UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the Quarterly Period Ended June 30, 2019

OR

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

For the Transition Period From to

Commission file number: 001-38677

Ra Medical Systems, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**38-3661826**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2070 Las Palmas Drive **Carlsbad, California** **(Address of principal executive offices)**	**92011** **(Zip Code)**

(760) 804-1648

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	RMED	New York Stock Exchange

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

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

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

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

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

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

As of November 20, 2019, the registrant had 13,407,995 shares of common stock, par value $0.0001 per share, outstanding.

RA MEDICAL SYSTEMS, INC.
QUARTERLY REPORT ON FORM 10-Q

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EXPLANATORY NOTE

We were unable to timely file our Quarterly Report on Form 10-Q for the second quarter ended June 30, 2019 due to the previously reported Audit Committee investigation, which has now been substantially completed, and the previously reported Department of Justice investigation, both of which are more fully described herein.

PART I — FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Ra Medical Systems, Inc.
Condensed Balance Sheets
(Unaudited)
(in thousands, except share and per share data)

	June 30, 2019	December 31, 2018
ASSETS		
Current Assets		
Cash and cash equivalents	$ 11,787	$ 64,315
Short-term investments	36,601	—
Accounts receivable, net	1,454	1,320
Inventories	2,344	2,097
Prepaid expenses and other current assets	1,302	1,501
Total current assets	53,488	69,233
Property and equipment, net	5,767	4,757
Operating lease right-of-use-assets	3,002	—
Other non-current assets	217	45
TOTAL ASSETS	$ 62,474	$ 74,035
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 1,515	$ 1,125
Accrued expenses	2,074	2,809
Current portion of deferred revenue	2,039	1,723
Current portion of equipment financing	367	293
Current portion of operating lease liabilities	300	—
Total current liabilities	6,295	5,950
Deferred revenue	992	767
Equipment financing	510	557
Operating lease liabilities	2,782	—
Other liabilities	—	56
Total liabilities	10,579	7,330
Commitments and contingencies (Note 11)		
Stockholders' Equity		
Preferred stock, $0.0001 par value, 10,000,000 authorized at June 30, 2019 and December 31, 2018, respectively; none issued	—	—
Common stock, $0.0001 par value, 300,000,000 shares authorized; 13,220,951 and 12,689,251 issued and outstanding at June 30, 2019 and December 31,2018, respectively	1	1
Additional paid-in capital	141,839	126,925
Accumulated deficit	(89,996)	(60,221)
Accumulated other comprehensive income	51	—
Total stockholders' equity	51,895	66,705
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 62,474	$ 74,035

See notes to condensed financial statements.

Ra Medical Systems, Inc.
Condensed Statements of Operations
(Unaudited)
(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net revenue				
Product sales	$ 1,284	$ 475	$ 2,178	$ 710
Service and other	869	761	1,723	1,495
Total net revenue	2,153	1,236	3,901	2,205
Cost of revenue				
Product sales	1,935	647	3,330	989
Service and other	798	343	1,345	737
Total cost of revenue	2,733	990	4,675	1,726
Gross (loss) profit	(580)	246	(774)	479
Operating expenses				
Selling, general and administrative	13,789	7,615	27,018	10,254
Research and development	979	1,022	2,510	1,308
Total operating expenses	14,768	8,637	29,528	11,562
Operating loss	(15,348)	(8,391)	(30,302)	(11,083)
Other income (expense), net				
Interest income	297	—	625	—
Interest expense	(66)	(1)	(114)	(2)
Total other income (expense), net	231	(1)	511	(2)
Loss before income tax expense	(15,117)	(8,392)	(29,791)	(11,085)
Income tax expense	5	3	5	3
Net loss	(15,122)	(8,395)	(29,796)	(11,088)
Basic and diluted net loss per share	$ (1.16)	$ (1.03)	$ (2.32)	$ (1.38)
Basic and diluted weighted average common shares outstanding	13,000	8,113	12,847	8,020

See notes to condensed financial statements.

Ra Medical Systems, Inc.
Condensed Statements of Comprehensive Loss
(Unaudited)
(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net loss	$ (15,122)	$ (8,395)	$ (29,796)	$ (11,088)
Other comprehensive income (loss):				
Unrealized gains related to short-term investments	51	—	51	—
Total other comprehensive loss	$ 51	$ —	$ 51	$ —
Comprehensive loss	$ (15,071)	$ (8,395)	$ (29,745)	$ (11,088)

See notes to condensed financial statements.

Ra Medical Systems, Inc.
Condensed Statements of Cash Flows
(Unaudited)
(in thousands)

