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, 2018**

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	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

As of June 29,2018, 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 $68,489,676

Number of shares outstanding of the Registrant's common stock, as of March 8, 2019: 46,364,570

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2018 Annual Meeting of Stockholders, which the registrant intends to file with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days after the end of the registrant's fiscal year ended December 31, 2018, are incorporated by reference into Part III of this Annual Report on Form 10-K.

VIVEVE MEDICAL, INC.

Table of Contents

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.

PART I

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;
- whether we are successful in having our medical device approved or cleared for sale by the U.S. Food and Drug Administration ("FDA") for all indications;
- 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 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;
- 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.

Item 1. Business

Viveve designs, develops, manufactures and markets a platform medical technology, which we refer to as Cryogen-cooled Monopolar RadioFrequency, or 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 stress urinary incontinence 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 stress urinary incontinence 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, provides 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 North America, which includes the U.S. and Canada, the Viveve System is sold through a direct sales force, as well as distribution partners. In most other regions, we market and sell primarily through a network of distribution partners.

Currently, the Viveve System is cleared for marketing in 60 countries throughout the world under the following indications for use:

Indication for Use:	**No. of Countries:**
General surgical procedures for electrocoagulation and hemostasis (including the U.S.)	3
General surgical procedures for electrocoagulation and hemostasis of vaginal tissue and for the treatment of vaginal laxity	32
For treatment of vaginal laxity	6
For treatment of the vaginal introitus, after vaginal childbirth, to improve sexual function	16
General surgical procedures for electrocoagulation and hemostasis and for the treatment of vaginal laxity	1
For vaginal rejuvenation	1
For treatment of vaginal laxity, urinary incontinence and sexual function	1

The Viveve System is comprised of three main components: a radiofrequency generator housed in a table-top console; a reusable handpiece; and a single-use treatment tip. Single-use accessories (e.g. RF return pad, coupling fluid), a cryogen canister that can be used for approximately two to five procedures (depending on the procedure type and pulses used), and a foot pedal are also included with the System. Practitioners attach the single-use treatment tip to the handpiece. The generator then authenticates the treatment tip and programs the system for the desired 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.

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 pursuing clearance/approval in the U.S. for the improvement of sexual function, we intend to conduct several clinical trials, and if successful, submit for regulatory clearance/approval in the U.S. and abroad for stress urinary incontinence and potentially vulvovaginal atrophy.

- *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 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 high volume Viveve practices.

- *Broadening Our Customer Base*. While our initial focus is on marketing our procedure to the aesthetics and OB/GYN specialty, we intend to selectively expand our sales efforts into other physician specialties, such as urology, urogynecology, general surgery and family practice. Additionally, we intend to pursue sales from physician-directed medi-spas with track records of safe and successful treatments.

- *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.

As of December 31, 2018, we have sold 703 Viveve Systems and approximately 33,300 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"). 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 sexual well-being and quality of life of women suffering from vaginal laxity and/or urinary incontinence, 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 is comprised of three main components: a radiofrequency generator housed in a table-top console; a reusable handpiece; and a single-use treatment tip. Single-use accessories (e.g. RF return pad, coupling fluid), cryogen canister for approximately two to five procedures (depending on the procedure type and pulses used), and a foot pedal are also included with the System. 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.

- *Radiofrequency 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 radiofrequency (RF) energy for treating tissue:

- *Monopolar Radiofrequency 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 radiofrequency 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 Vaginal Laxity and Sexual Function

Vaginal laxity and tissue architecture have often been overlooked as contributing etiological factors to female sexual dysfunction. 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, urinary incontinence and stretch marks, and believe that it is under-reported by their patients. Additionally, in a separate international survey of urogynecologists, 83% 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. Despite the lack of communication regarding this issue, we believe there is a strong interest among patients and doctors for a treatment that is clinically proven and safe.

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.

Current Approved 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 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 stress urinary incontinence. 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"), approximately 114,135 LVR surgeries were performed world-wide in 2013. 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.

Overview of Stress Urinary Incontinence

Urinary incontinence (UI) is defined by the International Continence Society (ICS) as "the complaint of involuntary leakage of urine." UI is increasingly recognized globally as a health and economic problem, which affects the physical, psychological, social and economic well-being of individuals and their families and poses a substantial economic burden on health and social services.

Women with urinary incontinence have a significantly poorer quality of life than their continent counterparts. The psychological impact of this condition must neither be underestimated nor ignored. The need to use an external pad to absorb urine leakage associated with even normal activities such as coughing or laughing is unsatisfactory, inconvenient, often embarrassing and negatively impacts a woman's quality of life. The main impact urinary incontinence has on women's lives, in terms of social and recreational withdrawal, stems from the fear and anxiety related to becoming incontinent in public and the possibility that others may find out. The result is often reduced activities, decreased productivity, isolation, and depression. Additionally, between 25% to 50% of women with urinary incontinence experience sexual dysfunction.

There are three types of UI. Stress Urinary Incontinence (SUI) is the complaint of involuntary leakage of urine due to increased abdominal pressure caused by exertion, sneezing or coughing. Urge Urinary Incontinence (UUI) is the complaint of involuntary leakage of urine accompanied by or immediately preceded by urgency. Mixed Urinary Incontinence (MUI) is the complaint of involuntary leakage of urine associated with urgency and also with exertion, sneezing, or coughing.

According to the most recent National Center for Health Statistics (NCHS) Health Survey in the U.S., the prevalence of UI in adult women is 33% which is the highest among the ten conditions tracked including obesity, joint pain and hypertension. Additionally, a review of the epidemiologic literature on incontinence showed a prevalence range of 16% to 51% depending on UI definitions, severity levels, and other factors included in the surveys. The average across the literature is 33%, which is similar to the NCHS survey. This translates to 35 million women in the U.S. Of those 35 million 86% have SUI or MUI, 80% of them are bothered and only approximately 700,000 are receiving treatment in the form of conservative therapy or surgical procedures. Accordingly, over 23 million women in the US are bothered by SUI or MUI symptoms and are untreated. Viveve believes that its non-invasive treatment option for SUI may fulfill this large unmet need.

SUI has two major subtypes: intrinsic sphincter deficiency (ISD) and urethral hypermobility. Patients with ISD leak urine because their urethral sphincters do not effectively seal off the inner muscle of the bladder. Urethral hypermobility (UH) refers to the urethral shift that occurs when there is an increase in intrabdominal pressure (e.g., cough/sneeze/jump) and insufficient urethral support by the surrounding pelvic floor muscles and tissue. Most women with SUI have a degree of both ISD and UH.

Risk factors for SUI include pregnancy, childbirth, and menopause. For example, more than 55% of women who have delivered a child vaginally will show symptoms of SUI and are twice as likely to suffer from long-term SUI when compared to cesarean delivery.

Current Cleared Treatments for Stress Urinary Incontinence and Their Limitations

Currently available and effective treatment options for SUI are limited to conservative physiotherapy and more aggressive, invasive options with a lack of efficacious options in between. Pelvic floor muscle training (Kegels), with or without use of a device to assist in Kegels, are generally prescribed as a first step in treatment. Some women may find benefit from these exercises, but long-term compliance and sustainability is challenging. At the other end of the treatment spectrum are bulking agents and surgery with native tissue or mesh or a sling. Bulking agents are best used for women with primarily ISD and can be done in a clinic, however they have limited efficacy and durability. Surgeries including synthetic sling placement have a proven success rate, however, mesh surgery often leads to complications. In addition, surgery requires recovery time for the patient and often comes with risks including recurrence, infection, pain, voiding dysfunction, and anesthetic concerns, leading many women to agree to surgery as a last resort for treatment. The large gap between conservative and highly-invasive treatment options presents an opportunity to provide more effective, safe, and less-invasive treatments for women suffering from SUI.

The Viveve Solution

Radiofrequency (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 that the Viveve System provides a compelling, safe, non-invasive treatment for vaginal laxity, improvement of sexual function that is supported by clinical studies, and improvement of the symptoms of SUI. The Viveve treatment is conducted on an outpatient basis in a practitioner's office. The procedure typically takes approximately 30 - 45 minutes depending on the indication being treated and does not require any form of anesthesia. 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 physicians have treated approximately 15,000 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 30 – 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 30 – 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 pursuing clearance/approval in the U.S. for the improvement of sexual function, we intend to conduct several clinical trials, and if successful, submit for regulatory clearance/approval in the U.S. and abroad for stress urinary incontinence and potentially vulvovaginal atrophy.

- *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 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.

- *Broadening Our Customer Base*. While our initial focus is on marketing our procedure to the aesthetics and OB/GYN specialty, we intend to selectively expand our sales efforts into other physician specialties, such as urology, urogynecology, general surgery and family practice. Additionally, we intend to pursue sales from physician-directed medi-spas with track records of safe and successful treatments.

- *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, including; plastic surgeons, aesthetic dermatologists, OBGYNs, urogynecologists, urologists and others.

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

International

We currently market the Viveve treatments and sell the Viveve System, including the single-use treatment tips in over 50 countries outside of the United States. At the present time, trained direct sales employees or distribution partners represent Viveve and its products in 59 countries in markets in Canada, Europe, the Middle East, Asia Pacific, and Latin America.

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 tradeshows 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.

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, and in January 2017 we hired our inaugural direct sales team. Currently, we have 14 direct sales reps covering the United States and two distribution partners. We are actively seeking regulatory clearance from the FDA to allow us to begin to market the Viveve System for the treatment of vaginal tissue to improve sexual function and the symptoms of stress urinary incontinence, to physicians practicing in the U.S. and to build awareness of the Viveve treatment among patients residing in the U.S. If we are successful in obtaining these clearances, we may expand our direct sales efforts in the future.

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/sexual function and SUI. We are currently conducting a sexual function trial under IDE in the U.S. (VIVEVE II), an international trial in Canada for SUI (LIBERATE-International) and are preparing to conduct a clinical study in the U.S. for SUI (LIBERATE-US), when we receive approval of our IDE application from the FDA. 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.

Pre-clinical Studies

In 2010, in collaboration with West Virginia University, we conducted an animal study in sheep to assess the safety, and further understand the mechanism of action, of the Viveve treatment. The vaginal introitus of five parous sheep were treated once with the Viveve System using a variety of energy levels (75−90 Joules/cm2). Each sheep 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 sheep. 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 haematoxylin and eosin ("H&E") stained slides that were reviewed by pathologists who were blinded as to the treated and untreated sheep.

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.

Clinical Studies – Vaginal Laxity and Sexual Function

United States Pilot Study

We conducted our first human study beginning in November 2008. The study was a single-arm study (without a control group) 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, with no anesthesia – 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 to pre-childbirth levels. 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. 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, with no anesthesia, 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 to pre-childbirth levels. 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 (VIveve treatment of the Vaginal introitus to EValuate Effectiveness), 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.

We believe that the consistency of results across these three clinical study populations, is indicative of the cross-cultural similarities in this medical condition and the positive impact that an effective non-invasive treatment can have on the sexual health of women after vaginal childbirth.

VIVEVE II Clinical Study

In March 2019, enrollment was completed for the VIVEVE II (VIveve treatment of the Vaginal Introitus to EValuate Effectiveness) clinical study following IDE approval by the FDA. This is a prospective, randomized, double-blind, sham controlled study to evaluate the efficacy and safety of the Viveve System to improve symptoms of female sexual disfunction, associated with vaginal laxity. 19 active clinical sites in the United States enrolled 250 female patients who were pre-menopausal, 18 years of age or older who experienced at least one full term vaginal delivery at least twelve months prior to enrollment date, randomized in a 2:1 ratio to either an active treatment group or sham-control group. Patients will be followed for twelve months post-treatment to assess the primary effectiveness and safety endpoints of the study with data being collected at one, three, six, nine and twelve months. Patients randomized to the sham arm will be offered the opportunity to receive a Viveve treatment once they had completed the twelve-month evaluation following the sham intervention.

The primary efficacy endpoint of the study is the mean change from baseline in the Female Sexual Function Index (FSFI) total score at twelve months posttreatment. Secondary endpoints include evaluation of the mean change from baseline of the total FSFI score at six months, as well as evaluation of the mean change from baseline of the six different domains within the FSFI at six and twelve months. At months six and twelve, in addition to the FSFI, subjects will be asked to complete the Patient's Global Impression of Improvement (PGI-I). Subjects will also be assessed for adverse events throughout the study. The Company intends to report final twelve-month clinical data from the study in the second quarter of 2020.

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 is a randomized, double-blind, sham-controlled study conducted at 9 sites in Canada and included enrollment of 99 patients suffering from mild-to-moderate SUI. Patients were randomized in a 2:1 ratio to either an active treatment group or sham-control group. Patients will be 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 primary efficacy endpoint is the 6-month change from baseline in the one-hour pad weight test, and the study protocol includes 6 months of safety follow-up, as well as assessments of other secondary endpoints, including: 24-hour pad weight test, daily incontinence episodes, as well as composite scores from the validated UDI-6, IIQ-7, and ICIQ-UI-SF outcome questionnaires.

Health Canada issued an authorization to conduct the investigational testing. The treatment portion of the trial has been completed, and if the results are favorable, the company expects to use the study for a registration filing in Canada, the EU and other countries outside the US for the improvement of SUI symptoms. There can be no assurance that any regulatory authority will approve our applications.

