

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2016

OR

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

For the transition period from _____ to _____

Commission File Number 1-11388

VIVEVE MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

04-3153858

(I.R.S. Employer Identification No.)

150 Commercial Street
Sunnyvale, California 94086
(Address of principal executive offices)
(Zip Code)

(408) 530-1900

(Registrant's telephone number, including area code)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period than the registrant was required to submit and post such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

As of November 10, 2016 the issuer had 10,648,407 shares of common stock, no par value, outstanding.

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NOTE ABOUT FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (the "Quarterly Report") contains forward-looking statements that involve substantial risks and uncertainties. All statements contained in this Quarterly Report other than statements of historical fact, including statements regarding our future results of operations and financial position, our business strategy and plans, and our objectives for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part II, Item 1A. "Risk Factors" in this Quarterly Report. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this Quarterly Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results, performance or achievements may be materially different from what we expect. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

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

PART I. FINANCIAL INFORMATION

ITEM 1. Financial Statements (unaudited)

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

	<u>September 30,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
	(unaudited)	(1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 14,011	\$ 7,360
Accounts receivable	1,807	593
Inventory	1,413	1,549
Prepaid expenses and other current assets	1,298	1,228
Total current assets	<u>18,529</u>	<u>10,730</u>
Property and equipment, net	445	239
Other assets	133	138
Total assets	<u>\$ 19,107</u>	<u>\$ 11,107</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,477	\$ 1,432
Accrued liabilities	1,978	1,293
Note payable, current portion	865	4,446
Total current liabilities	<u>5,320</u>	<u>7,171</u>
Note payable, noncurrent portion	8,730	-
Total liabilities	<u>14,050</u>	<u>7,171</u>
Commitments and contingences (Note 6)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized as of September 30, 2016; no shares issued	-	-
Preferred stock, no par value; unlimited shares authorized as of December 31, 2015; no shares issued	-	-
Common stock, \$0.0001 par value; 75,000,000 shares authorized as of September 30, 2016; 10,648,407 shares issued and outstanding as of September 30, 2016	1	-
Additional paid-in capital	67,858	-
Common stock and paid-in capital, no par value; unlimited shares authorized as of December 31, 2015; 7,490,288 shares issued and outstanding as of December 31, 2015	-	52,447
Accumulated deficit	<u>(62,802)</u>	<u>(48,511)</u>
Total stockholders' equity	<u>5,057</u>	<u>3,936</u>
Total liabilities and stockholders' equity	<u>\$ 19,107</u>	<u>\$ 11,107</u>

(1) The condensed consolidated balance sheet as of December 31, 2015 has been derived from the audited consolidated financial statements as of that date.

Note: All share and per share data has been adjusted to reflect the 1-for-8 reverse stock split which became effective April 15, 2016, as discussed in Note 2.

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

VIVEVE MEDICAL, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Revenue	\$ 1,849	\$ 584	\$ 4,689	\$ 695
Cost of revenue	1,158	417	3,116	520
Gross profit	691	167	1,573	175
Operating expenses:				
Research and development	2,054	1,515	6,313	3,446
Selling, general and administrative	3,272	1,757	8,435	5,155
Total operating expenses	5,326	3,272	14,748	8,601
Loss from operations	(4,635)	(3,105)	(13,175)	(8,426)
Interest expense, net	(221)	(114)	(1,094)	(302)
Other expense, net	(13)	-	(22)	(21)
Comprehensive and net loss	\$ (4,869)	\$ (3,219)	\$ (14,291)	\$ (8,749)
Net loss per share:				
Basic and diluted	\$ (0.46)	\$ (0.50)	\$ (1.63)	\$ (1.99)
Weighted average shares used in computing net loss per common share				
Basic and diluted	10,630,468	6,418,457	8,741,667	4,403,620

Note: All share and per share data has been adjusted to reflect the 1-for-8 reverse stock split which became effective April 15, 2016, as discussed in Note 2.

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

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

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$ (14,291)	\$ (8,749)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	78	57
Stock-based compensation	662	145
Fair value of warrants issued	162	152
Fair value of warrants issued to employees for bonuses	-	244
Non-cash interest expense	422	151
Changes in assets and liabilities:		
Accounts receivable	(1,214)	(233)
Inventory	76	(534)
Prepaid expenses and other current assets	(70)	(861)
Other noncurrent assets	5	10
Accounts payable	1,045	685
Accrued liabilities	931	604
Net cash used in operating activities	(12,194)	(8,329)
Cash flows from investing activities:		
Purchase of property and equipment	(224)	(48)
Net cash used in investing activities	(224)	(48)
Cash flows from financing activities:		
Proceeds from sale of common stock, net of issuance costs	13,886	11,040
Proceeds from note payable	9,910	2,500
Repayments of note payable	(4,833)	-
Proceeds from exercise of warrants	92	3
Proceeds from exercise of stock options	14	-
Net cash provided by financing activities	19,069	13,543
Net increase in cash and cash equivalents	6,651	5,166
Cash and cash equivalents - beginning of period	7,360	895
Cash and cash equivalents - end of period	\$ 14,011	\$ 6,061
Supplemental disclosure:		
Cash paid for interest	\$ 636	\$ 151
Cash paid for income taxes	\$ 1	\$ 1
Supplemental disclosure of cash flow information as of end of period:		
Issuance of warrant in connection with note payable	\$ 350	\$ 10
Restricted stock awards granted to employees for 2015 accrued bonuses	\$ 246	\$ -
Net transfer of equipment between inventory and property and equipment	\$ 60	\$ 20

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

VIVEVE MEDICAL, INC.
NOTES TO CONDENSED 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 health industry by marketing Geneveve™ as a way to improve the overall sexual well-being and quality of life of women suffering from vaginal laxity.

Public Offering

On June 17, 2016, in connection with the closing of a public offering (the “June 2016 Offering”), we issued an aggregate of 3,105,000 shares of common stock, including the shares issued in connection with the exercise of the underwriters’ overallotment option, at a public offering price of \$5.00 per share for gross proceeds of approximately \$15,525,000. The net proceeds to the Company, after the deduction of underwriting discounts, commissions and other offering expenses, were approximately \$13,886,000.

Change of Corporate Domicile

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 Incorporation with the Secretary of State of the State of Delaware to move its domicile from the Yukon Territory to Delaware. In connection with the incorporation in Delaware, the Company's stock now has a par value of \$0.0001 per share.

Interim Unaudited Financial Information

The accompanying unaudited condensed consolidated financial statements of Viveve Medical have been prepared in accordance with accounting principles generally accepted in the United States of America (“US GAAP”) for interim financial information and pursuant to the instructions to Form 10-Q and Article 8-03 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by US GAAP for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation of the condensed consolidated financial statements have been included.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Annual Report on Form 10-K for the year ended December 31, 2015, which was filed with the Securities and Exchange Commission on March 24, 2016. The results of operations for the three and nine months ended September 30, 2016 are not necessarily indicative of the results for the year ending December 31, 2016 or any future interim period.

2. Summary of Significant Accounting Policies

Financial Statement Presentation

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

Reclassification of Prior Year Presentation

Certain prior year amounts have been reclassified for consistency with the current period presentation. These reclassifications had no effect on the reported results of operations. Accounting Standards Update (“ASU”) 2015-03 requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. ASU 2015-03 is effective for the Company’s fiscal year beginning January 1, 2016. We adopted this guidance in the first quarter of 2016. Accordingly, the Company has revised the classification in the condensed consolidated balance sheet to report debt issuance costs as a contra debt liability as of December 31, 2015. This resulted in a decrease of \$387,000 to the December 31, 2015 amounts reported as prepaid expenses and other current assets, total assets, note payable, total liabilities, and total liabilities and stockholders’ equity.

Reverse Stock Split

On April 15, 2016, the Company effected a 1-for-8 reverse stock split of its common stock. On the effective date of the reverse stock split, (i) each 8 shares of outstanding common stock were reduced to one share of common stock; (ii) the number of shares of common stock into which each outstanding warrant or option to purchase common stock is exercisable were proportionately reduced on an 8-to-1 basis; and (iii) the exercise price of each outstanding warrant or option to purchase common stock were proportionately increased on a 1-to-8 basis. All of the share numbers, share prices, and exercise prices have been adjusted, on a retroactive basis, to reflect this 1-for-8 reverse stock split.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with US 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.

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.

The Company's products may require approval from the U.S. Food and Drug Administration 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 approvals. If the Company was denied such approvals or such 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 for the non-invasive treatment of vaginal laxity that it refers to as the Geneveve™, which includes the Viveve System™, single-use treatment tips and other ancillary consumables. 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 Geneveve 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.

During the three months ended September 30, 2016, two customers accounted for 89% of the Company's revenue. During the three months ended September 30, 2015, three customers accounted for 93% of the Company's revenue. During the nine months ended September 30, 2016, three customers accounted for 83% of the Company's revenue. During the nine months ended September 30, 2015, three customers accounted for 83% of the Company's revenue.

Revenue Recognition

The Company recognizes revenue from the sale of its products, the Viveve System, single-use treatment tips and ancillary consumables. Revenue is recognized upon shipment, provided that persuasive evidence of an arrangement exists, the price is fixed or determinable and collection of the resulting receivable is reasonably assured. Sales of our products are subject to regulatory requirements that vary from country to country. The Company has regulatory clearance, 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.

The Company does not provide its customers with a contractual 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 and revenue is recognized upon shipment of the product assuming all other revenue recognition criteria are met.

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. The Company will continue to assess the need to record a warranty accrual at the time of sale going forward.

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 three and nine months ended September 30, 2016 and 2015, 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.