	Six Months Ended June 30,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (29,796)	$ (11,088)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	669	231
Operating lease right-of-use-assets amortization	162	—
Provision for doubtful accounts	266	88
Stock-based compensation	14,877	5,204
Changes in operating assets and liabilities:		
Accounts receivable	(400)	(332)
Inventories	(1,542)	(1,140)
Prepaid expenses and other assets	313	(165)
Accounts payable	390	760
Accrued expenses	(735)	495
Deferred revenue	187	18
Other liabilities	(138)	(37)
Net cash used in operating activities	(15,747)	(5,966)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of available-for-sale securities	(36,461)	—
Purchases of property and equipment	(196)	(251)
Net cash used in investing activities	(36,657)	(251)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	37	7,901
Payments on equipment financing	(161)	(21)
Initial public offering costs	—	(131)
Net cash (used in) provided by financing activities	(124)	7,749
NET CHANGE IN CASH AND CASH EQUIVALENTS	(52,528)	1,532
CASH AND CASH EQUIVALENTS, beginning of period	64,315	8,237
CASH AND CASH EQUIVALENTS, end of period	$ 11,787	$ 9,769
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Settlement of stock-based compensation liability	$ —	$ 18,243
Forfeitures of liability-classified awards	$ —	$ 1,313
Deferred initial public offering costs in accounts payable and accrued expenses	$ —	$ 2,104
Unpaid property and equipment included in equipment financing	$ 175	$ —
Transfer from inventories to property and equipment for demonstration lasers and lasers placed with customers	$ 1,295	$ 1,078
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash payments for interest	$ 26	$ 1
Cash payments for taxes	$ 8	$ —

See notes to condensed financial statements.

Ra Medical Systems, Inc.
Condensed Statements of Stockholders' Equity
(Unaudited)
(in thousands)

	Common Stock Shares	Common Stock Amount	Additional Paid- in- Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balances at December 31, 2018	12,689	$ 1	$ 126,925	$ —	$ (60,221)	$ 66,705
Adoption of accounting standard (See Note 2)	—	—	—	—	21	21
Balances at January 1, 2019	12,689	1	126,925	—	(60,200)	66,726
Common stock issued	148	—	—	—	—	—
Stock-based compensation	—	—	7,745	—	—	7,745
Net loss	—	—	—	—	(14,674)	(14,674)
Balances at March 31, 2019	12,837	1	134,670	—	(74,874)	59,797
Common stock issued	384	—	37	—	—	37
Stock-based compensation	—	—	7,132	—	—	7,132
Other comprehensive income	—	—	—	51	—	51
Net loss	—	—	—	—	(15,122)	(15,122)
Balances at June 30, 2019	13,221	$ 1	$ 141,839	$ 51	$ (89,996)	$ 51,895

	Common Stock Shares	Common Stock Amount	Additional Paid- in- Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balances at December 31, 2017	7,888	$ 1	$ 21,773	$ —	$ (29,389)	$ (7,615)
Common stock issued	56	—	1,401	—	—	1,401
Net loss	—	—	—	—	(2,693)	(2,693)
Balances at March 31, 2018	7,944	1	23,174	—	(32,082)	(8,907)
Common stock issued	260	—	6,500	—	—	6,500
Settlement of stock-based compensation liability	—	—	18,243	—	—	18,243
Forfeitures of liability-classified awards	—	—	1,313	—	—	1,313
Stock-based compensation	—	—	1,024	—	—	1,024
Net loss	—	—	—	—	(8,395)	(8,395)
Balances at June 30, 2018	8,204	$ 1	$ 50,254	$ —	$ (40,477)	$ 9,778

See notes to condensed financial statements.

Note 1—Organization and Nature of Operations

Ra Medical Systems, Inc. (the "Company") was formed in September 4, 2002, in the state of California and reincorporated in Delaware on July 14, 2018. The Company is a medical device company that develops, manufactures and markets advanced excimer lasers for use in the treatment of vascular and dermatological diseases. The Company's product development centers around proprietary applications of its advanced excimer laser technology for use as a tool in the treatment of peripheral artery disease ("PAD") and psoriasis, vitiligo, atopic dermatitis and leukoderma.

Reincorporation—In July 2018, the Company reincorporated in Delaware, the par value of each share of common stock was established to be $0.0001 and the number of authorized shares of common stock was increased from 10,000,000 to 25,000,000. In connection with the reincorporation, common stock and additional paid-in capital amounts in these financial statements have been adjusted to reflect the par value of common stock. All share information included in these financial statements has been adjusted to reflect this reincorporation.

Initial Public Offering—On October 1, 2018, the Company closed its initial public offering ("IPO") of 4,485,000 shares of common stock at an offering price to the public of $17.00 per share, resulting in gross proceeds of approximately $76.2 million. These amounts include the exercise in full by the underwriters of their option to purchase 585,000 additional shares of common stock at the same price to the public to cover over-allotments. The aggregate net proceeds to the Company from its IPO were $67.3 million after deducting the underwriters discount and offering costs of $5.3 million and $3.6 million, respectively. The Company's registration statement on Form S-1 relating to its IPO was declared effective by the Securities and Exchange Commission on September 26, 2018.

In connection with the IPO, the Company filed an Amended and Restated Certificate of Incorporation which authorizes the issuance of 300,000,000 shares of common stock with a par value of $0.0001 and 10,000,000 shares of preferred stock with a par value of $0.0001.

Liquidity — The Company believes that its cash and cash equivalents and short-term investments as of the date of these financial statements will be sufficient to fund its operations for at least the next 12 months. The Company continuously monitors and reevaluates its liquidity needs. Certain future events may occur that are outside the Company's control which could negatively impact the Company's cash position. These events may cause the Company to undertake additional cost savings measures or seek additional sources of financing.