LIBERATE - US

In 2018, the Company submitted an IDE to conduct LIBERATE-US to the FDA. LIBERATE-US is intended to be a randomized, double-blind, sham-controlled study in up to 25 centers across the U.S. and including up to 240 patients who are suffering from mild-to-moderate SUI. Subjects will be randomized in a 2:1 ratio to either an active treatment group or sham-control group. The primary efficacy endpoint is expected to be a comparison of the proportion of patients who experience greater than a 50% reduction in leakage at twelve months, as measured by the one-hour pad weight test, between the active treatment group and a sham control group. Additionally, the trial will include 12 months of safety follow-up, as well as assessments of other secondary endpoints. Currently, the Company is addressing requests for additional pre-clinical animal testing from the FDA. If the results of the pre-approval testing are favorable, the Company anticipates resubmitting the IDE in the second or third quarter of 2019.

The FDA must approve the Company's IDE application before the Company may begin conducting the LIBERATE-US study. There can be no assurance that the FDA will approve our IDE application, or that the FDA may not require that the protocols be changed or that additional pre-clinical work be conducted prior to approving the IDE.

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, 2018 and 2017 were $13,716,000 and $12,343,000, 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.

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 commercial Viveve system which consists of a generator, handpiece and disposable tip was designed and is currently manufactured by Stellartech Research Corporation ("Stellartech"). Stellartech is the sole source supplier for this version of the Viveve system. We have manufacturing, quality and regulatory agreements with Stellartech that define the relationship and responsibilities of both parties in these areas. We also 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 Sparton Corporation ("Sparton"), and a disposable treatment tip designed and manufactured by Cirtec Corporation ("Cirtec"). Both Sparton and Cirtec are sole source suppliers for their respective components. We have a Professional Services Agreement with Sparton 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

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. We currently have two sterilization vendors to mitigate risks. Other products and components come from single suppliers, but alternate suppliers have been qualified or, we believe, can be readily identified and qualified. 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 9001:2000 and CAN/CSA ISO 13485:2003. 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, or 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, 2018 and 2017.

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 issue U.S. patent and own 3 issued U.S. patents directed to our technology and the Viveve System. Additionally, we have 9 pending U.S. patent applications, 65 issued foreign patents, and 32 pending foreign patent applications, some of which foreign applications preserve an opportunity to pursue patent rights in multiple countries.

U.S. Patents		Foreign Patents	
Issued	**Pending**	**Issued**	**Pending**
3	**9**	**65**	**32**

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 200,000 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, 2018, the Company has purchased 809 units. In conjunction with the Agreement, Stellartech purchased 37,500 shares of Viveve, Inc.'s common stock at $0.008. Under the Stellartech Agreement, we paid Stellartech $10,150,000 and $7,912,000 for goods and services during the years ended December 31, 2018 and 2017, 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. If Stellartech refuses or is unable to meet our delivery requirements for the Viveve System, our business could be materially adversely affected.

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 approvals already received in connection with the sale of the Viveve System in the foreign jurisdictions described below and the approvals/clearances already received and being sought in the U.S., we are currently seeking regulatory approval or clearance for the sale of our product in many other countries around the world.

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 60 countries throughout the world under the following indications for use:

Indication for Use:	No. of Countries:
General surgical procedures for electrocoagulation and hemostasis (including the U.S.)	3 (including the U.S.)
General surgical procedures for electrocoagulation and hemostasis of vaginal tissue and for the treatment of vaginal laxity	32
For treatment of vaginal laxity	6
For treatment of the vaginal introitus, after vaginal childbirth, to improve sexual function	16
General surgical procedures for electrocoagulation and hemostasis and for the treatment of vaginal laxity	1
For vaginal rejuvenation	1
For treatment of vaginal laxity, 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 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 tip to the product family.

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 sexual function and to improve SUI by utilizing the direct de novo process. However, we cannot predict when or if approval of such a petition will be obtained. In addition, if FDA fails to grant a de novo petition, we will be required to seek FDA premarket approval (via the more stringent PMA process). Delays in receipt of FDA clearance 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 reclassification 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.

In June 2012, we submitted a pre-IDE application and requested an in-person meeting with the FDA to solicit feedback in advance of filing an IDE to conduct a clinical study of the Viveve System to support regulatory submission for the sexual function indication. In August 2012, we met with the FDA and received feedback on our pre-clinical data, historical clinical data, and a clinical protocol for a prospective randomized controlled trial. We had a second meeting with the FDA on December 17, 2015 and received additional feedback on our clinical protocol design and indication for use. In September 2016 we submitted an IDE application to FDA to begin a U.S. clinical study and the FDA has responded with additional questions regarding the proposed protocol and other aspects of the clinical study design, which we addressed. Approval of the IDE was received in 2018, and we began our U.S. clinical study to demonstrate the safety and effectiveness of the device to improve sexual function. Completion of enrollment for the clinical study is anticipated in March 2019.

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 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 to treat vaginal laxity and SUI 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 vaginal laxity, women's sexual function, and incontinence remain tremendous, under-developed opportunities. 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 female sexual dysfunction and incontinence. 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, Hologic, Syneron Medical, Fotona, Thermi Aesthetics, Cutera, Inmode, BTL, Venus Concepts and others, some of whom have more established products and customer relationships than we have.

Employees

As of March 8, 2019, we had 67 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.

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 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 (radiofrequency 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 60 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 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.

Performing clinical studies with the Viveve System, and collecting data from the Viveve treatment is inherently subjective, and 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 believe that in order to significantly grow our business, we will need to conduct in process and future clinical studies of the effectiveness of the Viveve System and Viveve treatment. Clinical studies of sexual function and SUI are subject to a number of limitations. First, some of these studies do not involve objective standards for measuring the effectiveness of treatment. Subjective, patient reported outcomes are the most common method of evaluating effectiveness. As a result, clinical studies may conclude that a treatment is effective even in the absence of objective measures. Second, as with other non-invasive, energy-based treatments, the effect of the Viveve treatment varies from patient to patient and can be influenced by a number of factors, including the age, ethnicity and degree of vaginal laxity, sexual function, and SUI of the patient, among other things.

Current reported studies of Viveve's CMRF technology have investigated improvement in vaginal laxity, sexual function and SUI using single-arm studies 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. In the fourth quarter of 2014, we initiated a randomized, blinded and sham-controlled clinical trial in Europe and Canada designed to demonstrate the efficacy of the Viveve procedure versus a sham-controlled procedure for the treatment of vaginal laxity and sexual function (the "OUS Clinical Trial"). In April 2016, we completed this study. In the second quarter of 2018, we initiated a randomized, double-blind, sham-controlled clinical trial in the United States designed to evaluate the efficacy and safety on the Viveve procedure versus the sham-controlled procedure for the treatment of vaginal laxity and sexual function. We expect to complete this study at the end of the first quarter of 2020 (*See discussion under the heading* "**Clinical Studies**".)

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 stress urinary incontinence. 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 stress urinary incontinence, 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 stress urinary incontinence. We intend to seek clearance or approval from the FDA to expand our marketing efforts and have engaged with the FDA to help improve our likelihood of success. However, we cannot predict whether we will receive such clearances or approvals. The FDA has required us to conduct clinical trials to support regulatory clearance or approval, which trials are be 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 vaginal laxity, sexual function, or stress urinary incontinence, we will be unable to promote it in the U.S. for those indications, and the ability to grow our revenues 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, 2018, we have incurred losses since inception of approximately $155.4 million. In 2018, we incurred a loss of $50.0 million and in 2017 a loss of $37.0 million. 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 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 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 a Viveve System depends on the success of our sales and marketing efforts. Our business model involves both a capital equipment 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.

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 27%, 28% and 96% of our revenue during the year ended December 31, 2018, 2017 and 2016, 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
- 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.

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. We now expect to rely more heavily on distribution partnerships, including (i) our existing partnership with Aesthetic Management Partners (AMP), which is a network of independent partnership sales representatives, and regional distribution partners for the sales and marketing of our products. We believe our reorganization will help reduce our operating expenses through 2019 and 2020. We do not currently anticipate making any significant changes to our international distribution network.

Our reorganization 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 and successfully execute the reorganization 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 dysfunction, 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 a single manufacturing partner.

We outsource the manufacture and repair of the Viveve System to a single contract manufacturer, Stellartech. If Stellartech's operations are interrupted or if Stellartech is 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. Stellartech has limited manufacturing capacity, is itself dependent upon third-party suppliers and is dependent on trained technical labor to effectively repair components making up the Viveve System. In addition, Stellartech is a medical device manufacturer and is required to demonstrate and maintain compliance with the FDA's Quality System Regulation, or QSR. If Stellartech or any future manufacturing partner fails to comply with the FDA's QSR, its 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. In addition, as of the date of this report, the development and manufacturing agreement under which Viveve and Stellartech operate has expired without any subsequent extension or renewal by the parties and the minimum conditions to the licenses granted therein have not been satisfied by us. Although the parties continue to operate under the terms of this agreement, our manufacturing operations could be adversely impacted if we are unable to enforce Stellartech's performance under this agreement, or enter into a new agreement with Stellartech, or 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 the Viveve System from Stellartech 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.

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 hydrofluorocarbon, or 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. 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.

In addition, 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, 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.

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 and we do not sell it to non-physicians, 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., we only sell the Viveve System to licensed physicians who have met certain training requirements. However, current federal regulations will 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.

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.

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 effectively making a cyber attack impossible.

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 Chief 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, 2018, we had federal and state net operating loss carryforwards ("NOLs"), of approximately $126.9 million and $97.7 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. 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.

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, or 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, or 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 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 it's 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 vaginal tissue to improve sexual function and 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. 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. Therefore, we may not provide information to physicians or patients that promote off-label uses, except in limited circumstances, such as in response to unsolicited requests for off-label information or the distribution of scientific and medical publications under certain circumstances. 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. 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 products, 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 investigational device exemption, or 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.

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 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.

Even if our clinical trials 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 revenues.

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, or 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 FDA's 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 with our activities outside the U.S. could subject us to penalties and other adverse consequences.

A significant portion of our revenues is and will be from jurisdictions outside of the U.S. We are subject to the U.S. Foreign Corrupt Practices Act, or 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, or 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 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 issue U.S. patent and own 3 issued U.S. patents primarily covering our technology and Viveve treatment and methods of use. Additionally, we have 9 pending U.S. patent applications; 65 issued foreign patents; and 32 pending foreign patent applications, some of which foreign applications preserve an opportunity to pursue patent rights in multiple countries. 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 Securities and Exchange Commission 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 8, 2019, our officers, directors and principal stockholders, i.e., stockholders who beneficially own greater than 10% of our outstanding common stock, collectively beneficially own approximately 18.5% 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 currency fluctuations.

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 Commission.

As of March 8, 2019, there were approximately 1,549,236 shares of common stock of the 46,364,570 shares issued and outstanding that could be sold pursuant to Rule 144, 420,947 shares of restricted stock, 642,622 shares subject to outstanding warrants, 5,808,625 shares subject to outstanding options and an additional 488,632 shares reserved for future issuance under our 2013 Employee Stock Option and Incentive Plan, as amended, all of which will become eligible for sale in the public market to the extent permitted by any applicable vesting requirements or Rule 144 under the Securities Act.

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, 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.

Item 1B. Unresolved Staff Comments

None

Item 2. Properties

In January 2012, we entered into a lease agreement for office and laboratory facilities in Sunnyvale, California. The term of the lease agreement, dated January 25, 2012, as amended, commenced in March 2012 and terminated on April 30, 2018.

On February 1, 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, which was effective as of January 26, 2017. The lease term is 36 months. The lease term commenced on June 1, 2017 and will terminate in May 2020. The Company relocated its corporate headquarters from Sunnyvale, California to Englewood, Colorado in June 2017. We believe that these facilities are adequate for our current business operations.

Rent expense for the years ended December 31, 2018 and 2017 was $358,000 and $442,000, respectively. Future minimum payments under the lease are approximately as follows:

Year Ending December 31,
2019 – $296,000
2020 – $143,000
2021 – $23,000

Item 3. Legal Proceedings

In December 2018, the Company settled an arbitration matter with a former employee, and the arbitration has now been dismissed with prejudice. The matter involved affirmative claims for negligence by the Company against the employee arising out of her negligent performance of certain work duties, as well as various employment-related counterclaims by the employee.

On June 4, 2018, the Company 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 the Company's patent litigation against ThermiGen and Dr. Alinsod. The Settlement Agreement also resolved ThermiGen's inter partes review proceedings against the Company. The litigation arose from the Company's claim that ThermiGen and Dr. Alinsod were improperly using the Company's patented technology without consent. Pursuant to the Settlement Agreement, the parties agreed to resolve all currently pending disputes between them.

Under the terms of the Settlement Agreement, the Company received an initial monetary payment to settle the litigation and past claims and an on-going royalty for future sales. Viveve granted to ThermiGen a non-exclusive, non-transferable license to use the Company's U.S. patent for the current version of ThermiGen's ThermiVa system (which includes RF generators and consumables).

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 8, 2019, our common stock is trading on The Nasdaq Capital Market under the symbol “VIVE”.

Holders of Common Stock

As of March 8, 2019, there were approximately 640 holders of record of our common stock.

Dividends

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

Not applicable.

Item 6. Selected Financial Data

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 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*, or 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 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 60 countries throughout the world under the following indications for use:

Indication for Use:	**No. of Countries:**
General surgical procedures for electrocoagulation and hemostasis (including the U.S.)	3 (including the U.S.)
General surgical procedures for electrocoagulation and hemostasis of vaginal tissue and for the treatment of vaginal laxity	32
For treatment of vaginal laxity	6
For treatment of the vaginal introitus, after vaginal childbirth, to improve sexual function	16
General surgical procedures for electrocoagulation and hemostasis and for the treatment of vaginal laxity	1
For vaginal rejuvenation	1
For treatment of vaginal laxity, 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, 2018, we have sold 703 Viveve Systems and approximately 33,300 single-use treatment tips worldwide.