	September 30,	
	2016	2015
Stock options to purchase common stock	1,315,808	419,127
Warrants to purchase common stock	425,274	358,119
Restricted common stock awards	64,405	-

Recently Issued and Adopted Accounting Standards

In May 2014, as part of its ongoing efforts to assist in the convergence of US GAAP and International Financial Reporting Standards ("IFRS"), the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09, "Revenue from Contracts with Customers (Topic 606)." The new guidance sets forth a new five-step revenue recognition model which replaces the prior revenue recognition guidance in its entirety and is intended to eliminate numerous industry-specific pieces of revenue recognition guidance that have historically existed in US GAAP. The underlying principle of the new standard is that a business or other organization will recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects what it expects in exchange for the goods or services. The standard also requires more detailed disclosures and provides additional guidance for transactions that were not addressed completely in the prior accounting guidance. The ASU provides alternative methods of initial adoption and is effective for annual and interim periods beginning after December 15, 2017. The FASB has issued several updates to the standard which i) defer the original effective date from January 1, 2017 to January 1, 2018, while allowing for early adoption as of January 1, 2017 (ASU 2015-14); ii) clarify the application of the principal versus agent guidance (ASU 2016-08); and iii) clarify the guidance on inconsequential and perfunctory promises and licensing (ASU 2016-10). In May 2016, the FASB issued ASU 2016-12, "Revenue from Contracts with Customers (Topic 606) Narrow-Scope Improvements and Practical Expedients", to address certain narrow aspects of the guidance including collectibility criterion, collection of sales taxes from customers, noncash consideration, contract modifications and completed contracts. This issuance does not change the core principle of the guidance in the initial topic issued in May 2014. We are currently evaluating the impact that this standard will have on our condensed consolidated financial statements.

In April 2015, the FASB issued ASU 2015-03, “Simplifying the Presentation of Debt Issuance Costs” (“ASU 2015-03”). ASU 2015-03 requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. ASU 2015-03 is effective for the Company’s fiscal year beginning January 1, 2016 and subsequent interim periods, with earlier adoption permitted. We adopted this guidance in the first quarter of 2016 and have reclassified our condensed consolidated balance sheets to comply with the new standard.

In July 2015, the FASB issued ASU 2015-11, “Simplifying the Measurement of Inventory” (“ASU 2015-11”). ASU 2015-11 requires that an entity should measure inventory within the scope of this pronouncement at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The pronouncement does not apply to inventory that is being measured using the last-in, first-out (“LIFO”) method or the retail inventory method. Subsequent measurement is unchanged for inventory measured using LIFO or the retail inventory method. ASU 2015-11 will be effective for the Company’s fiscal year beginning January 1, 2017 and subsequent interim periods, with earlier adoption permitted. We are currently evaluating the effect of the adoption of this guidance on our condensed consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, “Leases (Topic 842)”. Under this guidance, an entity is required to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. This guidance offers specific accounting guidance for a lessee, a lessor and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. This guidance is effective for annual reporting periods beginning after December 15, 2018, including interim periods within the reporting period, and requires a modified retrospective adoption, with early adoption permitted. We are currently evaluating the effect of the adoption of this guidance on our condensed consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, “Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting”. This guidance identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. This guidance is effective for annual reporting periods beginning after December 15, 2016, including interim periods within the reporting period, with early adoption permitted. We are currently evaluating the effect of the adoption of this guidance on our condensed consolidated financial statements.

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 are currently evaluating the effect of the adoption of this guidance on our condensed consolidated financial statements.

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 September 30, 2016 and December 31, 2015.

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 September 30, 2016 and December 31, 2015 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 notes payable approximates fair value.

4. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
Accrued professional fees	\$ 587	\$ 388
Accrued bonuses	513	613
Customer advance payments	442	20
Accrued payroll and other related expenses	251	113
Accrued clinical trial costs	4	112
Other accruals	181	47
Total accrued liabilities	<u>\$ 1,978</u>	<u>\$ 1,293</u>

5. Note Payable

On September 30, 2014, we entered into a Loan and Security Agreement, as amended on February 19, 2015, May 14, 2015, November 30, 2015 and March 18, 2016 (collectively, the "2014 Loan Agreement"), with Pacific Western Bank (as successor in interest by merger to Square 1 Bank) (the "Lender"), pursuant to which we received a term loan in the amount of \$5,000,000, funded in three tranches. The first tranche of \$2,500,000 was provided to us on October 1, 2014 and proceeds of \$500,000 from the second tranche were received on each of February 19, 2015, March 16, 2015 and April 6, 2015 for aggregate proceeds of \$1,500,000. The terms of the loan required that the Company meet certain financial covenants and milestones in connection with the Company's randomized, blinded and sham-controlled clinical trial in Europe and Canada (the "OUS Clinical Trial"), and on July 15, 2015 we received the final \$1,000,000 of the term loan with a drawdown of funds from the third tranche.

In connection with the 2014 Loan Agreement, we entered into an Intellectual Property Security Agreement, dated September 30, 2014, pursuant to which a first priority security interest was created in all of our intellectual property, and we issued a 10-year warrant to the Lender for the purchase of 58,962 shares of the Company's common stock at an exercise price \$4.24 per share, and pursuant to the first amendment to the 2014 Loan Agreement in February 2015, such number of shares to automatically increase in the event the Company fails to meet certain covenants. In connection with the second amendment to the 2014 Loan Agreement in May 2015, we issued a second 10-year warrant to the Lender to purchase a total of 3,125 shares of common stock at an exercise price of \$2.96 per share. These two warrants were exercised in July and August 2016 (See Note 7).

On June 20, 2016, we entered into a Loan and Security Agreement (the “2016 Loan Agreement”) with Western Alliance Bank (the “WAB”), pursuant to which the WAB agreed to loan us 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 to us on June 20, 2016. The proceeds received were used to repay the outstanding existing indebtedness under the 2014 Loan Agreement and the remaining balance will be used for working capital purposes and to fund general business requirements. The borrowings are repayable in interest only payments until July 1, 2017 and then 30 monthly equal installments of principal and interest. The term loan shall bear interest on the outstanding obligations under the loan at a floating per annum rate equal to the greater of (i) the Index Rate (i.e., the 30 day U.S. LIBOR rate reported in the Wall Street Journal) plus 6.96%, determined as of the last day of each month, and (ii) 7.40%.

In connection with the 2016 Loan Agreement, we issued a 10-year warrant to the 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 7).

All borrowings under the 2016 Loan Agreement are collateralized by substantially all of the Company’s assets, including intellectual property.

The Company is also required to meet certain financial and other covenants in connection with the 2016 Loan Agreement. As of September 30, 2016, the Company was in compliance with all covenants.

As of September 30, 2016, future minimum payments under the note payable are as follows (in thousands):

Year Ending December 31,	
2016 (remaining 3 months)	\$ 187
2017	2,719
2018	4,463
2019	4,512
Total payments	11,881
Less: Amount representing interest	(1,881)
Present value of obligations	10,000
Less: Unamortized debt discount	(405)
	9,595
Less: Note payable, noncurrent portion	8,730
Note payable, current portion	\$ 865

6. Commitments and Contingencies

Operating Lease

In January 2012, the Company entered into a lease agreement for office and laboratory facilities. The lease agreement, as amended in September 2016, commenced in March 2012 and will terminate in March 2018. Rent expense for the three months ended September 30, 2016 and 2015 was \$55,000 and \$55,000, respectively. Rent expense for the nine months ended September 30, 2016 and 2015 was \$164,000 and \$156,000, respectively.

As of September 30, 2016, future minimum payments under the lease are as follows (in thousands):

Year Ending December 31,	
2016 (remaining 3 months)	\$ 58
2017	303
2018	81
Total minimum lease payments	\$ 442

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 its condensed consolidated financial statements.

7. Common Stock

On June 17, 2016, in connection with the closing of the June 2016 Offering, we issued an aggregate of 3,105,000 shares of common stock, including the exercise of the underwriters' overallotment option, at a public offering price of \$5.00 per share for gross proceeds of approximately \$15,525,000. The net proceeds to the Company, after the deduction of underwriting discounts, commissions and other offering expenses, were approximately \$13,886,000.

Warrants for Common Stock

As of September 30, 2016, outstanding warrants to purchase shares of common stock were as follows:

<u>Issuance Date</u>	<u>Exercisable for</u>	<u>Expiration Date</u>	<u>Exercise Price</u>	<u>Number of Shares Outstanding Under Warrants</u>
September 2014	Common Shares	September 23, 2019	\$ 4.24	91,532
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
				<u>425,274</u>

In connection with the 2014 Loan Agreement entered into on September 30, 2014, the Company issued a warrant to the Lender to purchase a total of 58,962 shares of common stock at an exercise price of \$4.24 per share. The fair value of the warrant was recorded as debt issuance costs, presented in the condensed consolidated balance sheets as a deduction from the carrying amount of the note payable, and was being amortized to interest expense over the loan term. The outstanding indebtedness was repaid in June 2016 from the proceeds of the new term loan in connection with the 2016 Loan Agreement and the remaining unamortized balance of debt issuance costs was recorded to interest expense for the quarter ended June 30, 2016. During the three and nine months ended September 30, 2016, the Company recorded zero and \$387,000, respectively, of interest expense relating to the debt issuance costs. During the three and nine months ended September 30, 2015, the Company recorded \$47,000 and \$141,000, respectively, of interest expense relating to the debt issuance costs. This warrant was exercised on a cashless basis in August 2016 and 17,295 net shares were issued.

In conjunction with the second amendment to the 2014 Loan Agreement in May 2015, the Company issued a warrant to the Lender to purchase a total of 3,125 shares of common stock at an exercise price of \$2.96 per share. During the three and nine months ended September 30 2015, the Company recorded \$2,000 and \$10,000 of interest expense relating to the debt issuance costs for this warrant. The debt issuance costs for this warrant were fully amortized as of September 30, 2015. This warrant was exercised on a cashless basis in July 2016 and 885 net shares were issued.

In April 2016, the Company issued a common stock warrant to a distributor to purchase a total of 25,000 shares of common stock at an exercise price of \$6.08 per share. The warrant has a contractual life of ten years and is exercisable immediately in whole or in part, on or before ten years from the issuance date. The Company determined the fair value of the warrant using the Black-Scholes option pricing model. Assumptions used were dividend yield of 0%, volatility of 72.1%, risk free interest rate of 1.78% and a contractual life of ten years. The fair value of the warrant was recorded as sales costs, which are included in selling, general and administrative expenses in the condensed consolidated statements of operations.

In May 2016, the Company issued common stock warrants to nonemployee contractors to purchase a total of 5,000 shares of common stock at an exercise price of \$7.74 per share. The warrants have a contractual life of five years and are exercisable immediately in whole or in part, on or before five years from the issuance date. The Company determined the fair value of the warrants using the Black-Scholes option pricing model. Assumptions used were dividend yield of 0%, volatility of 61.6%, risk free interest rate of 1.20% and a contractual life of five years. The fair value of the warrants was recorded as clinical consulting costs, which are included in research and development expenses in the condensed consolidated statements of operations.

