from $6.10 per share to $3.40 per share. The exercise price for Series A-2 and B-2 warrants was reduced from $6.371 per share to $3.40 per share. There was no change to the quantity of warrant shares. The Company determined the incremental fair value on Series B, A-2 and B-2 warrants due to the reduction of exercise price on the date of such modification to be approximately $287,000 using the Black-Scholes option pricing model. Assumptions used were as follows:

Series B Warrants	Immediately before Modification	Immediately After Modification
Exercise price	$ 6.10	$ 3.40
Common stock price	$ 3.19	$ 3.19
Expected term (in years)	3.9	3.9
Average volatility	90%	90%
Risk-free interest rate	0.33%	0.33%
Dividend yield	0%	0%

Series A-2 and B-2 Warrants	Immediately before Modification	Immediately After Modification
Exercise price	$ 6.37	$ 3.40
Common stock price	$ 3.19	$ 3.19
Expected term (in years)	4.3	4.3
Average volatility	90%	90%
Risk-free interest rate	0.33%	0.33%
Dividend yield	0%	0%

On May 4, 2021, pursuant to the provisions under the Purchase Agreement as amended, LPC purchased 250,000 shares at $2.817 per share of the Company's common stock. As a result, the per share exercise price of our previously issued Series B, A-2 and B-2 common stock warrants was automatically reduced from $3.40 to $2.817 pursuant to the terms of the warrants. There was no change to the quantity of warrant shares. The Company determined the incremental fair value on Series B, A-2 and B-2 warrants due to the reduction of exercise price on the date of such modification to be approximately $86,000 using the Black-Scholes option pricing model. Assumptions used were as follows:

Series B, A-2 and B-2 Warrants	Immediately before Modification	Immediately After Modification
Exercise price	$ 3.40	$ 2.82
Common stock price	$ 3.01	$ 3.01
Expected term (in years)	3.6	3.6
Average volatility	80%	80%
Risk-free interest rate	0.58%	0.58%
Dividend yield	0%	0%

The incremental fair value of the Series B, A-2 and B-2 warrants is included in other income (expense) in the consolidated statement of operations, with a corresponding increase to additional paid-in capital in the consolidated balance sheet.

In February 2021, a total of 40,000 shares of common stock were issued in connection with the exercise of Series B warrants for gross proceeds of approximately $136,000 and a total of 8,760 shares of common stock were issued in connection with the exercise of January 2021 warrants for gross proceeds of approximately $30,000.

In March 2021, a total of 4,000 shares of common stock were issued in connection with the exercise of January 2021 warrants for gross proceeds of approximately $13,000.

During the year ended December 31, 2021, a total of 52,760 shares were issued in connection with the exercise of warrants for gross proceeds of approximately $179,000. During the year ended December 31, 2020, a total of 1,209,000 shares were issued in connection with the exercise of warrants for gross proceeds of approximately $8,407,000.

No shares issuable pursuant to warrants have been cancelled during the year ended December 31, 2021 and 2020.

A total of 6 shares issuable pursuant to warrants expired during the year ended December 31, 2021. A total of 42,404 shares issuable pursuant to warrants expired during the year ended December 31, 2020.

As of December 31, 2021, there were no Series A warrants remaining to purchase shares of common stock and Series B warrants to purchase a total of 285,632 shares of common stock still remaining and outstanding.

As of December 31, 2021, there were Series A-2 warrants to purchase a total of 392,830 shares of common stock, and Series B-2 warrants to purchase a total of 20,380 shares of common stock still remaining and outstanding.

As of December 31, 2021, there were January 2021 warrants to purchase a total of 8,104,880 shares of common stock still remaining and outstanding.

13. Summary of Stock Options

Stock Option Plans

The Company has issued equity awards in the form of stock options (both incentive stock options and non-qualified stock options) and deferred restricted stock awards or units, from two employee benefit plans. The plans include the Viveve Amended and Restated 2006 Stock Plan (the "2006 Plan") and the Company's Amended and Restated 2013 Stock Option and Incentive Plan (the "2013 Plan").