Because the revenues 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. As noted above, 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 revenues 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.

Recent Events

Effective Shelf Registration Statements

In November 2017, 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 $50,000,000 of our securities, including common stock, preferred stock, and/or warrants (the "2017 Shelf Registration Statement"). The 2017 Shelf Registration Statement currently has a remaining capacity of $25,000,000.

December 2018 Offering

In connection with the closing of the December 2018 Offering, the Company issued an aggregate of 14,728,504 shares of common stock, including the shares issued in connection with the exercise of the underwriters' overallotment option, at a public offering price of $1.50 per share for gross proceeds of approximately $22,093,000. The net proceeds to the Company, after deducting underwriting discounts and commissions and other offering expenses, were approximately $20,385,000.

February 2018 Offering

In connection with the closing of the February 2018 Offering, the Company issued an aggregate of 11,500,000 shares of common stock, including the shares issued in connection with the exercise of the underwriters' overallotment option, at a public offering price of $3.00 per share for gross proceeds of approximately $34,500,000. The net proceeds to the Company, after deducting underwriting discounts and commissions and other offering expenses, were approximately $32,214,000.

"At-the-Market" Offering

The Company established an "at-the-market" equity offering program through the filing of a prospectus supplement to its shelf registration statement on Form S-3, which was filed on November 8, 2017, under which the Company may offer and sell, from time-to-time, up to $25,000,000 aggregate offering price of shares of its common stock (the "November 2017 ATM Facility"). As of December 31, 2018, the Company has sold 336,498 shares of common stock under the November 2017 ATM Facility for gross proceeds of approximately $1,631,000. The net proceeds to the Company, after deducting underwriting discounts and commissions and other offering expenses, were approximately $1,318,000.

Adoption of New Accounting Standard

On January 1, 2018, the Company adopted Revenue from Contracts with Customers (Topic 606), which created Accounting Standards Codification Topic 606 ("ASC 606"), using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting under ASC 605.

Under ASC 605, revenue from extended assurance warranties was deferred and recognized over the period of the warranty. On the adoption of ASC 606, these warranties are not considered a separate performance obligation. Accordingly, on the transition date, the Company recorded a net adjustment in retained earnings of $177,000, resulting from the reclassification of $195,000 for the amount of extended warranties previously recorded in noncurrent liabilities, offset by $18,000 recorded in accrued liabilities for future costs associated with the assurance-type extended warranties.

Submission of IDE to FDA for Approval to Conduct SUI Trial in the United States

In September 2018, the Company submitted an Investigational Device Exemption (IDE) to the U.S. Food and Drug Administration (FDA) for authorization to begin LIBERATE-U.S., a multicenter, randomized, double-blinded, sham-controlled trial to evaluate the safety and efficacy of the Company's proprietary, cryogen-cooled monopolar radiofrequency (CMRF) technology for the improvement of stress urinary incontinence (SUI) in women. Intended enrollment for the LIBERATE-U.S. trial is approximately 240 subjects at up to 25 study sites in the United States. Subjects will be randomized in a 2:1 ratio for active and sham treatments.

The expected primary efficacy endpoint in the study is the proportion of patients experiencing a greater than 50% reduction in Pad Weight Gain in the standardized 1-hour Pad Weight Test at 12 months post-treatment. The 1-hour Pad Weight Test is an FDA recommended endpoint in SUI clinical research. The proposed study design also includes a variety of secondary and exploratory endpoints including safety, efficacy, as measured by a three-day voiding diary, and Quality of Life benefits measured by the Urogenital Distress Inventory-6 (UDI-6), International Consultation on Incontinence Modular Questionnaire-Urinary Incontinence Short Form (ICIQ-UI-SF), and Incontinence Quality of Life (I-QOL).

Viveve has had ongoing discussions with the FDA and a resultant safety case protocol is currently under formal review by the Agency. The Company anticipates positive feedback from the Agency in the near future and to conduct the additional safety testing. Upon completion of said testing, the Company plans to re-submit the IDE to the FDA in the third quarter 2019.

Enrollment Completed in LIBERATE-International SUI Trial

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 is a randomized, double-blind, sham-controlled study conducted at 9 sites in Canada and included enrollment of 99 patients suffering from mild-to-moderate SUI. Patients were randomized in a 2:1 ratio to either an active treatment group or sham-control group. Patients will be 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 primary efficacy endpoint is the 6-month change from baseline in the one-hour pad weight test, and the study protocol includes 6 months of safety follow-up, as well as assessments of other secondary endpoints, including: 24-hour pad weight test, daily incontinence episodes, as well as composite scores from the validated UDI-6, IIQ-7, and ICIQ-UI-SF outcome questionnaires.

Health Canada issued an authorization to conduct the investigational testing. The treatment portion of the trial has been completed, and if the results are favorable, the company expects to use the study for a registration filing in Canada, the EU and other countries outside the US for the improvement of SUI symptoms. There can be no assurance that any regulatory authority will approve our applications.

Reported Positive Twelve-Month Data from SUI Feasibility Study

In December 2018, the Company reported positive twelve-month interim data from its SUI feasibility study. At twelve months post-treatment, 72% of women experienced improvement in one-hour pad weight test and 60% of patients experienced significant benefit as they had ≤ 1 gram of urine leakage in the one-hour pad weight text at twelve months. A clinically meaningful benefit was achieved across all patient-reported SUI symptoms and quality of life outcome measures. No device-related safety issues were reported for any of the patients.

This single-arm feasibility study included 36 subjects with mild to moderate SUI (based on the one-hour pad weight test) who underwent treatment with Viveve's CMRF technology under a proprietary treatment protocol. Clinical results included the objective one-hour pad weight assessment and seven-day bladder voiding diary, as well as composite scores from multiple validated patient-reported outcomes, including: UDI-6 (Urogenital Distress Inventory-Short Form), IIQ-7 (Incontinence Impact Questionnaire) and ICIQ-UI-SF (International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form).

FDA Approval to Continue VIVEVE II Clinical Study

In March 2019, enrollment was completed for the VIVEVE II (VIveve treatment of the Vaginal Introitus to EValuate Effectiveness) clinical study following IDE approval by the FDA. This is a prospective, randomized, double-blind, sham controlled study to evaluate the efficacy and safety of the Viveve System to improve symptoms of female sexual disfunction, associated with vaginal laxity. 19 active clinical sites in the United States enrolled 250 female patients who were pre-menopausal, 18 years of age or older who experienced at least one full term vaginal delivery at least twelve months prior to enrollment date, randomized in a 2:1 ratio to either an active treatment group or sham-control group. Patients will be followed for twelve months post-treatment to assess the primary effectiveness and safety endpoints of the study with data being collected at one, three, six, nine and twelve months. Patients randomized to the sham arm will be offered the opportunity to receive a Viveve treatment once they had completed the twelve-month evaluation following the sham intervention.

The primary efficacy endpoint of the study is the mean change from baseline in the Female Sexual Function Index (FSFI) total score at twelve months posttreatment. Secondary endpoints include evaluation of the mean change from baseline of the total FSFI score at six months, as well as evaluation of the mean change from baseline of the six different domains within the FSFI at six and twelve months. At months six and twelve, in addition to the FSFI, subjects will be asked to complete the Patient's Global Impression of Improvement (PGI-I). Subjects will also be assessed for adverse events throughout the study. The Company intends to report final twelve-month clinical data from the study in the second quarter of 2020.

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 to include plastic surgeons, general surgeons, urologists, and urogynecologists.

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 activities for at least the next twelve months, however, we may require additional capital from the sale of equity or debt securities 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 $500,000 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, 2018 and 2017

Revenue

	Year Ended December 31,		Change	
	2018	2017	$	%
	(in thousands, except percentages)			
Revenue	$ 18,517	$ 15,288	$ 3,229	21%

We recorded revenue of $18,517,000 for the year ended December 31, 2018, compared to revenue of $15,288,000 for the year ended December 31, 2017, an increase of $3,229,000, or approximately 21%. The increase in revenue was primarily due to sales of 259 Viveve Systems (which included 203 Viveve Systems sold in the U.S. market - 183 Viveve Systems through direct sales and 20 Viveve Systems through our distribution partner), and higher quantities of disposable products sold (which included approximately 18,450 disposable treatment tips sold globally) in 2018. Sales in 2017 included 227 Viveve Systems (which included 160 Viveve Systems sold in the U.S. market through direct sales) and approximately 10,800 disposable treatment tips.

Gross Profit

	Year Ended December 31,		Change	
	2018	2017	$	%
	(in thousands, except percentages)			
Gross profit	$ 7,320	$ 7,444	$ (124)	(2)%

Gross profit was $7,320,000, or 40% of revenue, for the year ended December 31, 2018, compared to gross profit of $7,444,0000, or 49% of revenue, for the year ended December 31, 2017, a decrease of $124,000, or approximately 2%. The decrease in gross profit was primarily due to the unit mix of products sold during the year. Currently, the Viveve System has higher gross margins, as compared to disposable treatment tips. The decrease in gross profit was also affected by lower average selling prices of Viveve Systems in the U.S. market as a result of higher volumes of systems sold to our distribution partner during the year.

The decrease in gross margin was primarily due to the unit volume mix of products sold and the lower average selling prices of Viveve Systems sold in the U.S. market during the year. We expect our gross margin to fluctuate in future periods based on the mix of our products and direct sales versus distributor sales.

Research and development expenses

	Year Ended December 31,		Change	
	2018	2017	$	%
	(in thousands, except percentages)			
Research and development	$ 13,716	$ 12,343	$ 1,373	11%

Research and development expenses totaled $13,716,000 for the year ended December 31, 2018, compared to research and development expenses of $12,343,000 for the year ended December 31, 2017, an increase of $1,373,000, or approximately 11%. Spending on research and development increased in 2018 primarily due to costs associated with increased engineering and development work with our contract manufacturer related to product improvement efforts. Research and development expense during 2018 also included higher personnel costs for new employees and related additional stock-based compensation expense for stock options granted to new employees and additional stock options granted to existing employees for performance bonuses.

Selling, general and administrative expenses

	Year Ended December 31,		Change	
	2018	2017	$	%
	(in thousands, except percentages)			
Selling, general and administrative	$ 38,569	$ 28,831	$ 9,738	34%

Selling, general and administrative expenses totaled $38,569,000 for the year ended December 31, 2018, compared to $28,831,000 for the year ended December 31, 2017, an increase of $9,738,000, or approximately 34%. The increase in selling, general and administrative expenses in 2018 was primarily attributable to increased sales and marketing efforts to build brand and market awareness, expenses associated with being a public company and financing efforts. Selling, general and administrative expenses during 2018 also included higher personnel costs for new employees (primarily in connection with our sales and marketing efforts) and related additional stock-based compensation expense for stock options granted to new employees and additional stock options granted to existing employees for performance bonuses, partially offset by gains from litigation settlement payments.

Interest expense

	Year Ended December 31,		Change	
	2018	2017	$	%
	(in thousands, except percentages)			
Interest expense, net	$ 4,372	$ 3,169	$ 1,203	38%

During the year ended December 31, 2018, we had interest expense, net, of $4,372,000 compared to $3,169,000, for the year ended December 31, 2017. The increase of $1,203,000, or approximately 38%, resulted primarily from the additional interest expense in 2018, which was computed on a higher term loan balance compared to 2017 due to the drawdown of the remaining $10,000,000 available under the credit facility in December 2017 and the interest in-kind which was added to the total outstanding principal loan amount, partially offset by the additional interest expense in 2017 in connection with the May 2017 payoff of the previous term loan.

Loss from minority interest in limited liability company

	Year Ended December 31,		Change	
	2018	2017	$	%
	(in thousands, except percentages)			
Loss from minority interest in limited liability company	$ 657	$ -	$ 657	-

The Company uses the equity method to account for its investment in InControl Medical, LLC ("ICM"). For the year ended December 31, 2018, the allocated net loss from ICM's operations was $657,000. There was no income or loss recognized for the year ended December 31, 2017 as the investment in ICM was made late in the year and accounted for on a one quarter lag.

Other income (expense), net

	Year Ended December 31,		Change	
	2018	2017	$	%
	(in thousands, except percentages)			
Other income (expense), net	$ 13	$ (60)	$ 73	(122)%

During the year ended December 31, 2018 we had other income, net, of $13,000 as compared to other expense, net, of $60,000 for the year ended December 31, 2017.

Liquidity and Capital Resources

Comparison of the Year Ended December 31, 2018 and 2017

At December 31, 2018, we had $29.5 million in cash and cash equivalents. During 2018, we raised $53.8 million from the sale of common stock. At the date our financial statements for the year ended December 31, 2018 are issued, we did not have sufficient cash to fund our operation through March 31, 2020, 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. Based on management's plans to reduce operating expenses, including the reduction in force in January 2019, and the availability of our November 2017 ATM Facility, we believe that this substantial doubt has been alleviated.

Accordingly, we expect to satisfy our estimated liquidity needs for at least 12 months from the issuance of these consolidated financial statements and have mitigated our going concern risk. However, we cannot predict, with certainty, the outcome of our future actions to generate liquidity, including the availability of additional financing.