In connection with the 2016 Loan Agreement entered into on June 20, 2016, 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 warrant has a contractual life of ten years and is exercisable immediately in whole or in part, on or before ten years from the issuance date. The Company determined the fair value of the warrant on the date of issuance to be \$350,000 using the Black-Scholes option pricing model. Assumptions used were dividend yield of 0%, volatility of 63.0%, risk free interest rate of 1.67% and a contractual life of ten years. The fair value of the warrant, along with other legal fees totaling \$90,000, were recorded as debt issuance costs, presented in the condensed consolidated balance sheet as of September 30, 2016 as a deduction from the carrying amount of the note payable, and are being amortized to interest expense over the loan term. During the three and nine months ended September 30, 2016, the Company recorded \$35,000 of interest expense relating to the debt issuance costs. As of September 30, 2016, the unamortized debt issuance cost was \$405,000.

A total of 735 and 25,268 shares issuable pursuant to warrants issued in connection with a private offering on September 30, 2014 were exercised in 2015 and 2016, respectively.

A total of 5,157 and 1,094 shares issuable pursuant to warrants issued to two vendors in October 2014 were cancelled in 2015 and 2016, respectively, as the milestones related to these shares were not achieved.

The stock-based compensation expense related to warrants issued was zero and \$162,000 for the three and nine months ended September 30, 2016, respectively. The stock-based compensation expense related to warrants issued was \$16,000 and \$396,000 for the three and nine months ended September 30, 2015, respectively.

8. Summary of Stock Options

Stock Option Plans

The Company has issued equity awards in the form of stock options and restricted stock awards from three employee benefit plans. The plans include the Company's 2005 Stock Incentive Plan (the "2005 Plan"), 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 2005 Plan was adopted by the Company's board of directors and approved by its stockholders. As of September 30, 2016, 1,892 shares of common stock remain reserved for issuance under the 2005 Plan. The Company does not intend to grant further awards from the 2005 Plan, however, it will continue to administer the 2005 Plan until all outstanding awards are exercised, expire, terminate or are forfeited. There are currently outstanding stock option awards issued from the 2005 Plan covering a total of 1,892 shares of the Company's common stock. The weighted average exercise price of the outstanding stock options is \$116.29 per share and the weighted average remaining contractual term is 0.98 years.

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). The number of shares of the Company’s common stock into which the 2006 Plan options were converted was determined by multiplying the number of shares covered by each 2006 Plan option by the exchange ratio of 0.0080497 (or 0.0010062 on a post- reverse stock split basis). The exercise price of each 2006 Plan option was determined by dividing the exercise price of each 2006 Plan option immediately prior to the Merger by the exchange ratio of 0.0080497 (or 0.0010062 on a post- reverse stock split basis) (rounded up to the nearest cent). There are currently outstanding stock option awards issued from the 2006 Plan covering a total of 38,378 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 \$10.49 per share and the weighted average remaining contractual term is 6.13 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 increasing the maximum number of shares of common stock reserved and available for awards under the 2013 Plan (the “Stock Issuable”) by 737,500 shares from 1,262,500 shares to a total of 2,000,000 shares and to add an “evergreen” provision to the 2013 Plan which will automatically increase annually, on the first day of each January, 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. As of September 30, 2016, there are outstanding stock option awards issued from the 2013 Plan covering a total of 1,275,538 shares of the Company’s common stock and there remain reserved for future awards 610,736 shares of the Company’s common stock. The weighted average exercise price of the outstanding stock options is \$6.35 per share, and the remaining contractual term is 9.03 years.

Activity under the 2005 Plan, the 2006 Plan and the 2013 Plan is as follows:

	Nine Months Ended September 30, 2016			
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Options outstanding, beginning of period	1,022,195	\$ 6.47	9.37	\$ -
Options granted	378,932	\$ 7.25		
Options exercised	(3,020)	\$ 4.80		
Options canceled	(82,299)	\$ 7.55		
Options outstanding, end of period	<u>1,315,808</u>	\$ 6.63	8.93	\$ 1,615,644
Vested and exercisable and expected to vest, end of period	1,221,813	\$ 6.65	8.90	\$ 1,523,776
Vested and exercisable, end of period	279,725	\$ 8.05	7.84	\$ 473,807

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 September 30, 2016.

The options outstanding and exercisable as of September 30, 2016 are as follows:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding as of September 30, 2016	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Number Exercisable as of September 30, 2016	Weighted Average Exercise Price
\$2.64	12,500	\$ 2.64	8.62	4,428	\$ 2.64
\$3.68 - \$3.76	79,376	\$ 3.75	8.36	31,420	\$ 3.75
\$4.80	195,907	\$ 4.80	7.88	100,029	\$ 4.80
\$6.00	568,640	\$ 6.00	9.17	83,666	\$ 6.00
\$6.24 - \$6.40	129,267	\$ 6.35	9.40	-	\$ -
\$7.00 - \$7.92	284,203	\$ 7.71	9.74	14,267	\$ 7.74
\$9.92	38,135	\$ 9.92	6.14	38,135	\$ 9.92
\$56.00 - \$72.00	5,902	\$ 71.55	1.04	5,902	\$ 71.55
\$96.00 - \$149.04	1,846	\$ 118.68	1.23	1,846	\$ 118.68
\$296.00	32	\$ 296.00	0.98	32	\$ 296.00
	<u>1,315,808</u>	\$ 6.63	8.93	<u>279,725</u>	\$ 8.05

Restricted Stock Awards

In January 2016, the Company granted restricted stock awards (“RSAs”) for 39,494 shares of common stock under the 2013 Plan to employees for 2015 accrued bonuses with a weighted average grant date fair value of \$6.24 per share. The fair value of the RSAs was determined on the grant date based on the fair value of the Company’s common stock.

In August 2016, the Company granted RSAs for 5,998 shares of common stock under the 2013 Plan to board members as director compensation for the second quarter of 2016 with a weighted average grant date fair value of \$7.89 per share. The RSAs were fully vested on the date of grant. The fair value of the RSAs was determined on the date of grant to be \$47,000 based on the fair value of the Company’s common stock on that date.

In September 2016, the Company granted 25,000 shares to a consultant with a weighted average grant date fair value of \$7.58 per share. The RSA vests over one year at a rate of 1/4th per quarter beginning as of the award date. As of September 30, 2016, all 25,000 shares were unvested.

A total of 89 shares pursuant to a RSA granted in January 2016 were cancelled in September 2016.

The total number of shares pursuant to outstanding RSAs as of September 30, 2016 were 64,405 shares.

Stock-Based Compensation

During the three months ended September 30, 2016 and 2015, the Company granted stock options to employees to purchase 220,915 and 43,375 shares of common stock with a weighted average grant date fair value of \$3.58 and \$4.08 per share, respectively. During the nine months ended September 30, 2016 and 2015, the Company granted stock options to employees to purchase 378,932 and 135,250 shares of common stock with a weighted average grant date fair value of \$3.54 and \$2.56 per share, respectively. The aggregate intrinsic value of options exercised during the nine months ended September 30, 2016 and 2015 was \$5,000 and zero, respectively.

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 assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Expected term (in years)	5	5	5	5
Average volatility	46%	62%	54%	62%
Risk-free interest rate	1.14%	1.63%	1.31%	1.45%
Dividend yield	0%	0%	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 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 condensed consolidated statements of operations for the three and nine months ended September 30, 2016 and 2015 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Research and development	\$ 31	\$ 5	\$ 80	\$ 13
Selling, general and administrative	241	50	582	132
Total	\$ 272	\$ 55	\$ 662	\$ 145

As of September 30, 2016, the total unrecognized compensation cost in connection with unvested stock options was approximately \$2,874,000. These costs are expected to be recognized over a period of approximately 3.21 years.

9. Income Taxes

For interim periods, the Company estimates its annual effective income tax rate and applies the estimated rate to the year-to-date income or loss before income taxes. The Company also computes the tax provision or benefit related to items reported separately and recognizes the items net of their related tax effect in the interim periods in which they occur. The Company also recognizes the effect of changes in enacted tax laws or rates in the interim periods in which the changes occur.

The Company's effective tax rate is 0% for the three and nine months ended September 30, 2016 and 2015. The Company expects that its effective tax rate for the full year 2016 will be 0%.

10. 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 September 30, 2016, the Company has purchased 222 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 \$1,816,000 and \$1,871,000 for goods and services during the three months ended September 30, 2016 and 2015, respectively, and \$3,976,000 and \$3,082,000 for goods and services during the nine months ended September 30, 2016 and 2015, respectively.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion of our financial condition and results of operations in conjunction with the condensed consolidated financial statements and the related notes included elsewhere in this Quarterly Report and with our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the Securities and Exchange Commission on March 24, 2016. In addition to historical condensed consolidated financial information, the following discussion contains forward-looking statements that reflect our plans, estimates, and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Quarterly Report, particularly in Part II, Item 1A. "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 medical device for the non-invasive treatment of vaginal laxity that we refer to as Geneveve™, which includes a radio frequency (RF) generator, which we refer to as the Viveve System, single-use treatment tips and other ancillary disposables. Currently, Geneveve is cleared for marketing in 49 countries throughout the world under the following indications for use:

Indication for Use:	No. of Countries:
General Surgical procedures for coagulation and hemostasis	3 Countries
For treatment of vaginal laxity	35 Countries
For treatment of the vaginal introitus, after vaginal childbirth, to improve sexual function	10 Countries
For vaginal rejuvenation	1 Country

In the U.S., Geneveve is indicated for general surgical procedures for coagulation and hemostasis and we market and sell through a direct sales force. Outside the U.S., we market and sell through distribution partners. As of the date of this filing, we have sold 169 Viveve Systems and approximately 2,800 single-use treatment tips in countries outside of the U.S.

Because the revenues we have earned to date have not been sufficient to support our operations, we have relied on sales of our securities, loans from related parties and bank term loans to fund our operations. We are currently located in Sunnyvale, California.