As of December 31, 2021, there were outstanding stock option awards issued from the 2006 Plan covering a total of 12 shares of the Company's common stock and no shares are available for future awards. The weighted average exercise price of the outstanding stock options is $9,920.00 per share and the weighted average remaining contractual term is 1.1 years.

The 2013 Plan was also adopted by the Company's board of directors and approved by its stockholders. The 2013 Plan is administered by the compensation committee of the Company's board of directors (the "Administrator"). Under the 2013 Plan, the Company may grant equity awards to eligible participants which may take the form of stock options (both incentive stock options and non-qualified stock options), stock appreciation rights, restricted, deferred or unrestricted stock awards, performance-based awards or dividend equivalent rights. Awards may be granted to officers, employees, nonemployee directors (as defined in the 2013 Plan) and other key persons (including consultants and prospective employees). The term of any stock option award may not exceed 10 years and may be subject to vesting conditions, as determined by the Administrator. Options granted generally vest over four years. Incentive stock options may be granted only to employees of the Company or any subsidiary that is a "subsidiary corporation" within the meaning of Section 424(f) of the Internal Revenue Code. The exercise price of any stock option award cannot be less than the fair market value of the Company's common stock, provided, however, that an incentive stock option granted to an employee who owns more than 10% of the Company's outstanding voting power must have an exercise price of no less than 110% of the fair market value of the Company's common stock and a term that does not exceed five years.

On August 22, 2016, the Company's stockholders approved an amendment to the 2013 Plan to add an "evergreen" provision which will automatically increase annually, on the first day of each January, the maximum number of shares of common stock reserved and available under the 2013 plan (the "Stock Issuable") by an amount equal to the lesser of (i) the number of shares that will increase the Stock Issuable by 4% of the total number of shares of common stock outstanding (on a fully diluted basis) or (ii) an amount determined by the board of directors.

In January 2020, the board of directors approved the 2020 evergreen provision increasing the total stock reserved for issuance under the 2013 Plan by 263,993 shares from 1,187,253 shares to a total of 1,451,246 shares, which was effective January 1, 2020.

In January 2021, the total common stock reserved for issuance under the 2013 Plan was increased by 307,705 shares from 1,451,246 shares to a total of 1,758,951 shares under the evergreen provision of the 2013 Plan.

In June 2021, the Company's stockholders approved an amendment to the 2013 Plan to increase the number of shares of common stock reserved for issuance thereunder from 1,758,951 to a total of 3,940,136 shares. See Note 17 for increase in common stock available for issuance under the 2013 Plan subsequent to December 31, 2021.

As of December 31, 2021, there were outstanding stock option awards issued from the 2013 Plan covering a total of 3,173,091 shares of the Company's common stock and there remain reserved for future awards 94,392 shares of the Company's common stock. The weighted average exercise price of the outstanding stock options is $7.48 per share, and the remaining contractual term is 9.0 years.

Activity under the 2006 Plan and the 2013 Plan is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Options outstanding, January 1, 2021	986,399	$ 19.10	8.9	$ 675
Options granted	2,251,000	$ 2.73		
Options exercised	-			
Options canceled	(64,296)	$ 17.85		
Options outstanding, December 31, 2021	3,173,103	$ 7.51	9.0	$ -
Vested and exercisable and expected to vest, December 31, 2021	2,947,472	$ 7.83	9.0	$ -
Vested and exercisable, December 31, 2021	774,800	$ 18.81	8.5	$ -

The aggregate intrinsic value reflects the difference between the exercise price of the underlying stock options and the Company's closing share price as of December 31, 2021.