Management currently believes that it will be necessary for us to raise additional funding in the form of an equity financing of common stock, but there can be no assurance that such funding will be available to us on favorable terms, if at all. The failure to raise capital 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,	
	2018	2017
Net cash used in operating activities	$ (43,090)	$ (34,853)
Net cash used in investing activities	(2,142)	(3,405)
Net cash provided by financing activities	54,025	50,902
Net increase in cash and cash equivalents	$ 8,793	$ 12,644

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 $43,090,000 of cash for the year ended December 31, 2018 compared to $34,853,000 used for the year ended December 31, 2017. 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, 2018 consisted of a net loss of $49,981,000 adjusted for non-cash expenses including provision for doubtful accounts of $179,000, depreciation and amortization of $786,000, stock-based compensation of $3,035,000, fair value of restricted common shares issued of $256,000, non-cash interest expense of $1,580,000, loss from minority interest in limited liability company of $657,000, and cash inflows from changes in operating assets and liabilities of $398,000. Net cash used during the year ended December 31, 2017 consisted of a net loss of $36,959,000 adjusted for non-cash expenses including provision for doubtful accounts of $221,000, depreciation and amortization of $449,000, stock-based compensation of $1,872,000, fair value of restricted common shares issued of $260,000, non-cash interest expense of $1,049,000 and cash outflows from changes in operating assets and liabilities of $1,303,000.

Investing Activities

Net cash used in investing activities during the year ended December 31, 2018 and 2017 was $2,142,000 and $3,405,000, respectively. Net cash used in investing activities during 2018 was used for the purchase of property and equipment. Net cash used in investing activities during 2017 was used for the $2,500,000 equity investment in ICM and the purchase of property and equipment. 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, 2018 was $54,025,000, which was the result of the gross proceeds of $22,093,000 from our December 2018 offering (partially offset by transaction costs of $1,708,000), gross proceeds of $34,500,000 from our February 2018 offering (partially offset by transaction costs of $2,286,000), gross proceeds of $1,327,000 from our November 2017 ATM Facility (partially offset by transaction cost of $134,000), and proceeds from shares purchased under the Company's employee stock purchase plan of $233,000.

Net cash provided by financing activities during year ended December 31, 2017 was $50,902,000, which was the result of the gross proceeds of $34,500,000 from our March 2017 Offering (partially offset by transaction costs of $3,060,000), gross proceeds of $304,000 from our November 2017 ATM Facility (partially offset by transaction cost of $179,000), the debt proceeds of $30,000,000 from the drawdown of funds under the 2017 Loan Agreement (partially offset by debt issuance costs of $790,000), proceeds from shares purchased under the Company's employee stock purchase plan of $76,000, and proceeds from the exercise of stock options and a warrant of $51,000, partially offset by the repayment of the term loan under the 2016 Loan Agreement of $10,000,000.

As of December 31, 2018, there is a balance of $25,000,000 available for future issuance under the 2017 Shelf Registration Statement, and approximately $23,369,000 available for future issuance under the 2017 ATM Facility.

Contractual Payment Obligations

We have obligations under a non-cancelable operating lease and a bank term loan. As of December 31, 2018, our contractual obligations are as follows (in thousands):

Contractual Obligations:	**Total**	**Less than 1 Year**	**1 - 3 Year**	**3 -5 Years**	**More than 5 Years**
Debt obligations (including interest)	$ 47,878	$ 2,778	$ 19,574	$ 25,526	$ -
Non-cancellable operating lease obligations	462	296	166	-	-
Total	$ 48,340	$ 3,074	$ 19,740	$ 25,526	$ -

In January 2012, we entered into a lease agreement for office and laboratory facilities in Sunnyvale, California. The lease agreement, as amended, commenced in March 2012 and terminated in April 2018.

On February 1, 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 is 36 months and the monthly base rent for the first, second and third years is $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 provided 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 on June 1, 2017 and will terminate in May 2020.

On May 22, 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. On December 29, 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. The outstanding principal balance under the 2017 Loan Agreement is $31,751,000 as of December 31, 2018.

In September 2018, the Company entered into a 36-month noncancelable operating lease agreement for office equipment. The lease commenced on September 20, 2018. The monthly payment is approximately $2,600.

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, 2018 and 2017 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 normal business, the Company generally utilizes various finished goods inventory as sales demos to facilitate the sale of its products to prospective customers. The Company is amortizing these demos over an estimated useful life of five years. The amortization of the demos is charged to selling, general and administrative expense and the demos are included in the medical equipment line within the property and equipment, net balance on the consolidated balance sheets as of December 31, 2018 and 2017.

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 Recognition

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. Revenues, 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.

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 North America, we market and sell primarily through a direct sales force. Outside of North America, 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 collectibility 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, 2018 and 2017, the allowance for doubtful accounts was $284,000 and $221,000, 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, 2018 and 2017, 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 at their fair value on the measurement date and are subject to periodic adjustment as the underlying equity instruments vest.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which requires an entity that is a lessee to record a right of use asset and a corresponding lease liability on the balance sheet for all leases. This guidance also requires disclosures about the amount, timing, and uncertainty of cash flows arising from leases. This guidance is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those annual periods and early adoption is permitted. In July 2018, the FASB issued updated guidance which allows an additional transition method to adopt the new leases standard at the adoption date, as compared to the beginning of the earliest period presented, and allows entities to recognize a cumulative-effect adjustment to the beginning balance of retained earnings in the period of adoption. The Company expects to elect to use this transition method at the adoption date of January 1, 2019, and, as a result, will record a right of use asset and a corresponding lease liability on the balance sheet for all leases with terms longer than 12 months. The Company also plans to elect the practical expedient to not separate lease and non-lease components and to use the package of practical expedients upon transition that will retain the lease classification and initial direct costs for any leases that exist prior to adoption of the new guidance.

In August 2016, the FASB issued ASU No. 2016-15, "Statement of Cash Flows, Classification of Certain Cash Receipts and Cash Payments (Topic 230)". This guidance addresses specific cash flow issues with the objective of reducing the diversity in practice for the treatment of these issues. The areas identified include: debt prepayment or debt extinguishment costs; settlement of zero-coupon debt instruments; contingent consideration payments made after a business combination; proceeds from the settlement of insurance claims; proceeds from the settlement of corporate-owned life insurance policies; distributions received from equity method investees; beneficial interests in securitization transactions and application of the predominance principle with respect to separately identifiable cash flows. This guidance is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, with early adoption permitted. We adopted this guidance as of January 1, 2018 and the adoption of the guidance did not have a significant impact on the condensed consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-18, "Statement of Cash Flows, Restricted Cash (Topic 230)". This guidance requires that a statement of cash flows explain the total change during the period of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Amounts described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning of period and end of period to total amounts shown on the statement of cash flows. This guidance is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, with early adoption permitted. We adopted this guidance as of January 1, 2018 and the adoption of the guidance did not have a significant impact on the condensed consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, "Compensation - Stock Compensation (Topic 718), Scope of Modification Accounting". This pronouncement provides guidance about which changes to the terms or conditions of a share-based payment award may require an entity to apply modification accounting under Topic 718. This guidance is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, with early adoption permitted. We adopted this guidance as of January 1, 2018 and the adoption of the guidance did not have a significant impact on the condensed consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, "Stock Compensation (Topic 718) – Improvements to Nonemployee Share-Based Payment Accounting". The intent of this guidance is to simplify the accounting for nonemployee share-based payment accounting. The amendments in this guidance expand the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. Consistent with the accounting requirement for employee share-based payment awards, nonemployee share-based payment awards within the scope of Topic 718 are measured at grant-date fair value of the equity instruments that an entity is obligated to issue when the good has been delivered or the service has been rendered and any other conditions necessary to earn the right to benefit from the instruments have been satisfied. Equity- classified nonemployee share-based payment awards are measured at the grant date. Consistent with the accounting for employee share-based payment awards, an entity considers the probability of satisfying performance conditions when nonemployee share-based payment awards contain such conditions. This guidance is effective for annual reporting periods beginning after December 15, 2018, including interim periods within the reporting period. We do not expect the adoption of this guidance to have a significant effect on our 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.

Off-Balance Sheet Transactions

We do not have any off-balance sheet transactions.

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 revenues 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 Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial and accounting 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 Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2018, 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, 2018, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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 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, 2018. 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 Chief Financial Officer (principal financial and accounting officer), has concluded that, as of December 31, 2018, our internal control over financial reporting was effective based on those criteria.

Our independent registered public accounting firm, BPM LLP, which audited the consolidated financial statements in this Annual Report on Form 10-K, independently assessed the effectiveness of the Company's internal control over financial reporting. BPM LLP has issued an attestation report, which appears as part of this Annual Report on Form 10-K.

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.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of

Viveve Medical, Inc.

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Viveve Medical, Inc. (a Delaware corporation) and its subsidiaries (the "Company") as of December 31, 2018, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets as of December 31, 2018 and 2017 and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements") of the Company, and our report dated March 14, 2019, expressed an unqualified opinion on those consolidated financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Assessment of Internal Controls over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, 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.

/s/ BPM LLP

San Jose, California
March 14, 2019

Item 9B. Other Information

None.

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 2019 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 2019 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 2019 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 2019 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

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 2019 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	Amended and Restated Bylaws(4)
4.1	Common Stock Purchase Warrant issued on February 17, 2015 to Scott Durbin (6)+
4.2	Common Stock Purchase Warrant issued on February 17, 2015 to Jim Robbins (6)+
4.3	Common Stock Purchase Warrant issued on February 17, 2015 to Patricia Scheller (6)+
4.4	Common Stock Purchase Warrant issued on May 12, 2015 to James Atkinson (6)+
4.5	Common Stock Purchase Warrant issued on December 16, 2015 to James Atkinson (6)+
4.6	Common Stock Purchase Warrant issued on December 16, 2015 to Jim Robbins (6)+
4.7	Warrant to Purchase Common Stock issued on April 1, 2016 to Dynamic Medical Technologies (Hong Kong) Limited (3)
4.8	Warrant to Purchase Common Stock issued on May 11, 2016 to Theresa Stern (7)
4.9	Warrant to Purchase Common Stock issued on May 11, 2016 to Chris Rowan (7)
4.10	Warrant to Purchase Common Stock issued on June 20, 2016 to Western Alliance Bank (8)
4.11	Warrant to Purchase Shares of Common Stock of Viveve Medical, Inc., dated May 25, 2017, by and between Viveve Medical, Inc. and CRG Partners III - Parallel Fund "A" L.P. (9)
4.12	Warrant to Purchase Shares of Common Stock of Viveve Medical, Inc., dated May 25, 2017, by and between Viveve Medical, Inc. and CRG Partners III L.P. (9)
4.13	Specimen Common Stock Certificate (10)
10.1	Form of Securities Purchase Agreement dated May 9, 2014 (11)
10.2	Securities Purchase Agreement, dated May 9, 2014, by and among the Registrant and GBS Venture Partners as trustee for GBS BioVentures III Trust (11)
10.3	Escrow Deposit Agreement, dated May 9, 2014 by and among the Registrant, Palladium Capital Advisors LLC, Middlebury Securities and Signature Bank, as escrow agent (11)
10.4	Registration Rights Agreement, dated May 9, 2014 (11)
10.5	First Amendment to Registration Rights Agreement, dated February 19, 2015 (12)
10.6	Right to Shares Letter Agreement dated May 9, 2014 between the Registrant and GCP IV LLC (11)
10.7	Amendment dated September 10, 2014 to Securities Purchase Agreement dated February 22, 2013 (13)
10.8	Amendment dated September 11, 2014 to Securities Purchase Agreement dated February 22, 2013 (13)
10.9	PLC Systems Inc. 2013 Stock Option and Incentive Plan, as amended (14) +
10.10	Loan and Security Agreement dated September 30, 2014 between Viveve, Inc. and Square 1 Bank (16)

10.11	First Amendment to Loan and Security Agreement dated February 19, 2015 between Viveve, Inc. and Square 1 Bank (12)
10.12	Intellectual Property Security Agreement dated September 30, 2014 between Viveve, Inc. and Square 1 Bank (16)
10.13	Unconditional Guaranty issued by the Registrant in favor of Square 1 Bank (16)
10.14	Intellectual Property Assignment and License Agreement dated February 10, 2006, as amended, between Dr. Edward Knowlton and TivaMed, Inc (14)
10.15	Development and Manufacturing Agreement dated June 12, 2006 between TivaMed, Inc. and Stellartech Research Corporation (14)
10.16	Amended and Restated Development and Manufacturing Agreement dated October 4, 2007 between TivaMed, Inc. and Stellartech Research Corporation (14)
10.17	Right to Shares Letter Agreement, dated as of September 23, 2014 by and between the Registrant and GCP IV LLC (14)
10.18	Right to Shares Letter Agreement, dated as of September 23, 2014 by and between the Registrant and G-Ten Partners LLC (14)
10.19	Convertible Note Termination Agreement, dated May 9, 2014 by and between Viveve, Inc. and 5AM Ventures II, LP (17)
10.20	Convertible Note Termination Agreement, dated May 9, 2014 by and between Viveve, Inc. and 5AM Co-Investors II, LP (17)
10.21	Convertible Note Exchange Agreement, dated May 9, 2014 by and between Viveve, Inc. and GBS Venture Partners Limited, trustee for GBS BioVentures III (17)
10.22	Warrant Termination Agreement, dated as of May 9, 2014, by and between Viveve, Inc. and 5AM Ventures II, LP (17)
10.23	Warrant Termination Agreement, dated as of May 9, 2014, by and between Viveve, Inc. and 5AM Co-Investors II, LP (17)
10.24	Warrant Termination Agreement, dated as of May 9, 2014, by and between Viveve, Inc. and GBS Venture Partners Limited, trustee for GBS BioVentures III (17)
10.25	Employment Agreement by and between the Registrant and James G. Atkinson, dated February 27, 2018 (15)+
10.26	First Amendment to Lease dated January 15, 2015 between The Castine Group and Viveve, Inc. (18)
10.27	Second Amendment to Loan and Security Agreement dated May 14, 2015 between Viveve, Inc. and Square 1 Bank (18)
10.28	Form of Securities Purchase Agreement dated May 12, 2015 (18)
10.29	Form of Registration Rights Agreement dated May 12, 2015 (18)
10.30	Letter Agreement with Stonepine Capital dated May 12, 2015 (18)
10.31	Form of Securities Purchase Agreement dated November 20, 2015 (19)
10.32	Form of Registration Rights Agreement dated November 20, 2015 (19)
10.33	Third Amendment to Loan and Security Agreement dated November 30, 2015 between Pacific Western Bank, as successor in interest by merger to Square 1 Bank, and Viveve, Inc. (20)
10.34	Fourth Amendment to Loan and Security Agreement dated March 18, 2016 between Pacific Western Bank, as successor in interest by merger to Square 1 Bank, and Viveve, Inc. (6)
10.35	Viveve Medical, Inc. Amended and Restated Independent Director Compensation Policy (20)
10.36	Viveve Medical, Inc. Amended and Restated 2013 Stock Option and Incentive Plan (21)
10.37	Second Amendment to Standard Industrial/Commercial Multi-Tenant Lease- Gross, dated September 12, 2016 between Viveve, Inc. and Commercial Street Properties, LLC. (22)
10.38	Loan and Security Agreement dated as of June 20, 2016 by and among Viveve Medical, Inc., Viveve, Inc. and Western Alliance Bank (8)
10.39	Intellectual Property Security Agreement dated as of June 20, 2016 between Viveve Medical, Inc. and Western Alliance Bank (8)
10.40	Sublease Agreement, entered into on February 1, 2017 and effective as of January 26, 2017, between Viveve Medical, Inc. and Ingredion Incorporated (23)
10.41	Waiver and First Amendment to Loan and Security Agreement, dated January 13, 2017, between Viveve Medical, Inc., Viveve, Inc. and Western Alliance Bank (24)
10.42	Security Agreement, dated May 25, 2017, by and between Viveve Medical, Inc., Viveve, Inc. and CRG Servicing LLC (9)