Recent Events

On April 15, 2016, we effected a 1-for-8 reverse stock split of our common stock. On the effective date of the reverse stock split, (i) each 8 shares of outstanding common stock were reduced to one share of common stock; (ii) the number of shares of common stock into which each outstanding warrant or option to purchase common stock is exercisable were proportionately reduced on an 8-to-1 basis; and (iii) the exercise price of each outstanding warrant or option to purchase common stock were proportionately increased on a 1-to-8 basis. All of the share numbers, share prices, and exercise prices have been adjusted, on a retroactive basis, to reflect this 1-for-8 reverse stock split.

On May 9, 2016, we filed the necessary Application for Authorization to Continue into Another Jurisdiction and Statutory Declaration with the Yukon registrar. On May 10, 2016, we filed a Certificate of Incorporation with the Secretary of State of the State of Delaware to move our domicile from the Yukon Territory to Delaware.

On June 17, 2016, in connection with the closing of a public offering (the “June 2016 Offering”), we issued an aggregate of 3,105,000 shares of common stock, including the shares issued in connection with the exercise of the underwriters’ overallotment option, at a public offering price of \$5.00 per share for gross proceeds of approximately \$15.5 million. The net proceeds to us, after the deduction of underwriting discounts, commissions and other offering expenses, were approximately \$13.9 million.

On June 20, 2016, we entered into a Loan and Security Agreement (the “2016 Loan Agreement”) with Western Alliance Bank (the “Lender”), pursuant to which the Lender agreed to loan us up to an aggregate of \$10.0 million payable in two tranches of \$7.5 million and \$2.5 million. The funding conditions for both tranches were satisfied as of the closing date, and therefore, the aggregate principal amount of \$10.0 million was provided to us on June 20, 2016. The proceeds received were used to repay outstanding existing indebtedness and the remaining balance will be used for working capital purposes and to fund general business requirements. The borrowings are repayable in interest only payments until July 1, 2017 and then 30 monthly equal installments of principal and interest. The term loan shall bear interest on the outstanding obligations under the loan at a floating per annum rate equal to the greater of (i) the Index Rate (i.e., the 30 day U.S. LIBOR rate reported in the Wall Street Journal) plus 6.96%, determined as of the last day of each month, and (ii) 7.40%.

In connection with the 2016 Loan Agreement, we issued a ten year warrant to the Lender to purchase a total of 100,402 shares of Company's common stock at an exercise price of \$4.98 per share.

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 U.S. Food and Drug Administration (the "FDA") approval for the sale of our product and whether there will be a demand for the Geneveve, 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 approval for our products in locations in which we do not currently have approval to market our product, including 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, loans from related parties and bank term loans. Various factors, including our limited operating history with minimal revenues to date and our limited ability to market and sell our product have resulted in limited working capital available to fund our operations. The merger that took place on September 23, 2014 between PLC Systems Inc., Viveve, Inc. and PLC Systems Acquisition Corp. (the "Merger") and the concurrent private offering was consummated in an effort to raise additional capital and increase public awareness of Viveve, as well as to create opportunities for access to additional capital by increasing liquidity. While we believe that the going public transaction is attractive to investors and even though we completed several equity financings and debt financings, 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.

Plan of Operation

We intend to increase our sales both internationally and in the United States market by seeking regulatory approvals for the sale and distribution of our products, identifying and training qualified distributors and expanding the scope of physicians who offer the Geneveve to include plastic surgeons, dermatologists, general surgeons, urologists, urogynecologists and primary care physicians. Recently, we received regulatory clearance from the FDA, and are intending to sell through a direct sales force in the U.S., which we are currently assembling.

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, which may include increased security features to prevent piracy, or new cooling systems to maintain compliance with environmental regulations.

The net proceeds received from sales of our securities and the term loan 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 the next nine months, however, we will continue to require funds to fully implement our plan of operation. Our operating costs include employee salaries and benefits, compensation paid to consultants, professional fees and expenses, costs associated with our clinical trials, capital costs for research and other equipment, costs associated with research and development activities including travel and administration, legal expenses, sales and marketing costs, general and administrative expenses, and other costs associated with an early stage public company subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We also expect to incur expenses related to obtaining regulatory 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 \$250,000 annually.

We intend to continue to meet our operating cash flow requirements through the sales of our products and by raising additional funds 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 Quarterly Report, 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 Three Months Ended September 30, 2016 and 2015

Revenue

	Three Months Ended September 30,		Change	
	2016	2015	\$	%
Revenue	\$ 1,849	\$ 584	1,265	217%

(in thousands, except percentages)

We recorded revenue of \$1,849,000 for the three months ended September 30, 2016, compared to revenue of \$584,000 for the three months ended September 30, 2015, an increase of \$1,265,000 or approximately 217%. The increase in revenue was primarily due to sales of 47 Viveve Systems, disposable treatment tips and other ancillary consumables in the third quarter of 2016. Sales in the third quarter of 2015 included only twelve Viveve Systems and smaller quantities of disposable treatment tips and other ancillary consumables.

Gross profit

	Three Months Ended September 30,		Change	
	2016	2015	\$	%
Gross profit	\$ 691	\$ 167	\$ 524	314%

(in thousands, except percentages)

Gross profit was \$691,000, or 37% of revenue, for the three months ended September 30, 2016, compared to a gross profit of \$167,000, or 29% of revenue, for the three months ended September 30, 2015, an increase of \$524,000 or approximately 314%. The increase in gross profit was primarily due to sales of 47 Viveve Systems in the third quarter of 2016. Sales in the third quarter of 2015 included only twelve Viveve System and smaller quantities of disposable treatment tips and other ancillary consumables.

The increase in gross margin was primarily due to an increase in revenue from sales of higher margin products. We expect our gross margin to fluctuate in future periods based on the mix of our product and distributor sales.

Research and development expenses

	Three Months Ended September 30,		Change	
	2016	2015	\$	%
Research and development	\$ 2,054	\$ 1,515	\$ 539	36%

(in thousands, except percentages)

Research and development expense totaled \$2,054,000 for the three months ended September 30, 2016, compared to research and development expense of \$1,515,000 for the three months ended September 30, 2015, an increase of \$539,000 or approximately 36%. Spending on research and development increased primarily due to costs associated with increased engineering and development work with our contract manufacturer related to product improvement efforts. The third quarter of 2016 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

Three Months Ended		Change	
September 30,			
2016	2015	\$	%

(in thousands, except percentages)

Selling, general and administrative	\$	3,272	\$	1,757	\$	1,515	86%
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Selling, general and administrative expenses totaled \$3,272,000 for the three months ended September 30, 2016, compared to \$1,757,000 for the three months ended September 30, 2015, an increase of \$1,515,000 or approximately 86%. The increase in selling, general and administrative expenses 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 the third quarter of 2016 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.

Interest expense, net

Three Months Ended		Change	
September 30,			
2016	2015	\$	%

(in thousands, except percentages)

Interest expense, net	\$	221	\$	114	\$	107	94%
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During the three months ended September 30, 2016, we had interest expense, net of \$221,000, compared to \$114,000 for the three months ended September 30, 2015. The increase of \$107,000, or approximately 94%, resulted primarily from the additional interest expense for the term loan under the 2016 Loan Agreement, which was computed on a higher loan balance compared to the loan balance under the 2014 Loan Agreement in the third quarter of 2015.

Other expense, net

Three Months Ended		Change	
September 30,			
2016	2015	\$	%

(in thousands, except percentages)

Other expense, net	\$	(13)	\$	-	\$	(13)	N/A
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During the three months ended September 30, 2016, we had other expense, net, of \$13,000, compared to zero for the three months ended September 30, 2015.

Comparison of the Nine Months Ended September 30, 2016 and 2015

Revenue

Nine Months Ended		Change	
September 30,			
2016	2015	\$	%

(in thousands, except percentages)

Revenue	\$	4,689	\$	695	\$	3,994	575%
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We recorded revenue of \$4,689,000 for the nine months ended September 30, 2016, compared to revenue of \$695,000 for the nine months ended September 30, 2015, an increase of \$3,994,000 or approximately 575%. The increase in revenue was primarily due to sales of 120 Viveve Systems and disposable treatment tips and other ancillary consumables. Sales in 2015 included only thirteen Viveve Systems and were limited primarily because of insufficient commercial inventory available for sale as a result of an inventory production slowdown in 2014 due to funding constraints. The majority of inventory during the second half of 2014 and the first half of 2015 was used to support our OUS Clinical Trial.

Gross Profit

Nine Months Ended		Change	
September 30,			
2016	2015	\$	%
(in thousands, except percentages)			

Gross profit	\$	1,573	\$	175	\$	1,398	799%
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Gross profit was \$1,573,000, or 34% of revenue, for the nine months ended September 30, 2016, compared to gross profit of \$175,000, or 25% of revenue, for the nine months ended September 30, 2015, an increase of \$1,398,000. The increase in gross profit was primarily due to sales of 120 Viveve Systems in the nine months ended September 30, 2016. Sales in the nine months ended September 30, 2015 included only thirteen Viveve Systems and were limited to smaller quantities of disposable treatment tips and other ancillary consumables primarily because of insufficient commercial inventory available for sale as a result of an inventory production slowdown in 2014 due to funding constraints. The majority of inventory during the second half of 2014 and the first half of 2015 was used to support our OUS Clinical Trial.

The increase in gross margin was primarily due to an increase in revenue from sales of higher margin products. We expect our gross margin to fluctuate in future periods based on the mix of our product and distributor sales.

Research and development expenses

Nine Months Ended		Change	
September 30,			
2016	2015	\$	%
(in thousands, except percentages)			

Research and development	\$	6,313	\$	3,446	\$	2,867	83%
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Research and development expense totaled \$6,313,000 for the nine months ended September 30, 2016, compared to research and development expense of \$3,446,000 for the nine months ended September 30, 2015, an increase of \$2,867,000, or approximately 83%. Spending on research and development increased primarily due to costs associated with increased engineering and development work with our contract manufacturer related to product improvement efforts. The nine months ended September 30, 2016 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

Nine Months Ended		Change	
September 30,			
2016	2015	\$	%
(in thousands, except percentages)			

Selling, general and administrative	\$	8,435	\$	5,155	\$	3,280	64%
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Selling, general and administrative expenses totaled \$8,435,000 for the nine months ended September 30, 2016, compared to \$5,155,000 for the nine months ended September 30, 2015, an increase of \$3,280,000, or approximately 64%. The increase in selling, general and administrative expenses 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 2016 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.