The options outstanding and exercisable as of December 31, 2021 are as follows:

Range of Exercise Prices	Number Outstanding as of December 31, 2021	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Number Exercisable as of December 31, 2021	Weighted Average Exercise Price
$2.28- $2.96	2,208,063	$ 2.73	9.5	259,301	$ 2.73
$3.06- $3.40	10,000	$ 3.20	9.2	-	$ -
$4.45- $4.80	11,900	$ 4.72	8.9	3,088	$ 4.71
$5.10- $5.40	88,000	$ 5.28	8.8	62,219	$ 5.34
$6.90- $6.90	5,400	$ 6.90	8.3	2,364	$ 6.90
$8.60- $8.91	830,825	$ 8.69	7.9	433,263	$ 8.69
$10.90- $13.60	15,500	$ 12.64	8.2	11,271	$ 13.00
$380.00- $9,920.00	3,415	$ 2,873.63	6.2	3,294	$ 2,911.12
Total:	3,173,103	$ 7.51	9.0	774,800	$ 18.81

Deferred Restricted Stock Units

As of December 31, 2021, there are 674,000 shares of unvested restricted stock outstanding that have been granted by the Company pursuant to deferred restricted stock units ("RSUs") under the 2013 Plan.

In January 2021, the Company granted annual equity awards to employees and board members for 690,000 shares of common stock issuable upon vesting of RSUs under the 2013 Plan. The RSUs vest in full on the second anniversary of the grant date.

During the year ended December 31, 2021, RSUs for 16,000 shares of common stock were cancelled.

During the year ended December 31, 2020, no RSUs for shares of common stock under the2013 Plan were granted by the Company.

Deferred Restricted Stock Awards

As of December 31, 2021, there are 228 shares of unvested restricted stock outstanding that have been granted by the Company pursuant to deferred restricted stock awards ("RSAs") under the 2013 Plan.

During the year ended December 31, 2021 and 2020, no RSAs for shares of common stock were granted by the Company.

During the year ended December 31, 2021 and 2020, RSAs for 6 and 18 shares of common stock were cancelled, respectively.

2017 Employee Stock Purchase Plan

In August 2017, the stockholders approved the Company's 2017 Employee Stock Purchase Plan (the "2017 ESPP"). Eligible employees may purchase shares of common stock through periodic payroll deductions, with a maximum purchase of 200 shares of common stock in any offering period. The price of common stock purchased under the 2017 ESPP is equal to 85% of the lesser of the fair market value of common stock on thefirst or last day of the offering period. Each offering period is for a period of three months.

The activity of the Company's 2017 ESPP for the year ended December 31, 2020 is described as follows:

- The tenth offering period under the Company's 2017 ESPP began on January 1, 2020 and ended on March 31, 2020, and 32 shares were issued on March 31, 2020 at a purchase price of $5.86.
- The eleventh offering period under the Company's 2017 ESPP began on April 1, 2020 and ended on June 30, 2020, and 30 shares were issued on June 30, 2020 at a purchase price of $4.79.
- The twelfth offering period under the Company's 2017 ESPP began on July 1, 2020, and ended on September 30, 2020, and 22 shares were issued on September 30, 2020 at a purchase price of $4.44.

In September 2020, the board of directors approved the suspension of the2017 ESPP following the twelfth offering period and the ESPP purchase on September 30, 2020.

In June 2021, the Company's stockholders approved an amendment to the 2017 ESPP to increase the number of shares of common stock reserved for issuance thereunder from 400 to 500,378 shares and to increase the number of shares available in an offering period from2 to 2,000 per participant (subject to adjustment in the event of certain changes to the Company's capital structure and other similar events).

Following the Company's annual stockholders' meeting, the board of directors approved to reactivate the ESPP effective with the offering period beginning on July 1, 2021.

The activity of the Company's 2017 ESPP for the year ended December 31, 2021 is described as follows:

- The thirteenth offering period under the Company's 2017 ESPP began on July 1, 2021, and ended on September 30, 2021, and 10,844 shares were issued on September 30, 2021 at a purchase price of $1.94.
- The fourteenth offering period under the Company's 2017 ESPP began on October 1, 2021, and ended on December 31, 2021, and 17,286 shares were issued onDecember 31, 2021 at a purchase price of $0.97.

The Company estimated the fair value of purchase rights under the ESPP using the Black-Scholes option valuation model and the straight-line attribution approach.