Note 2—Significant Accounting Policies

Interim condensed financial information—The unaudited interim condensed financial statements have been prepared on the same basis as the annual financial statements and reflect all adjustments of a normal and recurring nature that are necessary for the fair presentation of the Company's condensed balance sheets, results of operations, cash flows and statement of stockholders' equity for the periods presented. The results of operations for the three and six months ended June 30, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019 or for any other future annual or interim period. The balance sheet as of December 31, 2018 included herein was derived from the audited financial statements as of that date. These unaudited condensed financial statements should be read in conjunction with the Company's audited financial statements included in the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2019.

Use of estimates—The financial statements of the Company have been prepared by management in accordance with accounting principles generally accepted in the United States of America. The preparation of the financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and reported disclosures of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates. The Company's financial statements are based upon a number of estimates, including but not limited to, allowance for doubtful accounts, reserves for warranty costs including product recalls, evaluation of probable loss contingencies, fair value of stock option awards granted and revenue recognition for multiple performance obligations.

Short-term Investments—Investments with original maturities of greater than three months are classified as short-term investments. Debt investments are classified as available-for-sale and realized gains and losses are recorded using the specific identification method. Changes in fair value, excluding other-than-temporary impairments, are recorded in other comprehensive income ("OCI"). Debt investments are impaired when a decline in fair value is judged to be other-than-temporary. Fair value is calculated based on publicly available market information or other estimates determined by management. The Company employs a systematic methodology on a quarterly basis that considers available quantitative and qualitative evidence in

evaluating potential impairment of our investments. If the cost of an investment exceeds its fair value, the Company evaluates, among other factors, general market conditions, credit quality of debt instrument issuers, and the duration and extent to which the fair value is less than cost. The Company also evaluates whether it has plans to sell the security or it is more likely than not that the Company will be required to sell the security before recovery. In addition, the Company considers specific adverse conditions related to the financial health of and business outlook for the investee, including industry and sector performance, changes in technology, and operational and financing cash flow factors. Once a decline in fair value is determined to be other-than-temporary, an impairment charge is recorded in other income (expense), net and a new cost basis in the investment is established.

Fair value measurements—Fair value represents the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants and is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. A three-tier value hierarchy is used to identify inputs used in measuring fair value as follows:

Level 1—Observable inputs that reflect quoted market prices (unadjusted) for identical assets or liabilities in active markets.

Level 2—Inputs other than the quoted prices in active markets that are observable either directly or indirectly in the marketplace for identical or similar assets and liabilities; and

Level 3—Unobservable inputs that are supported by little or no market data, which require the Company to develop its own assumptions.

The hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

The Company measures its cash equivalents and short-term investments at fair value.

Inventories—Inventories are stated at the lower of cost (first-in, first-out method) or net realizable value. Cost includes materials, labor and manufacturing overhead related to the purchase and production of inventories. The Company reduces the carrying value of inventories for those items that are potentially excess, obsolete or slow-moving based on changes in customer demand, technological developments or other economic factors.

Catheters are manufactured in-house and each catheter is tested at various stages of the manufacturing process for adherence to quality standards. Catheters that do not meet functionality specification at each test point are destroyed and immediately written off, with the expense recorded in cost of revenue in the statement of operations. Once manufactured, completed catheters that pass quality assurance, are sent to a third-party for sterilization and sealed in a sterile container. Upon return from the third-party sterilizer, a sample of catheters from each batch are re-tested. If the sample tests are successful, the batch is accepted into finished goods inventory and if the sample tests are unsuccessful, the entire batch is written off, with the expense recorded in cost of revenue in the statement of operations.

Revenue— The Company adopted ASC Topic 606 (Topic 606), *Revenue from Contracts with Customers*, on January 1, 2019 using the modified retrospective method to all contract agreements not completed as of January 1, 2019. Results for reporting periods beginning after January 1, 2019 are presented under Topic 606 while, as permitted by Topic 606, prior period amounts are not adjusted and continue to be reported under the accounting standards in effect for the prior period. The Company recorded a cumulative catch up adjustment to beginning accumulated deficit to reflect the impact of adopting Topic 606. The adoption of Topic 606 did not have a material effect on our results of operations for the three and six month periods ended June 30, 2019.

The Company generates revenue from the sale of products and services. Product sales consist of the sale of DABRA and Pharos laser systems, the sale of catheters for use with the DABRA laser, and the sale of consumables and replacement parts. The Company's sales agreements generally do not include right-of-return provisions for any form of consideration including partial refund or credit against amounts owed to the Company. Services and other revenue primarily consist of sales of extended warranty and billable services, including repair activity and income from rental of lasers.

The Company determines revenue recognition incorporating the following steps:

- Identification of each contract with a customer;
- Identification of the performance obligations in the contract;
- Determination of the transaction price;
- Allocation of the transaction price to the performance obligations in the contract; and

- Recognition of revenue when, or as, performance obligations are satisfied.

The Company accounts for a contract with a customer when it has a legally enforceable contract with the customer, the arrangement identifies the rights of the parties, the contract has commercial substance, and the Company determines it is probable that it will collect the contract consideration. The Company recognizes revenue when control of the promised goods or services transfers to customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods or services. Taxes collected from customers relating to goods or services and remitted to governmental authorities are excluded from revenue.