Interest expense, net

Nine Months Ended		September 30,		Change	
2016	2015	\$	%		
(in thousands, except percentages)					

Interest expense, net	\$	1,094	\$	302	\$	792	262%
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During the nine months ended September 30, 2016, we had interest expense, net of \$1,094,000, compared to \$302,000 for the nine months ended September 30, 2015. The increase of \$792,000, or approximately 262%, resulted primarily from the additional interest expense in connection with the payoff in June 2016 of the term loan under the 2014 Loan Agreement (including final payment fees of \$350,000 and the expensing of the remaining unamortized debt issuance costs of \$312,000) and interest expense paid for the term loan in 2016, which was computed on a higher loan balance compared to the loan balance in 2015.

Other expense, net

Nine Months Ended		September 30,		Change	
2016	2015	\$	%		
(in thousands, except percentages)					

Other expense, net	\$	(22)	\$	(21)	\$	(1)	(5)%
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During the nine months ended September 30, 2016 we had other expense, net, of \$22,000 as compared to other expense, net, of \$21,000 for the nine months ended September 30, 2015.

Liquidity and Capital Resources

Nine Months Ended September 30, 2016

Liquidity is our ability to generate sufficient cash flows from operating activities to meet our obligations and commitments. In addition, liquidity includes the ability to obtain appropriate financing or to raise capital. We have funded our operations since inception through the sale of our securities, loans from related parties and bank term loans. To date, we have not generated sufficient cash flows from operating activities to meet our obligations and commitments, and we anticipate that we will continue to incur losses for the foreseeable future.

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

	Nine Months Ended	
	September 30,	
	2016	2015
Net cash used in operating activities	\$ (12,194)	\$ (8,329)
Net cash used in investing activities	(224)	(48)
Net cash provided by financing activities	19,069	13,543
Net increase in cash and cash equivalents	\$ 6,651	\$ 5,166

Operating Activities

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

Operating activities used \$12,194,000 for the nine months ended September 30, 2016 compared to \$8,329,000 used for the nine months ended September 30, 2015. 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 nine months ended September 30, 2016 consisted of a net loss of \$14,291,000 adjusted for non-cash expenses including depreciation and amortization of \$78,000, stock-based compensation of \$662,000, fair value of warrants issued of \$162,000, and non-cash interest expense of \$422,000, and inflows from changes in operating assets and liabilities of \$773,000. The change in operating assets and liabilities was primarily due to a decrease in accounts payable of \$1,045,000 and a decrease in accrued liabilities of \$931,000 partially offset by an increase in accounts receivable of \$1,214,000. Net cash used during the nine months ended September 30, 2015 consisted of a net loss of \$8,749,000 adjusted for non-cash expenses including depreciation and amortization of \$57,000, stock-based compensation of \$145,000, fair value of warrants issued of \$152,000, fair value of warrants issued to employees for bonuses of \$244,000, and non-cash interest expense of \$151,000, and outflows from changes in operating assets and liabilities of \$329,000.

Investing Activities

Net cash used in investing activities during the nine months ended September 30, 2016 and 2015 was \$224,000 and \$48,000, respectively. Net cash used in investing activities during the nine months ended September 30, 2016 and 2015 was primarily used for 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 the nine months ended September 30, 2016 was \$19,069,000, which was primarily the result of the gross proceeds of \$15,525,000 from our June 2016 Offering (partially offset by transaction costs of \$1,639,000), the proceeds of \$10,000,000 from the drawdown of funds from the first and second tranches of the new term loan (partially offset by debt issuance costs of \$90,000), and proceeds from the exercise of warrants and stock options of \$106,000, partially offset by the repayment of the existing term loan of \$4,833,000. Cash provided by financing activities during the nine months ended September 30, 2015 was \$13,543,000, which was the result of the gross proceeds of \$12,000,000 from an offering we closed in May 2015, partially offset by transaction costs of \$960,000, proceeds of \$2,500,000 from the drawdown of funds from the second and third tranches of the term loan, and proceeds from the exercise of a warrant.

Contractual Payment Obligations

We have obligations under a non-cancelable operating lease, a bank term loan and a purchase commitment for inventory. As of September 30, 2016, 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
Non-cancellable operating lease obligations	\$ 442	\$ 279	\$ 163	\$ -	\$ -
Debt obligations (including interest)	11,881	1,744	8,775	1,362	-
Total	\$ 12,323	\$ 2,023	\$ 8,938	\$ 1,362	\$ -

In June 2006, we 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, we agreed to purchase 300 generators manufactured by Stellartech. As of September 30, 2016 and the date of this filing, we have purchased 222 units and 289 units, respectively. The price per unit is variable and dependent on the volume and timing of units ordered.

In January 2012, we entered into a lease agreement for office and warehousing facilities. The lease agreement, as amended in September 2016, commenced in March 2012 and will terminate in March 2018.

As described above, on June 20, 2016, we entered into the 2016 Loan Agreement with the Lender pursuant to which we received a term loan in the amount of \$10.0 million. The proceeds from the term loan were used to repay the existing outstanding indebtedness with another financial institution and to provide general working capital to fund our operations. As of September 30, 2016 and the date of this filing, the outstanding term loan principal balance was \$10.0 million.

Critical Accounting Policies and Estimates

The discussion and analysis of financial condition and results of operations is based upon our condensed consolidated financial statements, which have been prepared in conformity with accounting principles generally accepted in the United States of America ("US GAAP"). 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 audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2015, that was filed with the SEC on March 24, 2016, for a more complete description of our significant accounting policies. There have been no material changes to the significant accounting policies during the nine months ended September 30, 2016.

Recent Accounting Pronouncements

In May 2014, as part of its ongoing efforts to assist in the convergence of US GAAP and International Financial Reporting Standards (“IFRS”), the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, “Revenue from Contracts with Customers (Topic 606).” The new guidance sets forth a new five-step revenue recognition model which replaces the prior revenue recognition guidance in its entirety and is intended to eliminate numerous industry-specific pieces of revenue recognition guidance that have historically existed in US GAAP. The underlying principle of the new standard is that a business or other organization will recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects what it expects in exchange for the goods or services. The standard also requires more detailed disclosures and provides additional guidance for transactions that were not addressed completely in the prior accounting guidance. The ASU provides alternative methods of initial adoption and is effective for annual and interim periods beginning after December 15, 2017. The FASB has issued several updates to the standard which i) defer the original effective date from January 1, 2017 to January 1, 2018, while allowing for early adoption as of January 1, 2017 (ASU 2015-14); ii) clarify the application of the principal versus agent guidance (ASU 2016-08); and iii) clarify the guidance on inconsequential and perfunctory promises and licensing (ASU 2016-10). In May 2016, the FASB issued ASU 2016-12, “Revenue from Contracts with Customers (Topic 606) Narrow-Scope Improvements and Practical Expedients”, to address certain narrow aspects of the guidance including collectibility criterion, collection of sales taxes from customers, noncash consideration, contract modifications and completed contracts. This issuance does not change the core principle of the guidance in the initial topic issued in May 2014. We are currently evaluating the impact that this standard will have on our condensed consolidated financial statements.

In April 2015, the FASB issued ASU 2015-03, “Simplifying the Presentation of Debt Issuance Costs” (“ASU 2015-03”). ASU 2015-03 requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. ASU 2015-03 is effective for the Company’s fiscal year beginning January 1, 2016 and subsequent interim periods, with earlier adoption permitted. We have adopted this guidance in the first quarter of 2016.

In July 2015, the FASB issued ASU 2015-11, “Simplifying the Measurement of Inventory” (“ASU 2015-11”). ASU 2015-11 requires that an entity should measure inventory within the scope of this pronouncement at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The pronouncement does not apply to inventory that is being measured using the last-in, first-out (“LIFO”) or the retail inventory method. Subsequent measurement is unchanged for inventory measured using LIFO or the retail inventory method. ASU 2015-11 will be effective for the Company’s fiscal year beginning January 1, 2017 and subsequent interim periods, with earlier adoption permitted. We are currently evaluating the effect of the adoption of this guidance on our condensed consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, “Leases (Topic 842)”. Under this guidance, an entity is required to recognize right-of-use assets and lease liabilities on its balance sheet and disclose key information about leasing arrangements. This guidance offers specific accounting guidance for a lessee, a lessor and sale and leaseback transactions. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. This guidance is effective for annual reporting period beginning after December 15, 2018, including interim periods within that reporting period, and requires a modified retrospective adoption, with early adoption permitted. The Company is currently evaluating the impact on its condensed consolidated financial statements upon the adoption of this guidance.

In March 2016, the FASB issued ASU 2016-09, “Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting”. This guidance identifies areas for simplification involving several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross stock compensation expense with actual forfeitures recognized as they occur, as well as certain classifications on the statement of cash flows. This guidance is effective for annual reporting period beginning after December 15, 2016, including interim periods within that reporting period, with early adoption permitted. The Company is currently evaluating the impact on its condensed consolidated financial statements upon the adoption of this 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 are currently evaluating the effect of the adoption of this guidance on our condensed consolidated financial statements.

Off-Balance Sheet Transactions

We do not have any off-balance sheet transactions.

Trends, Events and Uncertainties

Research and development of new technologies is, by its nature, unpredictable. Although we will undertake development efforts with commercially reasonable diligence, there can be no assurance that we will have adequate capital to develop 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 Quarterly Report on Form 10-Q, we are not aware of any trends, events or uncertainties that are likely to have a material effect on our financial condition.

Item 3. 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 4. 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 principal executive officer and principal financial and accounting officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2016, the end of the period covered by this Quarterly Report. Based upon the evaluation of our disclosure controls and procedures as of September 30, 2016, our Chief Executive Officer (principal executive officer) and Chief Financial Officer (principal financial and accounting officer) concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No changes in the Company's internal control over financial reporting have come to management's attention during the Company's last fiscal quarter that have materially affected, or are likely to materially affect, the Company's internal control over financial reporting.

PART II-OTHER INFORMATION

Item 1. Legal Proceedings.

Except as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015 and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2016 and June 30, 2016, we are not subject to any material pending legal proceedings. From time to time, we may be involved in routine legal proceedings, as well as demands, claims and threatened litigation, which arise in the normal course of our business.