As of December 31, 2021, the remaining shares available for issuance under the 2017 ESPP were 471,870 shares.

Stock-Based Compensation

During the years ended December 31, 2021 and 2020, the Company granted stock options to employees and nonemployees to purchase2,251,000 and 146,700 of common stock with a weighted average grant date fair value of $1.75 and $4.08 per share, respectively. There were no stock options exercised by employees and nonemployees during the years ended December 31, 2021 and 2020.

The Company estimated the fair value of stock options using the Black-Scholes option pricing model. The fair value of stock options is being amortized on a straight-line basis over the requisite service period of the awards. The fair value of stock options granted was estimated using the following weighted average assumptions:

	Year Ended December 31,	
	2021	2020
Expected term (in years)	6	5
Average volatility	76%	82%
Risk-free interest rate	0.97%	0.37%
Dividend yield	0%	0%

Option-pricing models require the input of various subjective assumptions, including the option's expected life and the price volatility of the underlying stock. The expected stock price volatility is based on analysis of the Company's stock price history over a period commensurate with the expected term of the options, trading volume of comparable companies' stock, look-back volatilities and the Company specific events that affected volatility in a prior period. The expected term of stock options represents the weighted average period the stock options are expected to remain outstanding and is based on the history of exercises and cancellations on all past option grants made by the Company, the contractual term, the vesting period and the expected remaining term of the outstanding options. The risk-free interest rate is based on the U.S. Treasury interest rates whose term is consistent with the expected life of the stock options. No dividend yield is included as the Company has not issued any dividends and does not anticipate issuing any dividends in the future.

The following table shows stock-based compensation expense for options, RSUs and ESPP shares included in the consolidated statements of operations for the years ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,	
	2021	2020
Cost of revenue	$ 265	$ 208
Research and development	456	325
Selling, general and administrative	3,058	2,118
Total	$ 3,779	$ 2,651

As of December 31, 2021, the total unrecognized compensation cost in connection with unvested stock options was approximately $5,831,000. These costs are expected to be recognized over a period of approximately 2.8 years.

As of December 31, 2021, the total unrecognized compensation cost in connection with unvested RSUs was approximately $1,151,000. These costs are expected to be recognized over a period of approximately 1.1 years.

14. Income Taxes

No provision for income taxes has been recorded due to the net operating losses incurred from inception to date, for which no benefit has been recorded.

The Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was enacted on March 27, 2020 in the United States. The CARES Act includes several significant provisions for corporations, including the usage of net operating losses and payroll benefits. The Company is evaluating the impact, if any, the CARES Act and other economic stimulus measures will have on the Company's financials and disclosures.

The Company's effective tax rate is 0% for the years ended December 31, 2021 and 2020.

A reconciliation of the U.S. statutory income tax rate to the Company's effective tax rate is as follows:

	Year Ended December 31,	
	2021	2020
Income tax benefit at statutory rate	(21)%	(21)%
State income taxes, net of federal benefit	(3)%	(3)%
Change in valuation allowance	21%	20%
Other	3%	4%
Effective tax rate	0%	0%

The components of the Company's net deferred tax assets and liabilities are as follows (in thousands):

	Year Ended December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 25,092	$ 20,891
Capitalized start up costs	2,511	2,866
Research and development credits	781	631
Accruals and reserves	1,537	773
Fixed assets and depreciation	124	291
Total deferred tax assets	30,045	25,452
Deferred tax liabilities:		
Valuation allowance	(30,045)	(25,452)
Net deferred tax assets	$ -	$ -

The Company has recorded a full valuation allowance for its deferred tax assets based on its past losses and the uncertainty regarding the ability to project future taxable income. The valuation allowance increased by approximately $4,593,000 during the year ended December 31, 2021 and decreased by approximately $4,352,000 during the year ended December 31, 2020.

As of December 31, 2021, the Company has net operating loss ("NOL") carryforwards for federal and state income tax purposes of approximately $112,951,000 and $34,469,000, respectively. The federal NOLs do not expire and the state NOLs will begin to expire in the year 2028.