10.43	Patent and Trademark Security Agreement, dated May 25, 2017, by and between Viveve Medical, Inc., Viveve, Inc. and CRG Servicing LLC (9)
10.44	Term Loan Agreement, dated May 22, 2017, among Viveve Medical, Inc., Viveve, Inc., CRG Servicing LLC, as administrative agent, and certain lenders (25)
10.45	Exclusive Distributorship Agreement, dated August 8. 2017, by and between Viveve Medical, Inc. and InControl Medical, LLC (26)
10.46	Membership Subscription Agreement, dated August 1, 2017, by and between Viveve Medical, Inc. and InControl Medical, LLC (26)
10.47	Waiver No. 2 to Loan Agreement, dated December 12, 2017, among Viveve Medical, Inc., CRG Servicing LLC and the lenders party thereto (27)
10.48	Amendment to the Amended and Restated 2013 Stock Option and Incentive Plan (28)
10.49	2017 Employee Stock Purchase Plan (28)
10.50	Forms of Indemnification Agreement (34)
10.51	Separation Agreement and Release by and between the Registrant and Patricia K. Scheller, dated May 30, 2018, effective May 11, 2018 (29) +
10.52	Consulting Agreement by and between the Registrant and Patricia K. Scheller, dated May 30, 2018, effective May 11, 2018 (29) +
10.53	Amended and Restated Employment Agreement by and between the Registrant and Scott C. Durbin, dated May 11, 2018. (30) +
10.54	Amended and Restated Employment Agreement by and between the Registrant and Jim Robbins, dated May 11, 2018. (30) +
10.55	Settlement and License Agreement by and among the Registrant, ThermiGen LLC and ThermiAesthetics LLC, dated June 3, 2018. (31)†
10.56	Consulting Agreement by and between the Registrant and Debora Jorn, dated May 11, 2018 (31) +
10.57	Amendment No. 2 to Loan Agreement, dated November 29, 2018, among Viveve Medical, Inc., CRG Servicing LLC, as administrative agent and collateral agent, the lenders from time to time party thereto and Viveve, Inc., as subsidiary guarantor (32)
14.1	Code of Conduct, adopted September 23, 2014 (33)
21	List of the Registrant's Subsidiaries (34)
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*

* Filed herewith.
** These exhibits are furnished, not filed.
+ 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 Securities and Exchange Commission on August 11, 2014.
(2) Incorporated by reference to Annex B to the Registrant's Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on August 11, 2014.
(3) Incorporated by reference from the Form 10-Q filed with the Securities and Exchange Commission on May 13, 2016.
(4) Incorporated by reference from the Form 8-K filed with the Securities and Exchange Commission on August 17, 2017.
(5) Incorporated by reference from the Form 8-K filed with the Securities and Exchange Commission on April 14, 2016.
(6) Incorporated by reference from the Form 10-K filed with the Securities and Exchange Commission on March 24, 2016.
(7) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 11, 2016.
(8) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 21, 2016.
(9) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 1, 2017.

(10) Incorporated by reference to the Registrant's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on October 5, 2017.
(11) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 14, 2014.
(12) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 25, 2015.
(13) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 16, 2014.
(14) Incorporated by reference to the Registrant's on Form S-1 filed with the Securities and Exchange Commission on November 21, 2014.
(15) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 1, 2018.
(16) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 3, 2014.
(17) Incorporated by reference to the Amendment No. 1 Registrant's Form S-1 filed with the Securities and Exchange Commission on January 26, 2015.
(18) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015 filed with the Securities and Exchange Commission on May 15, 2015.
(19) Incorporated by reference to the registrants Current Report on Form 8-K filed with the Securities and Exchange Commission on November 25, 2015.
(20) Incorporated by reference to the registrants Current Report on Form 8-K filed with the Securities and Exchange Commission on May 16, 2017.
(21) Incorporated by reference to Appendix A to the Registrant's Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on July 7, 2017.
(22) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 10, 2016.
(23) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the SEC on February 3, 2017.
(24) Incorporated by reference from the Form 8-K filed with the Securities and Exchange Commission on January 13, 2017.
(25) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 24, 2017.
(26) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, filed with the SEC on November 8, 2017.
(27) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 14, 2017.
(28) Incorporated by reference to the Registrant's Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on July 7, 2017.
(29) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 5, 2018.
(30) Incorporated by reference to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 17, 2018.
(31) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 9, 2018.
(32) Incorporated by reference to the Registrant's Quarterly Report on Form 8-K filed with the Securities and Exchange Commission on December 4, 2018.
(33) Incorporated by reference to the Registrant's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2015.
(34) Incorporated by reference to the Registrant's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 16, 2017.

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the Registrant caused this report to be signed on its behalf by the undersigned, thereto duly authorized.

VIVEVE MEDICAL, INC.
(Registrant)

March 14, 2019

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 Patricia Scheller and Scott Durbin, 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 14, 2019
/s/Jim Robbins Jim Robbins	Vice President of Finance and Administration (Principal Accounting and Financial Officer)	March 14, 2019
/s/Steven Basta Steven Basta	Chairman of the Board of Directors	March 14, 2019
/s/Debora Jorn Debora Jorn	Director	March 14, 2019
/s/Arlene Morris Arlene Morris	Director	March 14, 2019
/s/Patricia Scheller Patricia Scheller	Director	March 14, 2019
/s/Karen Zaderej Karen Zaderej	Director	March 14, 2019

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 Financial Statements

We have audited the accompanying consolidated balance sheets of Viveve Medical, Inc. (a Delaware corporation) and its subsidiaries (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, stockholders'equity(deficit), and cash flows for each of the two years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 14, 2019, expressed an unqualified opinion.

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 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. 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.

/s/ BPM LLP

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

San Jose, California
March 14, 2019

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

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 29,523	$ 20,730
Accounts receivable, net of allowance for doubtful accounts of $284 and $221 as of December 31, 2018 and 2017, respectively	5,704	6,213
Inventory	4,119	2,390
Prepaid expenses and other current assets	2,558	2,741
Total current assets	41,904	32,074
Property and equipment, net	2,916	1,303
Investment in limited liability company	1,843	2,500
Other assets	171	202
Total assets	$ 46,834	$ 36,079
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 3,994	$ 4,799
Accrued liabilities	6,766	4,605
Total current liabilities	10,760	9,404
Note payable, noncurrent portion	30,528	28,948
Other noncurrent liabilities	634	327
Total liabilities	41,922	38,679
Commitments and contingences (Note 7)		
Stockholders’ equity (deficit):		
Common stock, $0.0001 par value; 75,000,000 shares authorized as of December 31, 2018 and 2017; 46,363,945 and 19,503,558 shares issued and outstanding as of December 31, 2018 and 2017, respectively	5	2
Additional paid-in capital	160,292	102,979
Accumulated deficit	(155,385)	(105,581)
Total stockholders’ equity (deficit)	4,912	(2,600)
Total liabilities and stockholders’ equity (deficit)	$ 46,834	$ 36,079

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,	
	2018	**2017**
Revenue	$ 18,517	$ 15,288
Cost of revenue	11,197	7,844
Gross profit	7,320	7,444
Operating expenses:		
Research and development	13,716	12,343
Selling, general and administrative	38,569	28,831
Total operating expenses	52,285	41,174
Loss from operations	(44,965)	(33,730)
Interest expense, net	(4,372)	(3,169)
Other income (expense), net	13	(60)
Net loss from consolidated companies	(49,324)	(36,959)
Loss from minority interest in limited liability company	(657)	-
Comprehensive and net loss	$ (49,981)	$ (36,959)
Net loss per share:		
Basic and diluted	$ (1.61)	$ (2.11)
Weighted average shares used in computing net loss per common share:		
Basic and diluted	31,059,483	17,496,942

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

VIVEVE MEDICAL, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
For each of the two years in the period ended December 31, 2018
(in thousands, except share data)

	Common Stock, $0.0001 par value		Additional Paid-In	Accumulated	Total Stockholders' Equity
	Shares	Amount	Capital	Deficit	(Deficit)
	-	-	-	-	-
Balances as of January 31, 2017	**10,661,201**	**1**	**68,216**	**(68,622)**	**(405)**
March 2017 Offering, net of issuance costs	8,625,000	1	31,439	-	31,440
Stock-based compensation expense	-	-	1,646	-	1,646
Issuance of warrant in connection with note payable	-	-	940	-	940
Issuance of restricted common shares	35,000	-	260	-	260
Issuance of restricted stock awards to directors, employees and consultants	77,783	-	226	-	226
November 2017 ATM Facility, net of issuance cost	59,249	-	125	-	125
Issuance of common shares from employee stock purchase plan	17,894	-	76	-	76
Exercise of stock options	7,730	-	31	-	31
Exercise of warrants	4,701	-	20	-	20
Cashless exercise of warrant	15,000	-	-	-	-
Net loss	-	-	-	(36,959)	(36,959)
Balances as of December 31, 2017	**19,503,558**	**$ 2**	**$ 102,979**	**$ (105,581)**	**$ (2,600)**
December 2018 Offering, net of issuance costs	14,728,504	2	20,383	-	20,385
February 2018 Offering, net of issuance costs	11,500,000	1	32,213	-	32,214
November 2017 ATM Facility, net of issuance cost	277,249	-	1,193	-	1,193
Stock-based compensation expense	-	-	2,699	-	2,699
Issuance of restricted stock awards to directors, employees and consultants	128,847	-	336	-	336
Issuance of restricted common shares	100,000	-	256	-	256
Issuance of common shares from employee stock purchase plan	125,787	-	233	-	233
Cumulative effect adjustment from adoption of new accounting standard – ASC 606	-	-	-	177	177
Net loss	-	-	-	(49,981)	(49,981)
Balances as of December 31, 2018	**46,363,945**	**$ 5**	**$ 160,292**	**$ (155,385)**	**$ 4,912**

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,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (49,981)	$ (36,959)
Adjustments to reconcile net loss to net cash used in operating activities:		
Provision for (recovery from) doubtful accounts	179	(221)
Depreciation and amortization	786	449
Stock-based compensation	3,035	1,872
Fair value of common stock issued	256	260
Non-cash interest expense	1,580	1,049
Loss from minority interest in limited liability company	657	-
Changes in assets and liabilities:		
Accounts receivable	330	(3,901)
Inventory	(1,986)	(67)
Prepaid expenses and other current assets	183	(1,675)
Other noncurrent assets	31	(66)
Accounts payable	(805)	1,713
Accrued and other liabilities	2,143	2,419
Other noncurrent liabilities	502	274
Net cash used in operating activities	(43,090)	(34,853)
Cash flows from investing activities:		
Purchase of property and equipment	(2,142)	(905)
Investment in limited liability company	-	(2,500)
Net cash used in investing activities	(2,142)	(3,405)
Cash flows from financing activities:		
Proceeds from sale of common stock, net of issuance costs	53,792	31,565
Proceeds from note payable	-	29,210
Repayments of note payable	-	(10,000)
Proceeds from issuance of common shares from employee stock purchase plan	233	76
Proceeds from exercise of stock options	-	31
Proceeds from exercise of warrant	-	20
Net cash provided by financing activities	54,025	50,902
Net increase in cash and cash equivalents	8,793	12,644
Cash and cash equivalents - beginning of period	20,730	8,086
Cash and cash equivalents - end of period	$ 29,523	$ 20,730
Supplemental disclosure:		
Cash paid for interest	$ 2,673	$ 2,066
Cash paid for income taxes	$ 2	$ -
Supplemental disclosure of cash flow information as of end of period:		
Issuance of warrants in connection with note payable	$ -	$ 940
Issuance of note payable in settlement of accrued interest	$ 1,256	$ 495
Net transfer of equipment between inventory and property and equipment	$ 257	$ 364

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") 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.