Catheter Revenue

The Company enters into a DABRA laser commercial usage agreement or DABRA laser placement acknowledgement with each customer that is supplied a DABRA laser, collectively the "usage agreement". The usage agreement provides for specific terms of continued use of DABRA laser, including a nominal periodic fee. The terms of a usage agreement typically allow the Company to place a DABRA laser at a customer's specified location without a specified contract term. Under the usage agreement terms, the Company retains all ownership rights to the DABRA laser and is allowed to request the return of the equipment within 10 business days of notification. While the laser periodic fees are nominal, the laser usage agreements provide the Company the exclusive rights to supply related single-use catheters to the customer which aggregate the majority of the vascular segment revenue. There are no specified minimum purchase commitments for the catheters.

The Company recognizes revenue associated with the usage agreement and catheter supply arrangements in accordance with Topic 606 as the contract primarily includes variable payments, the catheters are priced at their standalone selling price and the equipment is insignificant in the context of the contract. Revenue is recognized when the performance obligation is satisfied, which is generally upon shipment of the catheter.

Laser Sales

Laser sales consist of sales of DABRA and Pharos laser systems and are included in product sales in the statement of operations. The Company recognizes revenue on laser sales at the point in time that control transfers to the customer. Control of the product typically transfers upon shipment.

Warranty Service Revenue

The Company typically provides a 12-month warranty with the purchase of its laser systems. Customers can extend the warranty period through the purchase of extended warranty service contracts. Extended warranty service contracts are sold with contract terms ranging from 12 to 60 months and cover periods after the end of the initial 12-month warranty period. The warranty provides the customer with maintenance services in addition to the assurance that the laser product complies with agreed-upon specifications. Therefore, the warranty service is treated as a separate performance obligation from the laser system. Warranty services are a stand-ready obligation, and the Company recognizes revenue on a straight-line basis over the service contract term. Warranty service revenue is included in service and other revenue in the Statement of operations. Deferred revenue after adoption of Topic 606 on January 1, 2019 was $2.8 million. Revenue recognized in the three and six months ended June 30, 2019 relating to amounts previously included in deferred revenue was $0.6 million and $1.2 million, respectively. The deferred revenue greater than one year will be recognized during the remaining service period through June 2024.

Distributor Transactions

In certain markets outside the U.S., the Company sells products and provides services to customers through distributors that specialize in medical device products. The terms of sales transactions through distributors are generally consistent with the terms of direct sales to customers. The Company accounts for these transactions in accordance with the Company's revenue recognition policy described herein.

Contracts with multiple performance obligations

Certain of the Company's contracts with customers contain multiple performance obligations. For these contracts, the Company accounts for individual products and services as separate performance obligations if they are distinct, which is if (i) a product or service is separately identifiable from other items in the arrangement and (ii) the customer can benefit from the product or service on its own or with other readily available resources. The transaction price is allocated to the separate performance obligations on a relative standalone selling price basis. The Company determines standalone selling prices based on observable prices of products or services sold separately in comparable circumstances to similar customers.

Significant Financing Component

For multi-year warranty service contracts in which there is a difference between the cash selling price and the consideration in the contract and a significant amount of time between the payment, which is due up-front, and delivery of the services (greater than one year), the Company records an adjustment for significant financing to reflect the time value of money. The Company recognizes revenue associated with the cash selling price and interest expense using the effective interest method as the Company satisfies its performance obligation(s). The amount of interest expense the Company recognizes over the contract term is based on the contract liability balance, which increases for the accrual of interest and decreases as services are provided.

For services contracts that have an original duration of one year or less, the Company uses the practical expedient applicable to such contracts and does not adjust the transaction price for the time value of money.

Practical expedients elected

As part of the Company's adoption of Topic 606, the Company elected to use the following practical expedients:

- not to adjust the promised amount of consideration for the effects of a significant financing component when the Company expects, at contract inception, that the period between the Company's transfer of a promised product or service to a customer and when the customer pays for that product or service will be one year or less;
- to expense costs as incurred for costs to obtain a contract when the amortization period would have been one year or less;
- to exclude government assessed taxes from the transaction price; and
- not to recast revenue for contracts that begin and end in the same fiscal year.

Contract Costs

The Company capitalizes costs to obtain contracts that are considered incremental and recoverable, such as sales commissions. The capitalized costs are amortized to selling, general and administrative expense over the estimated period of benefit of the asset, which is the contract term. The Company elected to use the practical expedient to expense the costs to obtain a contract when the amortization period is less than one year. The Company has contract costs of $0.4 million capitalized at January 1, 2019 and June 30, 2019.

Rental Income

The Company also adopted ASC Topic 842, *Leases*, on January 1, 2019 using the optional transitional method. There was no adjustment to accumulated deficit at January 1, 2019.

The Company also derives income pursuant to product lease agreements for its Pharos laser systems, as operating leases. Consequently, the Company retains title to the equipment and the equipment remains on Company's balance sheet within property and equipment. Depreciation expense on these leased lasers is recorded to cost of revenues on a straight-line basis. The costs to maintain these leased lasers are charged to cost of revenues as incurred.

These lease arrangements contain one lease component (the laser) and one nonlease component (warranty service) for which the Company elected the practical expedient to not separate the nonlease component from the lease component. The Company accounts for the combined lease component as an operating lease and recognizes lease income on a straight-line basis over the lease term. Rental income from lease arrangements for the three and six months ended June 30, 2019 was $0.2 million and $0.3 million, respectively. Rental income from lease arrangements for the three and six months ended June 30, 2018 was $0.1 million and $0.2 million, respectively.