The Company has California research and development tax credits of approximately $768,000. The credits have no expiration date. The Company also has Colorado job growth incentive tax credits of approximately $451,000. The credits will begin to expire in the year 2028.

Utilization of the NOL and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership changes that have occurred previously or that could occur in the future, as provided by Section 382 of the Internal Revenue Code of 1986, as well as similar state provisions. Ownership changes may limit the amount of NOL and tax credit carryforwards that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. While the Company has not performed a formal study, it believes it experienced a change of control in November 2019, which will result in the expiration of a portion of the NOL and research and development credit carryforwards before utilization. Subsequent ownership changes, such as the January 2021 Offering, could further impact the limitation in future years. A full valuation allowance has been provided against the Company's NOL carryforwards and research and development credit carryforwards and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no net impact to the consolidated balance sheets or the consolidated statements of operations if an adjustment were required.

As of December 31, 2021, the Company had not accrued any interest or penalties related to uncertain tax positions.

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

	Year Ended December 31,	
	2021	2020
Balance at the beginning of the year	$ 245	$ 223
Additions (deletions) based upon tax positions related to the current year	(14)	22
Balance at the end of the year	$ 231	$ 245

If the ending balance of $231,000 of unrecognized tax benefits as of December 31, 2021 were recognized, none of the recognition would affect the income tax rate. The Company does not anticipate any material change in its unrecognized tax benefits over the next twelve months. The unrecognized tax benefits may change during the next year for items that arise in the ordinary course of business.

The Company files U.S. federal and state income tax returns with varying statutes of limitations. All tax years since inception remain open to examination due to the carryover of unused net operating losses and tax credits.

15. Related Party Transactions

In June 2006, the Company entered into a Development and Manufacturing Agreement (the "Agreement") with Stellartech Research Corporation ("Stellartech"). The Agreement was amended on October 4, 2007. Under the Agreement, the Company agreed to purchase 300 generators manufactured by Stellartech. As of December 31, 2021, the Company has purchased 855 units. The price per unit is variable and dependent on the volume and timing of units ordered. In conjunction with the Agreement, Stellartech purchased 38 shares of Viveve, Inc.'s common stock. Under the Agreement, the Company paid Stellartech $205,000 and $1,051,000 for goods and services during the years ended December 31, 2021 and 2020, respectively.

In August 2017, the Company entered into a Distributorship Agreement with ICM. Under the terms of the Distributorship Agreement, the Company had a minimum purchase requirement to purchase a certain quantity of ICM products per month during the term of this agreement. In February 2019, the Company executed a mutual termination of the Distributorship Agreement with ICM. As a result, the Company no longer has a minimum purchase requirement to purchase a certain quantity of ICM products per month. (See Note 5 – Investment in Limited Liability Company for transactions with ICM.)

16. Segments and Geographic Information

The Company's long-lived assets by geographic area were as follows (in thousands):

	December 31,	
	2021	2020
United States	$ 1,553	$ 2,622
Asia Pacific	-	76
Canada	1	54
Europe	-	7
Total	$ 1,554	$ 2,759

Long-lived assets, comprised of property and equipment, are reported based on the location of the assets at each balance sheet date.

17. Subsequent Events

2013 Plan - 2022 Evergreen

Effective January 1, 2022, the total common stock reserved for issuance under the 2013 Plan was increased by 1,076,833 shares from 3,940,136 shares to a total of 5,016,969 shares under the evergreen provision of the 2013 Plan.

Annual Equity Awards

In January 2022, the Company granted annual stock options to employees and board members to purchase 941,000 shares of common stock with a weighted average grant fair value of $1.26 per share under the 2013 Plan. The stock options vest and become exercisable in 48 equal monthly installments from the grant date.

Retention Bonus

On January 18, 2022, the board of directors approved the payment of retention bonuses to certain key employees. The bonus payments totaling approximately $700,000 are expected to be made in two equal installments during fiscal year 2022, subject to a claw back provision in the event the employee terminates his or her service before January 31, 2023.