Public Offerings

In December 2018, in connection with the closing of a public offering (the "December 2018 Offering"), the Company issued an aggregate of 14,728,504 shares of common stock, including the shares issued in connection with the exercise of the underwriters' overallotment option, at a public offering price of $1.50 per share for gross proceeds of approximately $22,093,000. The net proceeds to the Company, after deducting underwriting discounts and commissions and other offering expenses, were approximately $20,385,000.

In February 2018, in connection with the closing of a public offering (the "February 2018 Offering"), the Company issued an aggregate of 11,500,000 shares of common stock, including the shares issued in connection with the exercise of the underwriters' overallotment option, at a public offering price of $3.00 per share for gross proceeds of approximately $34,500,000. The net proceeds to the Company, after deducting underwriting discounts and commissions and other offering expenses, were approximately $32,214,000.

The Company established an "at-the-market" equity offering program through the filing of a prospectus supplement to its shelf registration statement on Form S-3, which was filed on November 8, 2017, under which the Company may offer and sell, from time-to-time, up to $25,000,000 aggregate offering price of shares of its common stock (the "November 2017 ATM Facility"). During the years ended 2018 and 2017, the Company sold 277,249 shares for net proceeds of approximately $1,193,000 and 59,249 shares for net proceeds of approximately $125,000, respectively. As of December 31, 2018, the Company has sold an aggregate of 336,498 shares of common stock under the November 2017 ATM Facility for net proceeds of approximately $1,318,000.

In March 2017, in connection with the closing of a public offering (the "March 2017 Offering"), the Company issued an aggregate of 8,625,000 shares of common stock, including the shares issued in connection with the exercise of the underwriters' overallotment option, at a public offering price of $4.00 per share for gross proceeds of approximately $34,500,000. The net proceeds to the Company, after the deduction of underwriting discounts, commissions and other offering expenses, were approximately $31,440,000.

Liquidity and Management Plans

The Company has adopted 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, 2018, the Company had accumulated deficit of $155,385,000, cash and cash equivalents of $29,523,000 and working capital of $31,144,000. Additionally, the Company used $43,090,000 in cash for operations in the year ended December 31, 2018. The Company will require additional cash funding to fund operations through March 31, 2020. Accordingly, management has concluded that the Company does not have sufficient funds to support operations within one year after the date the financial statements are issued and, therefore, the Company concluded there was substantial doubt about the Company's ability to continue as a going concern. Based on management's plans to reduce operating expenses, including the reduction in force in January 2019, and the availability of our November 2017 ATM Facility, the Company believes that this substantial doubt has been alleviated.

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.

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, revenues, 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.

Changes in Accounting Policies

Except for the changes for the adoption of the new revenue recognition accounting standard, the Company has consistently applied the accounting policies to all periods presented in these condensed consolidated financial statements.

Adoption of New Accounting Standard

On January 1, 2018, the Company adopted Revenue from Contracts with Customers (Topic 606), which created Accounting Standards Codification Topic 606 ("ASC 606"), using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting under Accounting Standards Codification Topic 605 ("ASC 605").

Previously under ASC 605, revenue from extended assurance warranties was deferred and recognized over the period of the warranty. Under ASC 606, these warranties are not considered a separate performance obligation. Accordingly, on the transition date, the Company recorded a net cumulative adjustment in accumulated deficit of $177,000, resulting from the release of $195,000 for the amount of extended warranties previously recorded in noncurrent liabilities, offset by $18,000 recorded in accrued liabilities for future costs associated with the assurance-type extended warranties.

The details for the impact of the adoption of ASC 606 are provided below:

	Balance as of December 31, 2017	Adjustment Due to Adoption of ASC 606	Balance as of January 1, 2018
Consolidated Balance Sheet:			
Liabilities			
Accrued liabilities	$ 4,605	$ 18[(1)]	$ 4,623
Other noncurrent liabilities	$ 327	$ (195)[(2)]	$ 132
Equity			
Accumulated deficit	$ (105,581)	$ 177[(3)]	$ (105,404)

(1) Change relates to future costs associated with extended warranties required to be recorded on adoption of ASC 606.

(2) Change relates to long-term deferred revenue related to the extended warranties not required to be recorded under ASC 606.

(3) Change relates to cumulative effect adjustment upon adoption of ASC 606.

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 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, but not 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 RF, or radio frequency, 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. RF 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 single contract manufacturer. 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 North America, the Company sells its products primarily through a direct sales force to health care practitioners. Outside North America, the Company sells through an extensive network of distribution partners. During the year ended December 31, 2018, one distributor accounted for 21% of the Company's revenue. During the year ended December 31, 2017, two distributors together accounted for 35% of the Company's revenue.

There are no direct sales to customers that accounted for more than 10% of the Company's revenue during the years ended December 31, 2018 and 2017.

As of December 31, 2018, three distributors, collectively, accounted for 54% of total accounts receivable, net. As of December 31, 2017, two distributors, collectively, accounted for 57% of total accounts receivable, net.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are recorded at the invoiced amount and are not 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 $284,000 and $221,000 as of December 31, 2018 and 2017, respectively.

Inventory

Inventory is stated at the lower of cost or net realizable value. Inventory as of December 31, 2018 consisted of $3,232,000 of finished goods and $887,000 of raw materials. Inventory as of December 31, 2017 consisted of $1,990,000 of finished goods and $40,000 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 normal business, the Company generally utilizes various finished goods inventory as sales demos to facilitate the sale of its products to prospective customers. The Company is amortizing these demos over an estimated useful life of five years. The amortization of the demos is charged to selling, general and administrative expense and the demos are included in the medical equipment line within the property and equipment, net balance on the consolidated balance sheets as of December 31, 2018 and 2017.

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 Recognition

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. Revenues, 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.

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 North America, we market and sell primarily through a direct sales force. Outside of North America, 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, 2018 or 2017. The Company had customer contract liabilities in the amount of $686,000, primarily related to marketing programs that performance had not yet been delivered to its customers as of December 31,2018. No such contract liabilities existed as of December 31, 2017. 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 year ended December 31, 2018, 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 has elected the practical expedient to recognize the incremental costs of obtaining a contract as an expense when incurred if the amortization period of the asset that the Company otherwise would have recognized is one year or less. During the year ended December 31, 2018, the Company expensed the incremental costs of obtaining the contract as an expense when incurred as the amortization period was one year or less.

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.

In accordance with the new revenue standard requirements, the disclosure of the impact of adoption on our consolidated statement of operations for the year ended December 31, 2018 and consolidated balance sheet as of December 31, 2018 was as follows (in thousands):

	For the year ended December 31, 2018		
	As Reported	Balances Without Adoption of ASC 606	Effect of Change Higher/(Lower)
Consolidated Statement of Operations			
Revenue	$ 18,517	$ 17,780	$ 737 (1)
Cost of revenue	$ 11,197	$ 11,209	$ (12) (2)
Gross profit	$ 7,320	$ 6,571	$ 749 (3)
Loss from operations	$ (44,965)	$ (45,714)	$ 749 (3)
Comprehensive and net loss	$ (49,981)	$ (50,730)	$ 749 (3)
Net loss per share:			
Basic and diluted	$ (1.61)	$ (1.63)	$ 0.02
Weighted average shares	31,059,483	31,059,483	

(1) Change relates to revenue from extended assurance warranties for which no deferral is required on the adoption of ASC 606.

(2) Change relates to the future costs associated with extended assurance warranties required to be recorded on the adoption of ASC 606.

(3) Change relates to the net gain adjustment on the adoption of ASC 606.

	As of December 31, 2018		
	As Reported	Balances Without Adoption of ASC 606	Effect of Change Higher/(Lower)
Consolidated Balance Sheets			
Liabilities			
Accrued liabilities	$ 6,766	$ 7,014	$ (248)[1]
Other noncurrent liabilities	$ 634	$ 1,313	$ (679)[2]
Equity			
Accumulated deficit	$ (155,385)	$ (156,311)	$ 926 [3]

(1) Change relates to the current portion of deferred revenue in connection with the extended warranties not required to be recorded under ASC 606, partially offset by future costs associated with extended warranties required to be recorded on the adoption of ASC 606.

(2) Change relates to noncurrent portion of deferred revenue in connection with the extended warranties not required to be recorded under ASC 606.

(3) Change relates to $177,000 cumulative effect adjustment on the adoption of ASC 606 and the net gain adjustment of $749,000 for the year ended December 31, 2018.

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).

	Year Ended December 31,	
	2018	2017
United States	$ 13,606	11,004
Asia Pacific	2,891	3,178
Europe and Middle East	1,369	667
Canada	563	79
Latin America	51	360
Other	37	-
Total	$ 18,517	$ 15,288

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 are 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, 2018 and 2017, no impairment charges have been recorded.

Product Warranty

The Company's products 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, 2018 and 2017.

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, 2018 and 2017. 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 at their fair value on the measurement date and are subject to periodic adjustment as the underlying equity instruments vest.

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, 2018 and 2017, 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 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,	
	2018	**2017**
Stock options to purchase common stock	4,014,475	2,694,224
Warrants to purchase common stock	642,622	642,622
Restricted common stock awards	57,500	10,000

Recently Issued and Adopted Accounting Standards

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which requires an entity that is a lessee to record a right of use asset and a corresponding lease liability on the balance sheet for all leases. This guidance also requires disclosures about the amount, timing, and uncertainty of cash flows arising from leases. This guidance is effective for annual reporting periods beginning after December 15, 2018, and interim periods within those annual periods and early adoption is permitted. In July 2018, the FASB issued updated guidance which allows an additional transition method to adopt the new leases standard at the adoption date, as compared to the beginning of the earliest period presented, and allows entities to recognize a cumulative-effect adjustment to the beginning balance of retained earnings in the period of adoption. The Company expects to elect to use this transition method at the adoption date of January 1, 2019, and, as a result, will record a right of use asset and a corresponding lease liability on the balance sheet for all leases with terms longer than 12 months. The Company also plans to elect the practical expedient to not separate lease and non-lease components and to use the package of practical expedients upon transition that will retain the lease classification and initial direct costs for any leases that exist prior to adoption of the new guidance.

In August 2016, the FASB issued ASU No. 2016-15, "Statement of Cash Flows, Classification of Certain Cash Receipts and Cash Payments (Topic 230)". This guidance addresses specific cash flow issues with the objective of reducing the diversity in practice for the treatment of these issues. The areas identified include: debt prepayment or debt extinguishment costs; settlement of zero-coupon debt instruments; contingent consideration payments made after a business combination; proceeds from the settlement of insurance claims; proceeds from the settlement of corporate-owned life insurance policies; distributions received from equity method investees; beneficial interests in securitization transactions and application of the predominance principle with respect to separately identifiable cash flows. This guidance is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, with early adoption permitted. We adopted this guidance as of January 1, 2018 and the adoption of the guidance did not have a significant impact on the condensed consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-18, "Statement of Cash Flows, Restricted Cash (Topic 230)". This guidance requires that a statement of cash flows explain the total change during the period of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Amounts described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning of period and end of period to total amounts shown on the statement of cash flows. This guidance is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, with early adoption permitted. We adopted this guidance as of January 1, 2018 and the adoption of the guidance did not have a significant impact on the condensed consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, "Compensation - Stock Compensation (Topic 718), Scope of Modification Accounting". This pronouncement provides guidance about which changes to the terms or conditions of a share-based payment award may require an entity to apply modification accounting under Topic 718. This guidance is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, with early adoption permitted. We adopted this guidance as of January 1, 2018 and the adoption of the guidance did not have a significant impact on the condensed consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, "Stock Compensation (Topic 718) – Improvements to Nonemployee Share-Based Payment Accounting". The intent of this guidance is to simplify the accounting for nonemployee share-based payment accounting. The amendments in this guidance expand the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. Consistent with the accounting requirement for employee share-based payment awards, nonemployee share-based payment awards within the scope of Topic 718 are measured at grant-date fair value of the equity instruments that an entity is obligated to issue when the good has been delivered or the service has been rendered and any other conditions necessary to earn the right to benefit from the instruments have been satisfied. Equity- classified nonemployee share-based payment awards are measured at the grant date. Consistent with the accounting for employee share-based payment awards, an entity considers the probability of satisfying performance conditions when nonemployee share-based payment awards contain such conditions. This guidance is effective for annual reporting periods beginning after December 15, 2018, including interim periods within the reporting period. We do not expect the adoption of this guidance to have a significant effect on our 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.

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 (Level 3 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 or no 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, 2018 and 2017.

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, 2018 and 2017 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, 2018 and 2017 (in thousands):

	Life (in years)	December 31, 2018	December 31, 2017
Medical equipment	5	$ 3,571	$ 1,299
Computer equipment	3	309	193
Leasehold Improvements	3	121	200
Furniture and fixtures	7	403	340
Software	3	25	-
		4,429	2,032
Less: Accumulated depreciation and amortization		(1,513)	(729)
Property and equipment, net		$ 2,916	$ 1,303

Depreciation and amortization expense for the years ended December 31, 2018 and 2017 was $786,000 and $449,000, 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.

Under the terms of the Distributorship Agreement, ICM agreed to not directly or indirectly appoint or authorize any third party to market, promote, distribute or sell any of the licensed products to any licensed medical professional offices and hospitals in the United States. In exchange, the Company agreed to not market, promote, distribute or sell (or contract to do so) any product which substantially replicates all or almost all of the key features of the licensed products. The Company has a minimum purchase requirement to purchase a certain quantity of ICM products per month during the term of this Distributorship Agreement. In addition, the parties agreed to certain mutual marketing obligations to promote sales of the licensed products. During the years ended December 31, 2018 and 2017, the Company has purchased 3,300 and 1,200 units of ICM products for approximately $327,000 and $89,000, respectively. As of December 31, 2018, the Company has purchased approximately 4,500 units of ICM products for approximately $416,000. The Company paid ICM approximately $337,000 and $94,000 for product related costs during the years ended December 31, 2018 and 2017, respectively.