Product warranty—The Company records estimated product warranty costs at the time of sale. Products are warrantied against defects in material and workmanship when properly used for their intended purpose and appropriately maintained. Accordingly, the Company generally replaces catheters that kink or fail to calibrate.The product warranty liability is determined based on historical information such as past experience, product failure rates or number of units repaired, estimated cost of material and labor. The product warranty liability also includes the estimated costs of a product recall. In September 2019, the Company initiated a voluntary recall of its DABRA laser system single-use catheters due to a change in product labeling.

Product warranties are included for the first year after the sale for laser sales. For lasers, the customer may purchase an extended service contract, which is either negotiated in the contract or sold as a separate component for which revenue is recognized over the term of the agreement.

The warranty accrual is included in accrued expenses in the accompanying balance sheets. Warranty expenses are included in cost of revenue in the accompanying statements of operations. Changes in estimates to previously established warranty accruals result from current period updates to assumptions regarding repair and product recall costs and are included in current period warranty expense.

Recently Issued Accounting Pronouncements— In June 2018, the FASB issued ASU 2018-07,*Improvements to Nonemployee Share-Based Payment Accounting.* ASU 2018-07 expands the scope of Topic 718, *Compensation—Stock Compensation*, to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. ASU 2018-07 supersedes Subtopic 505-50, *Equity—Equity-Based Payments to Non-Employees*. The amendments are effective for fiscal years beginning after December 15, 2019. Early adoption is permitted, but no earlier than a company's adoption date of Topic 606, Revenue from Contracts with Customers. The Company is evaluating the effect that this guidance will have on the financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820) - Disclosure Framework - Changes to the Disclosure Requirements for FairValue Measurement*, which is designed to improve the effectiveness of disclosures by removing, modifying and adding disclosures related to fair value measurements. ASU No. 2018-13 is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, and the ASU allows for early adoption in any interim period after issuance of the update. The adoption of this ASU is not expected to have a significant impact on the Company's financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326)*, to require the measurement of expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions and reasonable forecasts and applies to all financial assets, including trade receivables. The main objective of this ASU is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. ASU No. 2016-13 is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. The Company is currently assessing the impact this ASU will have on its financial statements and related disclosures.

Recently Adopted Accounting Pronouncements—On April 5, 2012, President Obama signed the Jump-Start Our Business Startups Act (the "JOBS Act") into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an emerging growth company. As an emerging growth company, the Company may elect to adopt new or revised accounting standards when they become effective for non-public companies, which typically is later than public companies must adopt the standards. The Company has elected to take advantage of the extended transition period afforded by the JOBS Act and, as a result, will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-public companies, which are the dates included below.

In May 2014, FASB issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers (Topic 606)*, and issued subsequent amendments to the initial guidance in August 2015, March 2016, April 2016 and May 2016 within ASU 2015-14, ASU 2016-08, ASU 2016-10 and ASU 2016-12, respectively. ASU 2014-09 supersedes nearly all existing revenue recognition guidance under generally accepted accounting principles in the United States ("US GAAP"). The core principle of ASU 2014-09 is to recognize revenue when promised goods or services are transferred to customers in an amount that reflects the consideration that the Company expects to receive for those goods or services. The Company adopted this accounting standard in the first quarter of fiscal year 2019 using the modified retrospective method. The Company recorded an adjustment to accumulated deficit in the first quarter of 2019 for the following items; (i) differences in the amount of revenue recognized for the Company's revenue streams as a result of allocating revenue based on standalone selling prices to the Company's various performance obligations, (ii) capitalization of incremental contract acquisition costs, such as sales commissions paid in connection with product sales with multi-year service contracts, which will be amortized over the contract service period and (iii) recognized a significant financing component for multi-year service contracts for customers who pay more than one year in advance of receiving the service. The Company recognized the significant financing component over the contract service period. The Company recorded a $21,000 reduction to accumulated deficit as a result of the adoption of Topic 606.

In February 2016, FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). This update requires lessees to recognize, on the balance sheet, a lease liability and a lease asset for all leases with a term greater than 12 months, including operating leases. The update also expands the required quantitative and qualitative disclosures surrounding leases. Under the new standard, the Company will have to recognize, on the balance sheet, a liability representing its lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term. ASU 2016-02 is effective for the Company beginning January 1, 2020, with early adoption permitted. Lessor accounting under ASU 2016-02 is similar to the current model but updated to align with certain changes to the lessee model. Lessors will continue to classify leases as operating, direct financing or sales-type leases. In addition, the new standard requires that lease and nonlease components of a contract be bifurcated, with nonlease components subject to the new revenue recognition standard effective upon adoption of the new leasing standard. Lessors are allowed to elect to account for the lease and nonlease components as a single combined lease component if (i) the timing and pattern of the revenue recognition is the same, and (ii) the combined lease component would continue to be classified as an operating lease.