Series C Convertible Preferred Stock

On March 14, 2022, the Company filed a Certificate of Elimination with the Delaware Secretary of State with respect to the authorized shares of Series C convertible preferred stock. As of the date of the filing of the Certificate of Elimination, no shares of Series C convertible preferred stock were outstanding. Upon filing the Certificate of Elimination, the 2,450,880 authorized shares of Series C convertible preferred stock were returned to the status of authorized but unissued shares of preferred stock of the Company, without designation as to series or rights, preferences, privileges or limitations.

Exhibit 3.9

CERTIFICATE OF ELIMINATION
OF
SERIES C CONVERTIBLE PREFERRED STOCK, A SERIES OF PREFERRED STOCK
OF
VIVEVE MEDICAL, INC.
(Pursuant to Section 151(g) of the
Delaware General Corporation Law)

VIVEVE MEDICAL, INC., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), does hereby certify that the following resolutions respecting Series C Convertible Preferred Stock, a series of preferred stock, par value $0.0001 per share (the "Series C Convertible Preferred Stock"), were duly adopted by the Corporation's Board of Directors (the "Board of Directors"):

WHEREAS: On January 15, 2021, the Corporation filed a Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock (the "Series C Certificate of Designation") with the Secretary of State of the State of Delaware pursuant to Section 151(g) of the Delaware General Corporation Law (the "DGCL") designating 2,450,880 shares of the Corporation's authorized preferred stock as Series C Convertible Preferred Stock.

RESOLVED: That no shares of the Series C Convertible Preferred Stock are outstanding and that no shares of the Series C Convertible Preferred Stock will be issued subject to the Series C Certificate of Designation.

RESOLVED: That pursuant to the authority conferred upon the Board of Directors by the provisions of the Corporation's Amended and Restated Certificate of Incorporation (as amended, the "Charter") and by Section 151(g) of the DGCL, the Board of Directors hereby eliminates the Series C Convertible Preferred Stock authorized by the Corporation, none of which is currently outstanding and none of which will be issued in the future, and that all matters set forth in the Series C Certificate of Designation be eliminated from the Charter.

RESOLVED: That the Corporation's officers be, and each of them hereby is, authorized and directed to execute and file with the Secretary of State of the State of Delaware a certificate pursuant to Sections 103 and 151(g) of the DGCL setting forth these resolutions in order to eliminate from the Charter all matters set forth in the Series C Certificate of Designation and all such other documents, supplements, exhibits and further information with respect thereto, in such form and with respect to such matters as the officer or officers so acting (individually or by power of attorney) may deem necessary or desirable.

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Elimination to be executed to be signed by its duly authorized officer this 14th day of March, 2022.

VIVEVE MEDICAL, INC.

By: /s/ Scott Durbin
Name: Scott Durbin
Title: Chief Executive Officer

Exhibit 4.20

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

As of December 31, 2021

Viveve Medical, Inc. ("Viveve") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): common stock, par value $0.0001 per share (the "common stock").

DESCRIPTION OF COMMON STOCK

The following summary description sets forth some of the general terms and provisions of the common stock. Because this is a summary description, it does not contain all of the information that may be important to you. For a more detailed description of the common stock, you should refer to the provisions of our amended and restated certificate of incorporation and amendments thereto and the form of certificate of designation of our Series B Preferred Stock (collectively, the "Charter") and our amended and restated bylaws, as amended ("Bylaws"), each of which is an exhibit to this Annual Report on Form 10-K to which this description is an exhibit.

General

Under the Charter, Viveve is authorized to issue up to 75,000,000 shares of common stock with a par value $0.0001 per share and 10,000,000 shares of preferred stock, par value $0.0001 per share. Of our 10,000,000 shares of preferred stock, 100,000 shares are designated Series B Preferred Stock. On December 16, 2020, Viveve filed a certificate of elimination with the State of Delaware to eliminate the Company's class of Series A Preferred Stock. On January 15, 2021, Viveve filed a certificate of designation with the State of Delaware to designate 2,450,880 shares of preferred stock as Series C Preferred Stock, and on March 14, 2022, Viveve filed a certificate of elimination with the State of Delaware to eliminate the Company's class of Series C Preferred Stock.