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, 2018, the Company owns approximately 9% 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 year ended December 31, 2018, the allocated net loss from ICM's operations was $657,000 that was recorded as a loss from minority interest in limited liability company in the consolidated statements of operations. For the year ended December 31, 2017, the allocated net loss from ICM's operations was immaterial.

6. Accrued Liabilities

Accrued liabilities consisted of the following as of December 31, 2018 and 2017 (in thousands):

	December 31, 2018	December 31, 2017
Accrued sales commission	$ 1,743	$ 1,067
Accrued professional fees	978	562
Accrued bonuses	837	1,597
Accrued interest	683	447
Customer contracts liabilities	686	-
Accrued payroll and other related expenses	877	488
Travel and entertainment	280	156
Accrued sales & use tax	259	149
Accrued clinical trial costs	84	30
Other accruals	339	109
Total accrued liabilities	$ 6,766	$ 4,605

7. Note Payable

On June 20, 2016, the Company entered into a Loan and Security Agreement, as amended January 13, 2017 (the "2016 Loan Agreement") with Western Alliance Bank ("WAB"), pursuant to which WAB agreed to loan the Company up to an aggregate of $10,000,000 payable in two tranches of $7,500,000 and $2,500,000. The funding conditions for both tranches were satisfied as of the closing date, and therefore, the aggregate principal amount of $10,000,000 was provided on June 20, 2016. The terms of the loan also required the Company to meet certain financial and other covenants in connection with the 2016 Loan Agreement. In addition to all outstanding principal and accrued interest on the term loan, the terms of the loan required the Company to pay a final payment fee equal to 4.00% of the original principal amount of the term loan. All borrowings under the 2016 Loan Agreement were collateralized by substantially all of the Company's assets, including intellectual property. The outstanding principal balance and accrued interest related to this note payable were repaid in May 2017.

In connection with the 2016 Loan Agreement, the Company issued a 10-year warrant to WAB to purchase a total of 100,402 shares of the Company's common stock at an exercise price of $4.98 per share (See Note 8).

On May 22, 2017, the Company entered into a Term Loan Agreement (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.

A portion of the initial loan proceeds were used to repay all of the amounts owed by the Company under its 2016 Loan Agreement with WAB. The remainder of the loan proceeds (after deducting loan origination costs and other fees and expenses incurred in connection with the 2017 Loan Agreement), plus any additional amounts that may be borrowed in the future, will be used for general corporate purposes and working capital.

The 2017 Loan Agreement has a six-year term with four years of interest-only payments after which quarterly principal and interest payments will be due through the maturity date. Amounts borrowed under the 2017 Loan Agreement accrue interest at an annual fixed rate of 12.5%, 4.0% of which may, at the election of the Company, be paid in-kind during the interest-only period by adding such accrued amount to the principal loan amount each quarter. During the years ended December 31, 2018 and 2017, the Company paid interest in-kind of $1,256,000 and $495,000, respectively, which was added to the total outstanding principal loan in that period. The Company is 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. The Company accounts for the final payment fee by accruing the fee over the term of the loan using the effective interest rate method. As of December 31, 2018, interest accrued related to the final payment fee in the amount of $484,000 was included in other noncurrent liabilities in the consolidated balance sheets.

The Company may prepay all or a portion of the outstanding principal and accrued unpaid interest under the 2017 Loan Agreement at any time upon prior notice to CRG, subject to a prepayment fee during the first five years of the term (which reduces each year) and no prepayment fee thereafter.

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 require the Company to meet certain financial and other covenants. These covenants require the Company to maintain cash and cash equivalents of $2.0 million and, each year through the end of 2022, to meet a minimum total annual revenue threshold. In the event that the Company does not meet the minimum total annual revenue threshold for a particular year, then the Company can retroactively cure the shortfall by either issuing additional equity in exchange for cash or incurring certain additional permitted indebtedness, in each case, in an amount equal to 2.0 times the shortfall. Any such amounts shall be applied to prepay the loans. The 2017 Loan Agreement also contains customary affirmative and negative covenants for a credit facility of this size and type, including covenants that limit or restrict the Company's ability to, among other things, incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into transactions with affiliates, pay dividends or make distributions, license intellectual property rights on an exclusive basis or repurchase stock, in each case subject to customary exceptions. As of December 31, 2018, the Company was in compliance with all covenants.

As of December 31, 2018 and 2017, $30,528,000 and $28,948,000 was recorded on the balance sheets under the 2017 Loan Agreement, which is net of the remaining unamortized debt discount.

In connection with the 2017 Loan Agreement, the Company issued two 10-year warrants to CRG to purchase a total of 222,049 shares of the Company's common stock at an exercise price of $9.50 per share (See Note 8).

As of December 31, 2018, future minimum payments under the note payable are as follows (in thousands):

Year Ending December 31,	
2019	$ 2,778
2020	2,901
2021	16,673
2022	19,306
2023	6,220
Total payments	47,878
Less: Amount representing interest	(16,127)
Present value of obligations	31,751
Less: Unamortized debt discount	(1,223)
Note payable, noncurrent portion	$ 30,528

8. Commitments and Contingencies

Operating Lease

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 will terminate in May 2020. The Company relocated its corporate headquarters from Sunnyvale, California to Englewood, Colorado in June 2017.

The monthly base rent under the Sublease is equal to $20.50 per rentable square foot of the Sublease Premises during the first year. The monthly base rent is 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.

Rent expense for the years ended December 31, 2018 and 2017 was $358,000 and $442,000, respectively.

In September 2018, the Company entered into a 36-month noncancelable operating lease agreement for office equipment. The lease commenced on September 20, 2018. The monthly payment is approximately $3,000.

As of December 31, 2018, future minimum principal and interest payments under the leases are as follows (in thousands):

Year Ending December 31,	
2019	$ 296
2020	143
2021	23
Total minimum lease payments	$ 462

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 amount 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 does not 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.

Legal Proceedings

In December 2018, the Company settled an arbitration matter with a former employee, and the arbitration has now been dismissed with prejudice. The matter involved affirmative claims for negligence by the Company against the employee arising out of her negligent performance of certain work duties, as well as various employment-related counterclaims by the employee.

On June 4, 2018, the Company 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 the Company's patent litigation against ThermiGen and Dr. Alinsod. The Settlement Agreement also resolved ThermiGen's inter partes review proceedings against the Company. The litigation arose from the Company's claim that ThermiGen and Dr. Alinsod were improperly using the Company's patented technology without consent. Pursuant to the Settlement Agreement, the parties agreed to resolve all currently pending disputes between them.

Under the terms of the Settlement Agreement, the Company received an initial monetary payment to settle the litigation and past claims and an on-going royalty for future sales. Viveve granted to ThermiGen a non-exclusive, non-transferable license to use the Company's U.S. patent for the current version of ThermiGen's ThermiVa system (which includes RF generators and consumables). The Company has recorded the monetary payment as a gain on litigation settlement in selling, general and administrative expenses on the consolidated statements of operations during the year ended December 31, 2018.

9. Common Stock

In December 2018, in connection with the closing of a public offering (the "December 2018 Offering"), the Company issued an aggregate of 14,728,504 shares of common stock, including the shares issued in connection with the exercise of the underwriters' overallotment option, at a public offering price of $1.50 per share for gross proceeds of approximately $22,093,000. The net proceeds to the Company, after deducting underwriting discounts and commissions and other offering expenses, were approximately $20,385,000.

In June 2018, the Company issued 100,000 restricted shares of its common stock at a value of $2.56 a share, or an aggregate value of approximately $256,000.

In February 2018, in connection with the closing of the February 2018 Offering, the Company issued an aggregate of 11,500,000 shares of common stock, including the shares issued in connection with the exercise of the underwriters' overallotment option, at a public offering price of $3.00 per share for gross proceeds of approximately $34,500,000. The net proceeds to the Company, after deducting underwriting discounts and commissions and other offering expenses, were approximately $32,214,000.

Through the November 2017 ATM Facility, the Company may offer and sell, from time-to-time, up to $25,000,000 aggregate offering price of shares of its common stock. During the years ended 2018 and 2017, the Company sold 277,249 shares for net proceeds of approximately $1,193,000 and 59,249 shares for net proceeds of approximately $125,000, respectively. As of December 31, 2018, the company has sold an aggregate of 336,498 shares of common stock under the November 2017 ATM Facility for net proceeds of approximately $1,318,000. As of December 31, 2018, the Company has sold 59,249 shares of common stock under the November 2017 ATM Facility for net proceeds of approximately $125,000.

In May 2017, the Company issued 35,000 restricted shares of its common stock at a value of $7.42 a share, or an aggregate value of approximately $260,000.

In March 2017, in connection with the closing of the March 2017 Offering, the Company issued an aggregate of 8,625,000 shares of common stock, including the exercise of the underwriters' overallotment option, at a public offering price of $4.00 per share for gross proceeds of approximately $34,500,000. The net proceeds to the Company, after the deduction of underwriting discounts, commissions and other offering expenses, were approximately $31,440,000.

Warrants for Common Stock

As of December 31, 2018 and 2017, 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
September 2014	Common Shares	September 23, 2019	$ 4.24	86,831
October 2014	Common Shares	October 13, 2019	$ 4.24	29,000
November 2014	Common Shares	November 12, 2019	$ 4.24	12,500
February 2015	Common Shares	February 17, 2025	$ 4.00	75,697
March 2015	Common Shares	March 26, 2025	$ 2.72	1,454
May 2015	Common Shares	May 12, 2025	$ 4.24	36,229
May 2015	Common Shares	May 17, 2020	$ 4.24	21,585
December 2015	Common Shares	December 16, 2025	$ 5.60	26,875
April 2016	Common Shares	April 1, 2026	$ 6.08	25,000
May 2016	Common Shares	May 11, 2021	$ 7.74	5,000
June 2016	Common Shares	June 20, 2026	$ 4.98	100,402
May 2017	Common Shares	May 25, 2027	$ 9.50	222,049
				642,622

In connection with the 2016 Loan Agreement, the Company issued a warrant to purchase a total of 100,402 shares of common stock at an exercise price of $4.98 per share. The Company determined the fair value of the warrant on the date of issuance to be $350,000. The fair value along with legal fees totaling $90,000, was recorded as debt issuance costs and was amortized to interest expense over the loan term. The debt issuance costs were presented in the consolidated balance sheet as a deduction from the carrying amount of the note payable. The outstanding indebtedness was repaid in May 2017 from the proceeds of the new term loan in connection with the 2017 Loan Agreement and the remaining unamortized balance of debt issuance costs was recorded to interest expense. During the year ended December 31, 2017, the Company recorded $371,000 of interest expense relating to the debt issuance costs.

In connection with the 2017 Loan Agreement, the Company issued warrants to purchase a total of 222,049, shares of common stock at an exercise price of $9.50 per share. The warrants have a contractual life of ten years and are exercisable immediately in whole or in part. The Company determined the fair value of the warrants on the date of issuance to be $940,000 using the Black-Scholes option pricing model. Assumptions used were dividend yield of 0%, volatility of 55.1%, risk free interest rate of 2.25% and a contractual life of ten years. The fair value of the warrants along with financing and legal fees totaling $790,000, are recorded as debt issuance costs and presented in the 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, 2018 and 2017, the Company recorded $325,000 and $183,000, respectively, of interest expense relating to the debt issuance costs using the effective interest method. As of December 31, 2018, the unamortized debt discount was $1,223,000.

No shares, issuable pursuant to warrants issued in connection with a private offering on September 30, 2014, were issued in connection with the exercise of warrants during the years ended December 31, 2018 and 2017, respectively.

No shares issuable pursuant to warrants have been cancelled during the year ended December 31, 2018 and 2017.

The stock-based compensation expense related to warrants issued was zero for the years ended December 31, 2018 and 2017, respectively.

10. Summary of Stock Options

Stock Option Plans

The Company has issued equity awards in the form of stock options and restricted stock awards ("RSAs") 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").

The 2006 Plan was adopted by the board of directors of Viveve, Inc. and was terminated in conjunction with the merger that took place on September 23, 2014 between PLC Systems Inc., Viveve, Inc. and PLC Systems Acquisition Corp. (the "Merger"). Prior to the Merger, the board of directors voted to accelerate the vesting of all unvested options that were outstanding as of the date of the Merger such that all options would be immediately vested and exercisable by the holders. In conjunction with the Merger, the Company agreed to assume and administer the 2006 Plan and all outstanding options to purchase shares of Viveve, Inc. common stock issued from the 2006 Plan were converted into options to purchase shares of the Company's common stock (rounded down to the nearest whole share). As of December 31, 2018, there are outstanding stock option awards issued from the 2006 Plan covering a total of 38,145 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 $9.96 per share and the weighted average remaining contractual term is 1.3 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. On December 23, 2016, the board of directors approved the 2017 evergreen increasing the total stock reserved for issuance under the 2013 Plan by 523,209 shares from 2,000,000 shares to a total of 2,523,209 shares, which was effective January 1, 2017. On August 15, 2017, the Company's stockholders approved an amendment to the 2013 Plan increasing the number of shares of common stock authorized for awards under the 2013 Plan from 2,523,209 shares to a total of 4,000,000 shares. On December 6, 2017, the board of directors approved the 2018 evergreen increasing the total stock reserved for issuance under the 2013 Plan from 4,000,000 shares to a total of 4,914,016 shares, which was effective January 1, 2018.