The Company adopted the standard using the optional transition method provided by ASC Update No. 2018-11, *Leases (Topic 842): Targeted Improvements*. Under this method, the Company applied the new leasing rules on January 1, 2019. As part of the adoption, the Company elected the package of practical expedients permitted under the new lease standard, which among other things, allowed the Company to carry forward the historical lease classification. The Company also elected the practical expedient to combine lease and non-lease components. The Company recognized right-of-use assets and lease liabilities of $3.2 million upon adoption of ASU 2016-02. The new lease standard did not change the Company's accounting for leases in which the Company is the lessor.

Note 3—Short-term Investments
A summary of debt securities by major security type is as follows as of June 30, 2019:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	FairValue
Debt Securities - available-for-sale:				
U.S. T-bills	$ 9,968	$ 3	$ —	$ 9,971
U.S. agency securities	6,705	2	—	6,707
U.S. government securities	19,877	46	—	19,923
Total debt securities	$ 36,550	$ 51	$ —	$ 36,601

All debt securities are due in less than one year.

The following table presents the hierarchy for assets measured at fair value on a recurring basis as of June 30, 2019 and December 31, 2018 (in thousands):

	Total Fair Value	Quoted Market Prices for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Observable Inputs (Level 3)
As of June 30, 2019				
Money market funds	$ 8,168	$ 8,168	$ —	$ —
U.S. T-bills	$ 9,971	$ 9,971	$ —	$ —
U.S. government securities	$ 19,923	$ 19,923	$ —	$ —
U.S. agency securities	$ 6,707	$ —	$ 6,707	$ —
As of December 31, 2018				
Money market funds	$ 61,134	$ 61,134	$ —	$ —

Note 4—Inventories
Inventories consisted of the following (in thousands):

	June 30, 2019	December 31, 2018
Raw materials	$ 2,184	$ 1,333
Work in process	88	88
Finished goods	72	676
Inventories	$ 2,344	$ 2,097

Note 5—Property and Equipment, net
Property and equipment consisted of the following (in thousands):

	June 30, 2019	December 31, 2018
Demonstration lasers and lasers placed with customers	$ 4,524	$ 3,254
Machinery and equipment	1,213	1,135
Automobiles	1,358	1,115
Computer hardware and software	359	366
Leasehold improvements	119	104
Furniture and fixtures	48	82
Construction in progress	—	14
Property and equipment, gross	7,621	6,070
Accumulated depreciation	(1,854)	(1,313)
Property and equipment, net	$ 5,767	$ 4,757

Depreciation expense was $0.4 million and $0.1 million for the three months ended June 30, 2019 and 2018, respectively and $0.7 million and $0.2 million for the six months ended June 30, 2019 and 2018, respectively.

Note 6—Accrued Expenses
Accrued expenses consisted of the following (in thousands):

	June 30, 2019	December 31, 2018
Compensation and related benefits	$ 644	$ 1,734
Accrued warranty (Note 7)	519	112
Accrued services	911	963
Accrued expenses	$ 2,074	$ 2,809

Note 7—Accrued Warranty
Activity in the product warranty accrual is included in accrued expenses above and consists of the following (in thousands):

	For the Six Months Ended June 30, 2019	Year Ended December 31, 2018
Balance at beginning of period	$ 112	$ 87
Increase in warranty accrual	751	287
Claims satisfied	(344)	(262)
Accrued warranty	$ 519	$ 112

Warranty expense was $0.5 million and nil for the three months ended June 30, 2019 and 2018, respectively,and $0.8 million and $0.1 million for the six months ended June 30, 2019 and 2018, respectively. The three and six month periods ended June 30, 2019 includes $0.2 million relating to the recall of catheters. Warranty expense is included in cost of revenue in the accompanying condensed statements of operations.

Note 8—Leases
The Company recognized non-cash right-of-use assets and lease liabilities of $3.2 million upon adoption of ASU 2016-02 on January 1, 2019.The Company has two operating leases for office and manufacturing space which requires it to pay base rent and certain utilities. Monthly rent expense is recognized on a straight-line basis over the term of the leases, which expire in 2027 and 2021.

At June 30, 2019 the weighted average remaining lease term was eight years. The operating leases are included in the balance sheet at the present value of the lease payments at a 7% discount rate using the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term and amount equal to the lease payments in a similar economic environment as the leases do not provide an implicit rate.

For the three and six months ended June 30, 2019, operating lease expense was $0.1 million and $0.3 million, respectively. For the three and six months ended June 30, 2019, cash paid was $0.1 million and $0.2 million, respectively. Rent expense was $0.1 million and $0.2 million for the three and six months ended June 30, 2018, respectively. Operating lease right-of-use assets amortization was $0.1 million and $0.2 million for the three and six months ended June 30, 2019, respectively. Variable costs are de minimis.

The following table presents the lease liabilities within the condensed balance sheet, related to the Company's operating leases as of June 30, 2019 (in thousands):

Years Ending December 31,	
2019 (remaining six months)	$ 250
2020	514
2021	528
2022	432
2023	445
2024	459
Thereafter	1,459
Total operating lease payments	$ 4,087
Less: imputed interest	(1,005)
Total operating lease liabilities	$ 3,082

The following table presents the future minimum rental payments due as of December 31, 2018 (in thousands):

Years Ending December 31,		
2019	$	500
2020		514
2021		528
2022		432
2023		445
Thereafter		1,918
Total	$	4,337

Note 9—Loss per Share

The Company calculates basic loss per share by dividing net loss by the weighted average number of common shares outstanding during the reporting period. Diluted loss per share would reflect the effects of potentially dilutive securities, if any.