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 report and in our other public filings. 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 Geneveve, which has a limited commercial history. If Geneveve fails to gain or loses market acceptance, our business will suffer.

In 2012, we began marketing Geneveve in Canada, Hong Kong and Japan, and we expect that sales of Geneveve, including the Viveve System (radio frequency generator), single-use treatment tips and other ancillary consumables, will account for substantially all of our revenue for the foreseeable future. Geneveve may not significantly penetrate current or new markets, including the U.S. and elsewhere. If demand for Geneveve does not increase 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 Geneveve could be diminished by equivalent or superior products and technologies developed by competitors. Specifically, Geneveve 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 and Geneveve 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 laser vaginal rejuvenation (“LVR”) surgery or vaginoplasty and thus may decide not to purchase, or to delay the purchase of, Geneveve. 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 on, and collecting data from, the Geneveve is inherently subjective, and we have limited data regarding the efficacy of Geneveve. 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 future clinical studies of the effectiveness of Geneveve. Clinical studies of vaginal laxity and sexual function are subject to a number of limitations. First, 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 devices, 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 level of vaginal laxity and sexual function of the patient, among other things.

Current published studies of Geneveve conducted in the U.S. and Japan have investigated the tissue-tightening effect of Viveve's monopolar RF technology using single-arm studies where all patients enrolled in the trial received the same treatment without comparison to randomized, blinded or controlled trials. Clinical studies designed in a randomized, blinded and controlled fashion represent the gold-standard in clinical trial design, which most effectively assess the efficacy of a product or therapy versus a placebo group. Future clinical studies, which may be required to drive physician adoption or support regulatory clearance or approval, may require randomized, blinded and controlled trial designs. In the fourth quarter of 2014, we initiated a new randomized, blinded and sham-controlled clinical trial in Europe and Canada designed to demonstrate the efficacy of the Viveve Treatment versus a sham-controlled procedure for the treatment of vaginal laxity (the "OUS Clinical Trials"). (See discussion under the heading "Clinical Studies".) 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.

Additionally, we have not conducted any head-to-head clinical studies that compare results from treatment with Geneveve 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 Geneveve. 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, Geneveve may not become widely adopted, physicians may recommend alternative treatments for their patients, and our business may be harmed.

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

Developing and promoting Geneveve in additional areas 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 in the U.S. to market Geneveve for the treatment of vaginal laxity or sexual function. We are in the process of seeking clearance or approval from the FDA to expand our marketing efforts. We cannot predict whether we will receive such clearances or approvals. The FDA will require us to conduct clinical trials to support regulatory clearance or approval, which trials may be time-consuming and expensive, and may produce results that do not result in clearance or approval of our FDA application. In the event that we do not obtain FDA clearance or approval, we will be unable to promote Geneveve in the U.S. for the treatment of vaginal laxity or sexual function 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, 2015, we have incurred losses since inception of approximately \$48.5 million. In 2015, we incurred a loss of \$12.4 million and in 2014 a loss of \$6.2 million. Our loss for the nine months ended September 30, 2016 was \$14.3 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 our aesthetic treatment systems are elective procedures that are not 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 Geneveve 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 Geneveve, 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 Geneveve 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 Geneveve could drop, resulting in unfavorable operating results.

Most procedures performed using Geneveve are elective procedures, the cost of which must be borne by the patient, and are not reimbursable through government or private health insurance. The decision to undergo the 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, are successful;
- the extent to which physicians recommend the Viveve Treatment to their patients;
- the cost, safety and effectiveness of a Viveve Treatment 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 Geneveve to meet patient expectations or the occurrence of unpleasant side effects from the 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 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 Viveve Treatments 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 a Viveve Treatment 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 Geneveve 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 Geneveve depends on the success of our sales and marketing efforts. Our business model involves both a capital equipment purchase of Geneveve 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 Geneveve 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 Geneveve and use of the treatment tips, our financial performance will be adversely affected.

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

Sales outside the U.S. accounted for 100% of our revenue during the years ended December 31, 2015, 2014 and 2013. We believe that a significant portion of our business will continue to come from sales outside the U.S. through increased penetration in countries where we currently sell Geneveve, combined with expansion into new international markets. However, 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;
- 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.

We depend on distributors to market and sell Geneveve 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 Geneveve 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 Geneveve. Distributors may not commit the necessary resources to market, sell and service Geneveve 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 Geneveve effectively could have a material adverse effect on our business.

We expect to rely on a direct sales force to sell Geneveve in the U.S. In order to meet our future anticipated sales objectives, we expect to grow our domestic sales organization significantly over the next several years. There are significant risks involved in building and managing our sales organization, including risks related to our ability to:

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

It is difficult to predict how well our sales force will perform. Our failure to adequately address these risks could have a material adverse effect on our ability to sell Geneveve, causing our revenue to be lower than expected and harming our results of operations.

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

While we attempt to protect Geneveve 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 and sexual dysfunction, 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 Geneveve and technology or develop new products to compete successfully. If we are unable to develop new products or innovate successfully, Geneveve could become obsolete and our revenue will decline as our customers purchase competing products.

We outsource the manufacturing and repair of key elements of Geneveve to a single manufacturing partner.

We outsource the manufacture and repair of Geneveve 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. 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 Geneveve. 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 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 upon favorable terms.

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 Geneveve from Stellartech could not be replaced without significant effort and delay in production. Also, several other components and materials that comprise Geneveve 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 Geneveve 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 Geneveve 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 Geneveve, may require us to recall product from customers or replace components and could disrupt our operations. For example, in December 2012, we began replacing handpiece assemblies that were causing system malfunctions due to fiber optic damage that occurred during the manufacturing process. We subsequently worked with our manufacturer to redesign and test the reliability of the newly designed handpiece. The problem was resolved within several weeks and did not have a significant impact on our ability to supply products to our customers or, more generally, on our results of operations. However, 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 overheating 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, Geneveve 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 Geneveve 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.

If Solta Medical refuses to sell to us the cryogen cooling method and coupling fluid for commercial reasons, or otherwise, our business could be materially adversely affected.

We entered into a Coupling Fluid License and Product Supply Agreement with Solta Medical (“Solta”) pursuant to which Solta agreed to grant to us a license for the coupling fluid and supply the coupling fluid at preferred pricing for two years and at non-preferred pricing after two years. The agreement was for an initial term of three years, after which it continues to remain in effect unless and until terminated in accordance with the terms therein. We use the cryogen cooling method and coupling fluid with our compatible radio frequency medical device for the purpose of conducting our clinical trials as well as for commercial purposes. Since we currently do not have any alternative sources of cryogen, if Solta refuses to sell to us for commercial reasons, or otherwise, our business could be materially adversely affected.

We forecast sales to determine requirements for components and materials used in Geneveve, 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 six 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 Geneveve 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 Geneveve and we do not sell Geneveve 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 Geneveve. We do not supervise the procedures performed with Geneveve, nor can we be assured that direct physician supervision of our equipment occurs according to our recommendations. We and our distributors require purchasers of Geneveve to undergo an initial training session as a condition of purchase, but do not require ongoing training. In addition, we prohibit the sale of Geneveve to companies that rent Geneveve 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 Geneveve to licensed physicians who have met certain training requirements. However, current federal regulations will allow us to sell Geneveve to “licensed practitioners,” if we receive FDA approval. The definition of “licensed practitioners” varies from state to state. As a result, Geneveve 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 Geneveve by non-physicians.

The use of Geneveve 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 Geneveve, and could result in expensive and time-consuming litigation, payment of substantial damages and an increase in our insurance rates.

If Geneveve 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 Geneveve 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 Geneveve. 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 Geneveve and available to practitioners at lower prices. If security features incorporated into the design of Geneveve 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.

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 and benefits of Geneveve. 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 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. 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. Furthermore, the integration of any acquisition 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. If we decide to expand our product offerings, we may spend time and money on projects that do not increase our revenues.

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 Geneveve 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 approval 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 all 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 Geneveve or any future products we may develop or acquire, including product enhancements, our business and results of operations could be adversely affected.

Geneveve 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 another 510(k)-cleared product, 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. 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 there is no known predicate for a device, a company can request a de novo classification of the product. De novo generally applies where there is no predicate device and the FDA believes the device is sufficiently safe so that no PMA should be required. FDA's de novo process has been streamlined to allow a company to request that a new product classification be developed based on information provided by the requesting company. Our plan is to utilize the de novo process for Geneveve. However, we cannot predict when or if such classification will be obtained, or whether FDA will create a new product code. Failure to classify the device pursuant to the de novo process could require us to seek a PMA for Geneveve. Delays in receipt or failure to receive clearances or approvals 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, for example, that we may not make claims about the use of any of our marketed products, outside of their approved or cleared indications and that our promotional materials and training methods do not promote or encourage unapproved use. Therefore, we may not proactively discuss or provide information on off-label uses. The FDA does not, however, restrict physicians from prescribing products for off-label uses in the 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 a product, the suspension or withdrawal of an approved product from the market, product recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecutions.

If the Office of Inspector General within the Department of Health and Human Services, the 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, several other types of 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 prescribe products for off-label uses and indications, if other federal or state regulatory authorities determine that we have engaged in off-label promotion through remuneration, kickbacks or other monetary benefits to prescribers, we may be subject to civil or criminal penalties and could be prohibited from participating in government healthcare programs such as Medicaid and Medicare. In addition, government agencies or departments could conclude that we have engaged in off-label promotion and, potentially, caused the submission of false claims. 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 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) or a 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 Geneveve. Initiating and completing clinical trials necessary to support a 510(k) or a PMA application for Geneveve, as well as other possible future product candidates, will be 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. Furthermore, if the results of our OUS Clinical Trials are not positive, we may not receive further funding from our lender. 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 Geneveve, 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 Health Services, or CDHS. 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 facility has been inspected by the FDA and CDHS, and observations were noted. The FDA and CDHS 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 Geneveve 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 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.

Geneveve 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 Geneveve 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 Geneveve. 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 Geneveve 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.