Common Stock

The holders of common stock are entitled to one vote per share. Our Charter does not expressly prohibit cumulative voting. The holders of our common stock are entitled to receive ratably such dividends, if any, as may be declared by the board of directors out of legally available funds. Upon liquidation, dissolution or winding-up, the holders of our common stock are entitled to share ratably in all assets that are legally available for distribution. The holders of our common stock have no preemptive, subscription, redemption or conversion rights.

The rights, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of any series of preferred stock, which may be designated solely by action of the board of directors and issued in the future.

Preferred Stock

Our board of directors is authorized, subject to any limitations prescribed by law, without further vote or action by our stockholders, to issue from time-to-time shares of preferred stock in one or more series. The directors may from time to time by resolution passed before the issue of any preferred stock of any particular series, fix the number of shares of preferred stock of any particular series, determine the designation of the shares of preferred stock of that series and create, define and attach special rights and restrictions to the shares of preferred stock of that series including, but without in any way limiting or restricting the generality of the foregoing: the rate or amount of dividends, whether cumulative, non-cumulative or partially cumulative; the dates, places and currencies of payment thereof; the consideration for, and the terms and conditions of, any purchase for cancellation or redemption thereof, including redemption after a fixed term or at a premium; conversion or exchange rights or rights of retraction (provided that any such conversion or exchange rights or rights of retraction shall be in accordance with the provisions existing at the time of creation of such series relating to conversion, exchange, or retraction as prescribed by the policies of any stock exchange on which our shares are then listed); the terms and conditions of any share purchase plan or sinking fund; and voting rights and restrictions.

Holders of preferred stock will be entitled, on the distribution of our assets or in the event of our liquidation, dissolution or winding-up, whether voluntary or involuntary, or on any other distribution of our assets among our stockholders for the purpose of winding-up our affairs, to receive before any distribution to be made to holders of common stock or any other shares of stock ranking junior to the preferred stock with respect to repayment of capital, but after any distributions shall be made on any Series B preferred stock or any of our existing or future indebtedness, the amount due to the holders of preferred stock in accordance with our Charter with respect to each share of preferred stock held by them, together with all accrued and unpaid cumulative dividends on Series B preferred stock and any preferential dividends on any other series of preferred stock, and all declared and unpaid non-cumulative dividends (if any and if preferential) on any series of preferred stock.

Except for voting rights that may be attached to any series of the preferred stock by the directors, holders of preferred stock will not be entitled to vote at any meeting of our stockholders. Holders of Series B Preferred Stock do not have any rights with respect to such shares prior to conversion of such shares to common stock. Holders of preferred stock will be given notice of and be invited to attend meetings of our voting stockholders.

It is not possible to state the actual effect of the issuance of any other preferred stock upon the rights of holders of our common stock until the board of directors determines the specific rights of the holders of such preferred stock. However, the effects might include, among other things:

- impairing dividend rights of our common stock;
- diluting the voting power of our common stock;
- impairing the liquidation rights of our common stock; and
- delaying or preventing a change of control without further action by our stockholders.

Listing
Our common stock is listed on The NASDAQ Capital Market under the symbol “VIVE.”