Anti-dilutive common share equivalents excluded from the computation of diluted net loss per share at June 30, 2019 consisted of stock options of 1,892,200, restricted stock units of 1,237,895 and Employee Stock Purchase Plan shares of 30,046. At June 30, 2018 basic and diluted loss per share were the same.

Note 10—Stock-Based Compensation

In 2003, the Company adopted a stock option plan (the "2003 Plan"), which authorized the board of directors to grant stock option awards to eligible employees, directors, consultants and service providers (together the "Optionees") of the Company. In April 2012, such plan expired. In 2014, the Company established the 2014 Stock Option Plan (the "2014 Plan") whereby 1,000,000 shares of the Company's common stock were reserved for issuance to eligible Optionees. The 2014 Plan provided for the grant of incentive stock options, non-statutory stock options, stock bonuses and rights to acquire restricted stock. Option awards under the 2014 Plan expired up to a maximum of 10 years from the date of the grant. On May 17, 2018, the Company's board of directors terminated the 2014 Plan.

Obligations under the 2003 Plan and 2014 Plan included time and performance-based awards. For time-based awards, vesting generally occurred over the service period of up to four years. Performance based awards vested at the time that the underlying performance conditions were met.

In prior years, the Company concluded that option awards communicated to Optionees (the "Communicated Option Awards") under the 2003 Plan and 2014 Plan were not validly authorized and therefore were not valid outstanding option awards. Although the Communicated Option Awards were not outstanding options, the Company believed the Communicated Option Awards represented a contractual obligation to the Optionees and therefore the Company classified the Communicated Option Awards as liabilities in the financial statements which were remeasured at fair value each reporting period.

On June 4, 2018, the 2014 Plan was replaced with the 2018 Stock Compensation Plan (the "Compensation Plan") whereby 3,300,000 shares of the Company's common stock were reserved for issuance. On June 4, 2018, the Company's board of directors authorized 1,901,900 replacement equity awards of stock options and, on June 8, 2018, 1,340,832 restricted stock units (collectively, the "Replacement Awards") to the Optionees. On various dates in June 2018, but after the board of directors' authorization, the Replacement Awards were communicated to the Optionees in exchange for the cancellation of, and waiver to any claims related to, the Communicated Option Awards granted under the 2003 Plan and 2014 Plan which were determined to be not validly authorized. The issuance of the Replacement Awards and cancellation of the Communicated Option Awards was treated as a modification. The modification date is the date of the grant of the Replacement Awards, such date being June 4, 2018 for options and June 8, 2018 for restricted stock unit awards. The Company is recognizing the remaining unrecognized compensation cost, as well as any incremental compensation cost of the Replacement Awards of $17.2 million, over the remaining service period of the Replacement Awards, as described below. As the Replacement Awards have been determined to be equity-classified awards, the Company no longer records such awards as liabilities. The Compensation Plan terminated in connection with the adoption of the Company's 2018 Equity Incentive Plan, described below, and, accordingly no new awards are available for issuance under this plan. The Compensation Plan continues to govern awards granted thereunder.

Stock options granted under the Compensation Plan, including those granted as a component of the Replacement Awards, generally vest 33% on the first anniversary of the grant date with the balance vesting monthly over the remaining two years. The restricted stock units granted under the Compensation Plan, including those granted as a component of the Replacement Awards, include a service condition and a performance condition. The service condition generally begins on the grant date and continues through January 2020 and the restricted stock units vest at various times commencing March 27, 2019 until January 2020. The performance condition related to the Company completing its IPO and the vesting of the restricted stock units were contingent upon the achievement of such IPO, which was achieved on October 1, 2018.

In September 2018, the Company's board of directors adopted, and the Company's stockholders approved, the Company's 2018 Equity Incentive Plan (the "2018 Plan"). The 2018 Plan became effective on September 25, 2018. As of June 30, 2019, 1,918,439 shares of common stock are reserved for future issuance pursuant to the Company's 2018 Plan. In addition, the shares reserved for issuance under the 2018 Plan include (1) those shares reserved but unissued under the Compensation Plan as of the date of stockholder approval of the 2018 Plan and (2) shares of common stock subject to or issued pursuant to awards granted under the Compensation Plan that, after the date of stockholder approval of the 2018 Plan, expire or otherwise terminate without having been exercised in full or are forfeited to or repurchased by us (provided that the maximum number of shares that may be added to the 2018 Plan pursuant to (1) and (2) is 3,300,000 shares). The 2018 Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code to the Company's employees and any of the Company's parent and subsidiary corporations' employees, if applicable, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to the Company's employees, directors and consultants and the Company's parent and subsidiary corporations' employees, if applicable, and consultants. The number of shares available for issuance under the Company's 2018 Plan also includes an annual increase on the first day of each fiscal year beginning with our 2019 fiscal year, equal to the least of (1) 1,632,134 shares; (2) five percent (5%) of the outstanding shares of our common stock as of the last day of the immediately preceding fiscal year; or (3) such other amount as our board of directors may determine.