Geneveve may, in the future, be subject to product 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. In addition, foreign governmental bodies have the authority to require the recall of our product in the event of material deficiencies or defects in design or manufacture. 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 recalls involving our product that we determine do not require notification to the FDA. If the FDA disagrees with our determinations, they 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 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 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 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) premarket 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, including revising existing guidance or developing guidance to clarify various aspects of the 510(k) process and to streamline the review process for innovative, lower risk products (the "de novo" process); improving training for the Center for Devices and Radiological Health staff; increasing reliance on external experts; and addressing and improving internal processes. The FDA may implement other reforms in the future. Future reforms could have the effect of making it more difficult and expensive for us to obtain 510(k) clearance.

In addition, 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.

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 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. Although we have not conducted formal FCPA compliance training, 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.

Risks Related to Our Intellectual Property

Intellectual property rights may not provide adequate protection for Geneveve, 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 Geneveve. We have an exclusive license to or own 10 issued U.S. patents primarily covering Geneveve and methods of use, 2 of which have expired. The remaining 8 will expire between 2016 and 2029. Additionally, we have 4 pending U.S. patent applications; 16 issued foreign patents; and 20 pending foreign patent applications, some of which foreign applications preserve an opportunity to pursue patent rights in multiple countries. Some of Geneveve 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 Geneveve 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 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 Geneveve and the methods we employ are covered by their patents. If Geneveve or methods are found to infringe, we could be prevented from marketing Geneveve. 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 Geneveve. 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. If we initiate litigation to protect our rights, we run the risk of having our patents invalidated, which would undermine our competitive position.

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 Geneveve, 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 Geneveve 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 Geneveve in one or more countries.

In addition, we may hereafter become involved in litigation to protect our trademark rights associated with our name or the names used with Geneveve. Names used with Geneveve and procedures 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 or Geneveve, 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 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 November 7, 2016, our officers, directors and principal stockholders, i.e., stockholders who beneficially own greater than 10% of our outstanding common stock, collectively beneficially own approximately 44% 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.

As a result of the Merger, 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 November 7, 2016, there were approximately 3,801,075 shares of common stock of the 10,648,407 shares issued and outstanding that could be sold pursuant to Rule 144, 64,405 shares of restricted stock, 425,274 shares subject to outstanding warrants, 1,315,808 shares subject to outstanding options and an additional 610,736 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. We intend to retain any earnings to develop, carry on, and expand our business.

Item 2. Unregistered Sales of Equity Securities and Use Of Proceeds.

Unregistered Sales of Securities

None.

Use of Proceeds

Not applicable.

Issuer Repurchases of Company Equity Securities.

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Press Release Reporting Third Quarter Financial Results.

Attached as Exhibit 99.1 and incorporated herein by reference is a copy of a press release dated November 10, 2016, reporting the Company's 2016 third quarter financial results. The information set forth under this Item 5 is intended to be furnished under this Item 5 and also "Item 7.01, Regulation FD Disclosure" and "Item 2.02, Results of Operations and Financial Condition" of Form 8-K. Such information, including Exhibit 99.1 attached to this Form 10-Q, shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, nor shall it be deemed incorporated by reference in any filing under the Securities Act, except as shall be expressly set forth by specific reference in such filing.

Item 6. Exhibits.

Exhibit

Number Document

3.1(1)	Certificate of Conversion for Delaware
3.1.1(1)	Certificate of Incorporation
3.1.2(2)	Articles of Amendment to the Articles of Continuance of Viveve Medical, Inc.
3.2(1)	Bylaws
10.1#(3)	Amendment No. 1 to the Viveve Medical, Inc. Independent Director Compensation Policy
10.2#(4)	Viveve Medical, Inc. Amended and Restated 2013 Stock Option and Incentive Plan
10.3*	Second Amendment to Standard Industrial/Commercial Multi-Tenant Lease – Gross, dated September 12, 2016 between Viveve, Inc. and Commercial Street Properties, LLC.
31.1*	Certification of the Company’s Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of the Company’s Principal Financial and Accounting Officer pursuant to Rule 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
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 Financial and Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99.1+	Press Release announcing 2016 Third Quarter Financial Results issued on November 10, 2016
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.

+ This document is deemed not filed for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

Indicates a management contract or any compensatory plan, contract or arrangement.

- (1) Incorporated by reference from the Form 10-Q filed with the Securities and Exchange Commission on May 13, 2016.
- (2) Incorporated by reference from the Form 8-K filed with the Securities and Exchange Commission on April 14, 2016.
- (3) Incorporated by reference from the Form 8-K filed with the Securities and Exchange Commission on July 12, 2016.
- (4) Incorporated by reference to Appendix A to the Registrant’s Proxy Statement on Schedule 14A (SEC File No. 001-11388) filed with the Commission by the Registrant on July 28, 2016.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: November 10, 2016

VIVEVE MEDICAL, INC.
(Registrant)

By: /s/ Patricia Scheller

Patricia Scheller
Chief Executive Officer
Principal Executive Officer

By: /s/ Scott Durbin

Scott Durbin
Chief Financial Officer
Principal Financial and Accounting Officer

**SECOND AMENDMENT TO
STANDARD INDUSTRIAL/COMMERCIAL
MULTI-TENANT LEASE - GROSS**

This Second Amendment to Standard Industrial/Commercial Multi-Tenant Lease - Gross (the "Second Amendment") is entered into as of September 12, 2016 ("Amendment Date") by and between COMMERCIAL STREET PROPERTIES, LLC, a California limited liability company ("Lessor"), and VIVEVE, INC., a California corporation ("Lessee"), with reference to the following:

RECITALS

A. The Castine Group, a California corporation ("Castine"), and Lessee entered into that certain Standard Industrial/Commercial Multi-Tenant Lease - Gross dated as of January 25, 2012, as amended by that certain First Amendment to Lease dated January 15, 2015 (the "First Amendment," and collectively, the "Lease") for the premises located at 150-154 Commercial Street, Sunnyvale California 94086 (the "Premises").

B. The Lease incorrectly identified Castine as the lessor of the Premises rather than Lessor. Lessor is the entity that is and was the true owner and lessor of the Premises at all times relevant to the Lease.

C. Lessor and Lessee now wish to amend the Lease on the terms and conditions set forth in this Amendment to reflect (i) the proper identification of Lessor as the lessor of the Premises pursuant to the Lease for all purposes, (ii) the leasing by Lessee of the Premises for an extended term, (iii) the establishment of Lessee's rental obligation for the extended term, and such other matters as set forth in this Second Amendment.

AGREEMENT

NOW, THEREFORE, in consideration of the covenants and agreements herein contained, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Recitals. Lessor and Lessee hereby agree that the hereinabove recitals are true and correct.
 2. Definitions. Unless defined otherwise in this Second Amendment, all capitalized terms used in this Second Amendment shall have the same meaning and definition given to them in the Lease.
 3. True Lessor. Lessor and Lessee acknowledge that the Lease incorrectly identified Castine as the lessor of the Premises. Lessor and Lessee hereby acknowledge and agree that Lessor, and not Castine, was at all times the true lessor of the Lease, and that all of Castine's purported rights, obligations and interests in, to and under the Lease were and are in fact Lessor's rights, obligations and interests in, to and under the Lease, all of which accrued to Lessor or otherwise arose on January 25, 2012.
-

4. Extension of Term. The Lease term as stated in Section 2 of the First Amendment is hereby extended to March 31, 2018 (the "Extended Term"), unless the Lease is sooner terminated as provided for in the Lease.

5. Base Rent. The Base Rent payable by Lessee for the Extended Term shall be as follows:

<u>Months of Extended Term</u>	<u>Monthly Base Rent</u>	<u>Annual Base Rent</u>
April 1, 2017 - March 31, 2018	\$ 27,219.50	\$ 326,634

6. Base Year. The Base Year as defined in Section 4.2 of the Lease is hereby amended to be defined as the 2017 calendar year.

7. Extension Option.

(a) Extension. Provided that Lessee is in possession of the Premises, and that this Lease is not previously cancelled or terminated by either party as provided in the Lease, by operation of law or otherwise, and further provided that Lessee has fully complied with and performed all of the covenants and conditions in the Lease, as amended, on its part to be performed during the Term and is not in default at the time of exercise of this option, then Lessor and Lessee covenant and agree that Lessee shall have the option to extend the term of the Lease for one (1) six (6) month period commencing upon the expiration of the term of this Lease (the "Extension"), upon the same terms, covenants and provisions herein set forth except that Base Rent during the Extension shall be adjusted to the Fair Market Rental Rate, as hereinafter defined. The option for the Extension shall be exercised written notice to Lessor by Lessee not less than ninety (90) days prior to the expiration of the term of this Lease.

(b) Fair Market Rental Rate. The term "Fair Market Rental Rate" shall mean the market rental rate for the time period such determination is being made for commercial space in Sunnyvale, California of comparable condition and of equivalent quality, size, utility, and location. Prior to the commencement of the Extension, Lessor and Lessee shall attempt to agree upon what the Fair Market Rental Rate will be. If agreement cannot be reached within thirty (30) days, then either:

(1) Lessor and Lessee shall immediately appoint a mutually acceptable appraiser or broker to establish the new Fair Market Rental Rate within the next thirty (30) days, with any associated costs to be split equally between the parties, or

(2) Both Lessor and Lessee shall each immediately make a reasonable determination of the Fair Market Rental Rate and submit such determination, in writing, to arbitration in accordance with the following provisions:

(i) Within fifteen (15) days thereafter, Lessor and Lessee shall each select an independent third party appraiser or broker of their choice to act as an arbitrator; provided, however, that the parties may not select any of the brokers involved in negotiating the Lease or any amendments thereto to so act. The two arbitrators so appointed shall immediately select a third mutually acceptable appraiser or broker to act as a third arbitrator.

(ii) The three arbitrators shall within thirty (30) days of the appointment of the third arbitrator reach a decision as to what the actual Fair Market Rental Rate for the Premises is, and whether Lessor's or Lessee's submitted Fair Market Rental Rate is the closest thereto. The decision of a majority of the arbitrators shall be binding on the parties. The submitted Fair Market Rental Rate which is determined to be the closest to the actual Fair Market Rental Rate shall thereafter be used by the parties.

(iii) If either of the parties fails to appoint an arbitrator within the specified fifteen (15) days, the arbitrator timely appointed by one of them shall reach a decision on his or her own, and said decision shall be binding on the parties.