Delaware as the Exclusive Jurisdiction for State Law Claims
Unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claim for: (1) any derivative action or proceeding brought on the Company's behalf; (2) any action asserting a claim of, or a claim based on, breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us or our directors, officers, employees or stockholders arising pursuant to any provision of the Delaware General Corporation Law or our Charter and Bylaws; or (4) any action asserting a claim governed by the internal affairs doctrine (the “Delaware Forum Provision”); provided, however, that this Delaware Forum Provision does not apply to any actions arising under the Securities Act or the Exchange Act. The Delaware Forum Provision may impose additional litigation costs on stockholders in pursuing such claims, particularly if the stockholders do not reside in or near the State of Delaware. Additionally, the Delaware Forum Provision may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of such lawsuits. The Court of Chancery of the State of Delaware may also reach different judgment or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Antitakeover Effects of Delaware Law and Provisions of our Charter and Bylaws
Certain provisions of the Delaware General Corporation Law and of our Charter and Bylaws could have the effect of delaying, deferring or discouraging another party from acquiring control of us unless such takeover or change of control is approved by the board of directors. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and, as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions are also designed in part to encourage anyone seeking to acquire control of us to first negotiate with our board of directors. These provisions might also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests. However, we believe that the advantages gained by protecting our ability to negotiate with any unsolicited and potentially unfriendly acquirer outweigh the disadvantages of discouraging such proposals, including those priced above the then-current market value of our common stock, because, among other reasons, the negotiation of such proposals could improve their terms.

Delaware Takeover Statute
We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or

- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge, exchange, mortgage or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Provisions of our Charter and Bylaws
Our Charter and Bylaws include a number of provisions that may have the effect of delaying, deferring or discouraging another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board composition and filling vacancies. In accordance with our Charter, our board is divided into three classes serving staggered three-year terms, with one class being elected each year. Our Charter also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of 75% or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum.

No written consent of stockholders. Our Charter provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our Bylaws or removal of directors by our stockholder without holding a meeting of stockholders.

Meetings of stockholders. Our Bylaws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our Bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance notice requirements. Our Bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days or more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. The notice must contain certain information specified in our Bylaws.

Amendment to Charter and Bylaws. As required by the Delaware General Corporation Law, any amendment of our Charter must first be approved by a majority of our board of directors, and if required by law or our Charter, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment, and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, directors, limitation of liability and the amendment of our Charter must be approved by not less than 75% of the outstanding shares entitled to vote on the amendment, and not less than 75% of the outstanding shares of each class entitled to vote thereon as a class. Our Bylaws may be amended by the affirmative vote of a majority vote of the directors then in office, subject to any limitations set forth in the Bylaws; and may also be amended by the affirmative vote of at least 75% of the outstanding shares entitled to vote on the amendment, or, if the board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated preferred stock. Our Charter provides for authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of us or our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our Charter grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-257648) and Form S-8 (Nos. 333-262007, 333-257649, 333-254916, 333-237279, 333-226152, 333-220833, 333-213363, 333-206041, 333-201551, 333-153535, and 333-127770) of Viveve Medical, Inc. of our report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1 to the financial statements) dated March 17, 2022 relating to the consolidated financial statements of Viveve Medical, Inc., which appears in this Annual Report on Form 10-K.

/s/ BPM LLP
San Jose, California
March 17, 2022

Exhibit 31.1

Certification of Principal Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

I, Scott Durbin, certify that:

1. I have reviewed this Annual Report on Form 10-K for Viveve Medical, 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(s) 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(s) 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 17, 2022

/s/ Scott Durbin
Scott Durbin
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Accounting and Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

I, Jim Robbins, certify that:

1. I have reviewed this Annual Report on Form 10-K for Viveve Medical, 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(s) 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(s) 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 17, 2022

/s/ Jim Robbins
Jim Robbins
Senior Vice President of Finance and Administration
(Principal Accounting and Financial Officer)

Exhibit 32.1

Certification
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (A) and (B) of Section 1350, Chapter 63 of Title 18,
United States Code)

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of Title 18, United States Code), the undersigned officer of Viveve Medical, Inc. (the "Company"), does hereby certify with respect to the Annual Report of the Company on Form 10-K for the period ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: March 17, 2022

/s/ Scott Durbin
Scott Durbin
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

Certification
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (A) and (B) of Section 1350, Chapter 63 of Title 18,
United States Code)

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of Title 18, United States Code), the undersigned officer of Viveve Medical, Inc. (the "Company"), does hereby certify with respect to the Annual Report of the Company on Form 10-K for the period ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: March 17, 2022

/s/ Jim Robbins
Jim Robbins
Senior Vice President of Finance and Administration
(Principal Accounting and Financial Officer)