As of December 31, 2018, there are outstanding stock option awards issued from the 2013 Plan covering a total of 3,976,330 shares of the Company's common stock and there remain reserved for future awards 603,712 shares of the Company's common stock. The weighted average exercise price of the outstanding stock options is $4.50 per share, and the remaining contractual term is 7.5 years.

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

	Year Ended December 31, 2018			
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Options outstanding, December 31, 2016	1,909,764	$ 6.19	9.1	$ 211,396
Options granted	1,000,985	$ 5.68		
Options exercised	(7,730)	$ 4.02		
Options canceled	(208,795)	$ 8.88		
Options outstanding, December 31, 2017	2,694,224	$ 5.80	8.6	$ 249,154
Options granted	2,358,559	$ 3.52		
Options exercised	-	$ -		
Options canceled	(1,038,308)	$ 5.43		
Options outstanding, December 31, 2018	4,014,475	$ 4.56	7.4	$ -
Vested and exercisable and expected to vest, end of period	3,825,887	$ 4.98	7.3	$ -
Vested and exercisable, end of period	1,637,474	$ 5.44	5.0	$ -

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, 2018.

The options outstanding and exercisable as of December 31, 2018 are as follows:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding as of Dec 31, 2018	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Number Exercisable as of Dec 31, 2018	Weighted Average Exercise Price
$1.75 - $1.97	535,000	$ 1.95	9.4	50,000	$ 1.97
$2.02 - $2.83	180,000	$ 2.40	9.4	11,459	$ 1.97
$3.03 - $3.82	546,876	$ 3.53	9.1	64,090	$ 2.64
$4.30 - $4.97	1,247,318	$ 4.54	7.3	503,934	$ 3.76
$5.01 - $5.67	693,067	$ 5.36	6.8	397,466	$ 4.62
$6.00 - $6.61	490,470	$ 6.04	4.1	412,662	$ 5.34
$7.00 - $7.92	283,599	$ 7.65	7.4	159,718	$ 6.02
$9.92	38,135	$ 9.92	1.3	38,135	$ 7.66
$59.60 - $149.04	10	$ 149.04	2.8	10	$ 9.92
	4,014,475	$ 4.56	7.4	1,637,474	$ 5.44

Stock Option Modifications

On May 30, 2018, under approval by the Company's Board of Directors, the Company entered in to a Separation and Release Agreement with the former Chief Executive Officer. The provisions of the agreement specify that the stock options previously granted to her will continue to vest through the earlier of the date she ends her consulting services to the Company or December 31, 2018. As of May 30, 2018, these stock options are being accounted for as a non-employee option through the consulting term and are being marked-to-market. Additionally, the former Chief Executive Officer will receive six months of accelerated vesting of the stock options and the post-termination exercise period was extended from three months to one year after the effective date of the agreement. The Company recognized stock-based compensation expense of $97,000 for the incremental value of the accelerated vesting and the change in the exercise period upon the signing of the agreement.

Restricted Stock Awards

As of December 31, 2018, there are 57,500 shares of unvested restricted stock outstanding that have been granted pursuant to RSAs.

In December 2018, the Company granted RSAs for 40,775 of common stock under the 2013 Plan to board members as director compensation with a weighted average grant date fair value of $1.05 per share, based on the market price of the Company's common stock on the award date. The RSAs were fully vested on the date of grant and 40,775 shares of common stock were issued.

In October 2018, the Company granted RSAs for 17,985 of common stock under the 2013 Plan to board members as director compensation with a weighted average grant date fair value of $2.48 per share, based on the market price of the Company's common stock on the award date. The RSAs were fully vested on the date of grant and 17,985 shares of common stock were issued.

In July 2018, the Company granted RSAs for 18,278 of common stock under the 2013 Plan to board members as director compensation with a weighted average grant date fair value of $2.63 per share, based on the market price of the Company's common stock on the award date. The RSAs were fully vested on the date of grant and 18,278 shares of common stock were issued.

In June 2018, the Company granted an RSA for 50,000 shares to a consultant with a weighted average grant date fair value of $3.58 per share, based on the market price of the Company's common stock on the award date. The RSA vests over two years beginning as of the award date. As of December 31, 2018, zero shares were vested and issued.

In April 2018, the Company granted RSAs for 14,672 shares of common stock under the 2013 Plan to board members as director compensation with a weighted average grant date fair value of $3.44 per share, based on the market price of the Company's common stock on the award date. The RSAs were fully vested on the date of grant and 14,672 shares of common stock were issued.

In January 2018, the Company granted RSAs for 9,637 shares of common stock under the 2013 Plan to board members as director compensation with a weighted average grant date fair value of $5.19 per share, based on the market price of the Company's common stock on the award date. The RSAs were fully vested on the date of grant and 9,637 shares of common stock were issued.

In January 2018, the Company granted an RSA for 25,000 shares to a consultant with a weighted average grant date fair value of $5.19 per share, based on the market price of the Company's common stock on the award date. The RSA vests over one year beginning as of the award date. As of December 31, 2018, 25,000 shares were vested and issued.

In December 2017, the Company granted an RSA for 10,000 shares to an employee with a weighted average grant date fair value of $4.94 per share, based on the market price of the Company's common stock on the award date. The RSA vests over four years at a rate of $1/4^{th}$ the first year beginning as of the award date and monthly thereafter. As of December 31, 2018, 2,500 shares were vested and issued.

In October 2017, the Company granted RSAs for 7,884 shares of common stock under the 2013 Plan to board members as director compensation with a weighted average grant date fair value of $5.55 per share, based on the market price of the Company's common stock on the award date. The RSAs were fully vested on the date of grant and 7,884 shares of common stock were issued.

In May 2017, the Company granted RSAs for 4,797 shares of common stock under the 2013 Plan to board members as director compensation with a weighted average grant date fair value of $7.07 per share, based on the market price of the Company's common stock on the award date. The RSAs were fully vested on the date of grant and 4,797 shares of common stock were issued. In September 2017, the Company granted RSAs for 6,947 shares of common stock under the 2013 Plan to board members as director compensation with a weighted average grant date fair value of $5.58 per share, based on the market price of the Company's common stock on the award date. The RSAs were fully vested on the date of grant and 6,947 shares of common stock were issued.

2017 Employee Stock Purchase Plan

The second offering period under the Company's 2017 Employee Stock Purchase Plan (the "2017 ESPP") began on January 1, 2018 and ended on March 31, 2018, and 20,744 shares were issued on March 29, 2018 at a purchase price of $3.11. The third offering period under the Company's 2017 ESPP began on April 1, 2018 and ended on June 30, 2018, and 25,618 shares were issued on June 29, 2018 at a purchase price of $2.31. The fourth offering period under the Company's 2017 ESPP began on July 1, 2018 and ended on September 30, 2018, and 28,698 shares were issued on September 28, 2018 at a purchase price of $2.24. The fifth offering period under the Company's 2017 ESPP began on October 1, 2018 and ended on December 31, 2018, and 50,727 shares were issued on December 31, 2018 at a purchase price of $0.89.

As of December 31, 2018, the remaining shares available for issuance under the 2017 ESPP were 256,319 shares.

The Company estimates the fair value of purchase rights under the ESPP using a Black-Scholes valuation model. The fair value of each purchase right was estimated on the date of grant using the Black-Scholes option valuation model and the straight-line attribution approach with the following weighted-average assumptions:

	Year Ended December 31,	
	2018	**2017**
Expected term (in years)	0.25	0.25
Average volatility	72%	61%
Risk-free interest rate	1.92%	1.06%
Dividend yield	0%	0%

The weighted average grant date fair value of the purchase rights issued under the 2017 ESPP during the year ended December 31, 2018 and 2017 was $0.89 and $1.51 per share, respectively.

Stock-Based Compensation

During the years ended December 31, 2018 and 2017, the Company granted stock options to employees to purchase 2,146,171 and 981,110 shares of common stock with a weighted average grant date fair value of $2.24 and $2.88 per share, respectively. There were no stock options exercised by employees during the year ended December 31, 2018. The aggregate intrinsic value of options exercised during the year ended December 31, 2017 was $31,000.

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

	Year Ended December 31,	
	2018	**2017**
Expected term (in years)	5	5
Average volatility	73%	59%
Risk-free interest rate	2.65%	1.89%
Dividend yield	0%	0%

During the years ended December 31, 2018 and 2017, the Company granted stock options to nonemployees to purchase 212,388 and 19,875 shares of common stock, with a weighted average grant date fair value of $1.62 and $4.09 per share. There were no stock options exercised by nonemployees during the years ended December 31, 2018 and 2017.

The fair value of nonemployee stock options granted was estimated using the following weighted average assumptions:

	Year Ended December 31,	
	2018	**2017**
Expected term (in years)	9	10
Average volatility	69%	72%
Risk-free interest rate	2.69%	2.38%
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 employee 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 included in the consolidated statements of operations for the years ended December 31, 2018 and 2017 (in thousands):

	Year Ended December 31,	
	2018	2017
Cost of revenue	$ 69	$ 19
Research and development	328	252
Selling, general and administrative	2,638	1,601
Total	$ 3,035	$ 1,872

As of December 31, 2018, the total unrecognized compensation cost in connection with unvested stock options was approximately $4,328,328. These costs are expected to be recognized over a period of approximately 2.72 years.

11. 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.

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

	Year Ended December 31,	
	2018	2017
Income tax provision (benefit) at statutory rate	(21)%	(34)%
State income taxes, net of federal benefit	(4)%	(4)%
Change in valuation allowance	23%	4%
Effect of tax legislation	0%	33%
Other	2%	1%
Effective tax rate	0%	0%

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

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$ 31,759	$ 19,699
Capitalized start up costs	3,555	3,963
Research and development credits	951	835
Accruals and reserves	1,272	1,403
Fixed assets and depreciation	69	39
Total deferred tax assets	37,606	25,939
Valuation allowance	(37,606)	(25,939)
Net deferred tax assets	$ -	$ -

The Company has recorded a full valuation allowance for its deferred tax assets based on it past losses and the uncertainty regarding the ability to project future taxable income. The valuation allowance increased by approximately $11,667,000 and $1,501,000 during the years ended December 31, 2018 and 2017, respectively.

As of December 31, 2018, the Company has net operating loss ("NOL") carryforwards for federal and state income tax purposes of approximately $126,893,000 and $97,677,000, respectively, which expire beginning in the year 2026.

The Company also has federal and California research and development tax credits of approximately $830,000 and $668,000, respectively. The federal research credits will begin to expire in 2026 and the California research and development credits have no expiration date.

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. If the Company has experienced a change of control, utilization of its NOL or tax credits carryforwards would be subject to an annual limitation under Section 382. Any limitation may result in expiration of a portion of the NOL or research and development credit carryforwards before utilization. Subsequent ownership changes could further impact the limitation in future years. Until a Section 382 study is completed and any limitation known, no amounts are being presented as an uncertain tax position. 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, 2018, 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,	
	2018	2017
Balance at the beginning of the year	$ 397	$ 268
Additions based upon tax positions related to the current year	53	129
Balance at the end of the year	$ 450	$ 397

If the ending balance of $450,000 of unrecognized tax benefits as of December 31, 2018 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.

On December 22, 2017, the United States enacted a law commonly known as the Tax Cuts and Jobs Act ("TCJA") which makes widespread changes to the Internal Revenue Code, including a reduction in the federal corporate tax rate to 21%, and repatriation of accumulated foreign accumulated earnings and profits, effective January 1, 2018.

The Company is required to recognize the effect on deferred tax assets and liabilities due to a change in tax rates in the period the tax rate change was enacted. The carrying value of the Company's U.S. deferred taxes is determined by the enacted U.S. corporate income tax rate. Consequently, the reduction in the U.S. corporate income tax rate impacts the carrying value of our deferred tax assets. Under the new corporate income tax rate of 21%, the Company's U.S. net deferred tax asset position has decreased as has the related valuation allowance. The Company has also considered the impact of the transition tax for which it has estimated it does not need to accrue a liability as the operations of Viveve BV are immaterial. Uncertainty regarding the impact of tax reform remains, as a result of factors including future regulatory and rulemaking processes, the prospects of additional corrective or supplemental legislation, potential trade or other litigation, and other factors.

12. 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, 2018, the Company has purchased 809 units. The price per unit is variable and dependent on the volume and timing of units ordered. In conjunction with the Agreement, Stellartech purchased 37,500 shares of Viveve, Inc.'s common stock. Under the Agreement, the Company paid Stellartech $10,150,000 and $7,912,000 for goods and services during the years ended December 31, 2018 and 2017, respectively.

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

	Year Ended December 31,	
	2018	2017
United States	$ 2,851	$ 1,192
Asia Pacific	24	52
Canada	28	46
Latin America	5	12
Europe	8	1
Total	$ 2,916	$ 1,303

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

13. Subsequent Events

In January 2019, the board of directors approved the 2019 evergreen provision increasing the total stock reserved for issuance under the 2013 Plan by 2,043,142 shares from 4,914,016 shares to a total of 6,957,158 shares, which was effective January 1, 2019.

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.

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. 333-221432) and Form S-8 (Nos. 333-226152, 333-220833, 333-213363, 333-206041, 333-201551, 333-153535 and 333-127770) of Viveve Medical, Inc. of our reports dated March 14, 2019 relating to the consolidated financial statements and internal control over financial reporting, which appear in this Annual Report on Form 10-K.

/s/ BPM LLP
San Jose, California
March 14, 2019

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 14, 2019

/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 14, 2019

/s/ Jim Robbins
Jim Robbins
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, 2018 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 14, 2019

/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, 2018 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 14, 2019

/s/ Jim Robbins
Jim Robbins
Vice President of Finance and Administration
(Principal Accounting and Financial Officer)