(iv) The entire cost of such arbitration shall be paid by the party whose submitted Fair Market Rental Rate is not selected, *i.e.*, the one that is NOT the closest to the actual Fair Market Rental Rate.

(c) Applicable Considerations. When determining Fair Market Rental Rate, the Lessor, Lessee and the arbitrators shall consider the terms of comparable market transactions which shall include, but not be limited to, rent, rental adjustments, abated rent, lease term and financial condition of tenants.

(d) Base Rent Minimum. Notwithstanding the foregoing, the Fair Market Rental Rate shall not be less than the rent payable for the month immediately preceding the commencement of the Extension.

8 . Lessee's Acceptance of Premises "AS IS". Lessor and Lessee acknowledge that Lessee currently occupies the Premises. Lessee accepts the Premises in its "AS IS" condition and as of the commencement of the above extended term in its then "AS IS" condition. During the remaining Lease term, Lessee shall continue to occupy the Premises in its "AS IS" condition.

9 . Security Deposit. The parties acknowledge and agree that the Security Deposit, as previously reduced from time to time in accordance with the Lease, shall continue to be held by Lessor for the Extended Term.

10. Brokers. Lessor has been represented in connection with this Amendment by Cushman & Wakefield U.S., Inc. acting solely as Lessor's agent, and Lessee has been represented by Jones Lang LaSalle ("JLL") acting solely as Lessee's agent. Lessor hereby agrees to pay JLL a commission in the amount of a market procuring commission for the Premises pursuant to a separate agreement by and between Lessor and JLL.

11 . Ratification. Except as expressly amended by this Amendment, the terms and provisions of the Lease, as amended, are hereby ratified, confirmed, and shall remain in full force and effect.

12. No Other Changes. Except as expressly set forth herein, the Lease, as amended by this Amendment, remains in full force and effect and unamended.

IN WITNESS WHEREOF, Lessor and Lessee have executed this Amendment as of the Amendment Date.

LESSOR:

COMMERCIAL STREET PROPERTIES, LLC, a California limited liability company

By: /s/ Marshall Goldman
MARSHALL GOLDMAN, General Manager

LESSEE:

VIVEVE, INC., a California corporation

By: /s/ Scott Durbin
SCOTT DURBIN, CFO

**Certification of Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.**

I, Patricia Scheller, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: November 10, 2016

/s/ Patricia Scheller

Patricia Scheller
Chief Executive Officer
(Principal Executive Officer)

**Certification of Chief Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.**

I, Scott Durbin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: November 10, 2016

/s/ Scott Durbin

Scott Durbin
Chief Financial Officer
(Principal Financial and Accounting Officer)

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 Quarterly Report of the Company on Form 10-Q for the period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), that, to the best of their knowledge:

- (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: November 10, 2016

/s/ Patricia Scheller

Patricia Scheller

Chief Executive Officer

(Principal Executive Officer)

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 Quarterly Report of the Company on Form 10-Q for the period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), that, to the best of their knowledge:

- (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: November 10, 2016

/s/ Scott Durbin

Scott Durbin
Chief Financial Officer
(Principal Financial and Accounting Officer)

Viveve® Reports Record Third Quarter Financial Results

Quarterly revenue increases 19% quarter-over-quarter and 217% year-over-year

SUNNYVALE, California -- (Marketwired) -- November 10, 2016 -- Viveve Medical, Inc. ("Viveve") (Nasdaq: VIVE), a medical technology company focused on women's health, today reported financial results for the quarter ended September 30, 2016.

"The third quarter continued to be a record breaking period for the company. We achieved our fifth consecutive quarter of double-digit growth, bringing our installed base to 162 Viveve Systems," said Patricia Scheller, Viveve's chief executive officer. "Additionally, we recently obtained regulatory clearances in six additional countries, including some of the largest aesthetic and sexual medicine markets in the world. As a result, we are working closely with our international distribution partners to launch the GENEVEVE™ by Viveve treatment into these new international markets, including S. Korea and Brazil. With the recent regulatory clearance in the U.S., we are now focused on building our commercial team and generating additional differentiating clinical data to treat female sexual dysfunction."

2016 Business Highlights

- Announced positive final results for both the primary and key secondary endpoints for the VIVEVE I clinical study – the first large-scale, randomized, blinded and sham-controlled study of an energy based treatment conducted in vaginal tissue.
 - Uplisted the company's common stock to The Nasdaq Capital Market.
 - Announced a distribution contract for the private China market.
 - Successfully raised gross proceeds of \$15.5 million in equity capital to support our clinical, regulatory and global commercialization efforts.
 - Executed a \$10 million term loan with Western Alliance Bank to meet our expanding working capital requirements.
 - Added three new, independent, and seasoned commercial executives to our Board of Directors.
 - Submitted our IDE to the FDA to conduct VIVEVE II: randomized, controlled and double-blinded trial to improve sexual function in women.
 - Announced key regulatory approvals in several large markets, including S. Korea, Brazil and the U.S., as well as approvals in other key countries including Lebanon, Singapore, the United Arab Emirates.
-

Q3 Financial Results

"Since launching commercially in Q3 2015, we have seen continued sales momentum around the globe. We believe we are well positioned to build on our rapidly expanding commercial footprint, particularly given recent regulatory clearances," stated Scott Durbin, Viveve's chief financial officer.

Revenue for the third quarter of 2016 totaled \$1,849,000 from the sale of 47 Viveve Systems, 522 disposable treatment tips and other ancillary consumables, compared to revenue of \$584,000 for the same period in 2015, an increase of \$1,265,000 or 217%.

Gross profit for the third quarter of 2016 was \$691,000, compared to gross profit of \$167,000, for the same period in 2015, an increase of \$524,000. The increase in gross profit was primarily due to the sale of 47 Viveve Systems during the quarter.

Total operating expenses for the third quarter of 2016 increased 63% to \$5,326,000 from \$3,272,000 in the same period in 2015, primarily as a result of increased efforts to support commercialization of our product in existing and new markets, increased research and development efforts, and implementation of strategies to protect our intellectual property. Spending on research and development during the third quarter of 2016 increased due to costs associated with increased engineering and development work with our contract manufacturer. Selling, general and administrative expenses for the third quarter of 2016 increased primarily due to increased sales and marketing efforts to build brand and market awareness.

Net loss for the third quarter of 2016 was \$4,869,000, or a loss of \$0.46 per share, compared with a net loss of \$3,219,000, or a loss of \$0.50 per share, for the same period in 2015.

Cash and cash equivalents were \$14,011,000 as of September 30, 2016, an increase of \$6,651,000 from \$7,360,000 as of December 31, 2015.

Conference Call Information

The company will host a live conference call at 5:00 p.m. ET today. The conference call can be accessed at <http://dpregrister.com/10095466>. The dial-in telephone number will be provided upon registration either in advance of or at the time of the conference call. The conference call will be archived on the company's website at <http://ir.viveve.com/ir-calendar>.

About Viveve

Viveve Medical, Inc. is a women's health company passionately committed to advancing new solutions to improve women's overall well-being and quality of life. The Viveve System has received regulatory approval in many countries throughout the world and is available through physician import license in Japan. For further information please visit www.viveve.com.

Safe Harbor Statement

All statements in this press release that are not based on historical fact are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. While management has based any forward-looking statements included in this press release on its current expectations, the information on which such expectations were based may change. These forward-looking statements rely on a number of assumptions concerning future events and are subject to a number of risks, uncertainties and other factors, many of which are outside of our control, which could cause actual results to materially differ from such statements. Such risks, uncertainties and other factors include, but are not limited to, the fluctuation of global economic conditions, the performance of management and our employees, our ability to obtain financing, competition, general economic conditions and other factors that are detailed in our periodic and current reports available for review at www.sec.gov. Furthermore, we operate in a highly competitive and rapidly changing environment where new and unanticipated risks may arise. Accordingly, investors should not place any reliance on forward-looking statements as a prediction of actual results. We disclaim any intention to, and undertake no obligation to, update or revise forward-looking statements to reflect events or circumstances that subsequently occur or of which we hereafter become aware.

Viveve® is a registered trademark of Viveve, Inc.

VIVEVE MEDICAL, INC.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	September 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 14,011	\$ 7,360
Accounts receivable	1,807	593
Inventory	1,413	1,549
Prepaid expenses and other current assets	1,298	1,228
Total current assets	18,529	10,730
Property and equipment, net	445	239
Other assets	133	138
Total assets	<u>\$ 19,107</u>	<u>\$ 11,107</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,477	\$ 1,432
Accrued liabilities	1,978	1,293
Note payable, current portion	865	4,446
Total current liabilities	5,320	7,171
Note payable, noncurrent portion	8,730	-
Total liabilities	14,050	7,171
Stockholders' equity:		
Preferred stock	-	-
Common stock and paid-in capital	67,859	52,447
Accumulated deficit	(62,802)	(48,511)
Total stockholders' equity	5,057	3,936
Total liabilities and stockholders' equity	<u>\$ 19,107</u>	<u>\$ 11,107</u>

VIVEVE MEDICAL, INC.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Revenue	\$ 1,849	\$ 584	\$ 4,689	\$ 695
Cost of revenue	1,158	417	3,116	520
Gross profit	<u>691</u>	<u>167</u>	<u>1,573</u>	<u>175</u>
Operating expenses:				
Research and development	2,054	1,515	6,313	3,446
Selling, general and administrative	<u>3,272</u>	<u>1,757</u>	<u>8,435</u>	<u>5,155</u>
Total operating expenses	<u>5,326</u>	<u>3,272</u>	<u>14,748</u>	<u>8,601</u>
Loss from operations	(4,635)	(3,105)	(13,175)	(8,426)
Interest expense, net	(221)	(114)	(1,094)	(302)
Other expense, net	(13)	-	(22)	(21)
Net loss	<u>\$ (4,869)</u>	<u>\$ (3,219)</u>	<u>\$ (14,291)</u>	<u>\$ (8,749)</u>
Net loss per share:				
Basic and diluted	<u>\$ (0.46)</u>	<u>\$ (0.50)</u>	<u>\$ (1.63)</u>	<u>\$ (1.99)</u>
Weighted average shares used in computing net loss per common share				
Basic and diluted	<u>10,630,468</u>	<u>6,418,457</u>	<u>8,741,667</u>	<u>4,403,620</u>

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