Stock options granted under the 2018 Plan generally vest 25% on the first anniversary of the vesting commencement date with the balance vesting monthly over the remaining three years. Restricted stock units granted under the 2018 plan generally have a vesting schedule with one third of the total number of shares underlying the restricted stock units vesting on the first anniversary of the vesting commencement date and one sixth of the total shares vesting every six months thereafter such that the award will be fully vested on the third anniversary of the vesting commencement date.

A summary of the activity and related information of the Communicated Option Awards classified as liabilities and communicated during the six months ended June 30, 2018, is presented below:

	Liability-Classified Awards (in shares)	Weighted Average Exercise Price	Weighted Average Remaining Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2017	933,500	$ 3.92	3.57	$ 19,676
Granted	170,000	25.00		
Forfeited	(67,000)	5.33		
Cancelled and settled with Replacement Awards	(1,036,500)	7.29		22,442
Outstanding at June 30, 2018	—	$ —	—	$ —
Exercisable at June 30, 2018	—	$ —	—	$ —
Vested and expected to vest at June 30, 2018	—	$ —	—	$ —

A summary of the activity and related information of the stock options issued during the six months ended June 30, 2019 is presented below:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2018	1,920,100	$ 28.59	9.43	$ —
Granted	—	—		
Forfeited	(27,900)	14.03		
Outstanding at June 30, 2019	1,892,200	$ 28.81	8.93	$ —
Exercisable at June 30, 2019	686,212	$ 28.94	8.93	$ —
Vested and expected to vest at June 30, 2019	1,892,200	$ 28.81	8.93	$ —

A summary of the activity and related information of the restricted stock units issued during the six months ended June 30, 2019 is presented below:

	Restricted Stock Units	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2018	1,494,111	$ 26.91
Granted	285,317	4.06
Vested and Released	(522,493)	28.94
Forfeited	(19,040)	9.35
Outstanding at June 30, 2019	1,237,895	$ 21.20

Stock-based compensation expense recorded in operating expenses was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Selling, general and administrative	$ 6,364	$ 3,588	$ 12,683	$ 3,958
Research and development	276	831	1,186	909
Stock-based compensation in operating expenses	$ 6,640	$ 4,419	$ 13,869	$ 4,867

Stock-based compensation amounts of $0.5 million and $0.3 million were capitalized to inventory and property and equipment during the three months ended June 30, 2019 and 2018, respectively. Stock-based compensation of $1.0 million and $0.3 million were capitalized to inventory and property and equipment during the six months ended June 30, 2019 and 2018, respectively.

Unrecognized compensation expense for stock options issued as of June 30, 2019 was $11.0 million and is expected to be recognized over a weighted-average period of 1.9 years. Unrecognized compensation expense for the restricted stock units as of June 30, 2019 was $11.6 million and is expected to be recognized over a weighted-average period of 0.8 years.

The Communicated Option Awards were presented as a stock-based compensation liability, until June 4, 2018, when they were settled and reclassified to equity. The Communicated Option Awards were revalued at each reporting period with the change in fair value recorded to compensation expense.

The fair value of the Communicated Option Awards was estimated using the Black Scholes option pricing model and the assumptions used in the model are noted in the following table:

	Six Months Ended June 30,
	2018
Risk-free interest rate	2.49 %
Volatility	34.13 %
Expected dividend yield	0.00 %
Expected life	2.9

The weighted-average fair value for Communicated Option Awards granted during the three months ended June 30, 2018 was $14.32 and during the six months ended June 30, 2018 was $14.00. The Company's shares were not traded on any public market during the term of the Communicated Option Awards. The common stock value as of the date of grant was based on the share price of recent equity issuances, if available. If there were no such recent transactions, the Company's share valuation was estimated. As of the date of the modification of the Communication Option Awards, which resulted in the settlement of the stock-based compensation liability, the common stock price was estimated utilizing a hybrid method, a combination of the Probability Weighted Expected Return Method ("PWERM") and Option Pricing Model ("OPM"). The estimate incorporated a near-term IPO scenario using PWERM weighted at 80%. Other near-term exit events, a long-term stay private case, and dissolution were all considered as non-IPO scenarios using OPM, and were weighted at 20%. The estimate also reflected a 10% and 15% discount for lack of marketability under PWERM and OPM, respectively. The risk free interest rate approximates the implied yield available on United States Treasury securities with an equivalent remaining term. Expected volatility is based on the historical volatilities of certain "guideline" companies. Expected dividend yield is based on dividends historically paid by the Company. The expected life is based on the "simplified" method using the average of the term and vesting period.

No stock options were issued under the 2018 Plan during the six months ended June 30, 2019.

The fair value of the stock options issued under the Compensation Plan was estimated using the Black Scholes option pricing model and the weighted-average assumptions used in the model are noted in the following table:

	Three Months Ended June 30, 2018	Six Months Ended June 30, 2018
Risk-free interest rate	2.84 %	2.84 %
Volatility	42.18 %	42.18 %
Expected dividend yield	0.00 %	0.00 %
Expected life	6.0	6.0

The Company's 2018 Employee Stock Purchase Plan (ESPP) became effective in September 2018. A total of 446,160 shares of common stock are available for sale under our ESPP as of June 30, 2019. Under the Company's ESPP, eligible employees are allowed to purchase the Company's stock at a discounted price, which is 85% of the lower market price of the Company's common stock at the beginning or at the end of the six-month purchase period. The Company issued 9,207 shares in exchange for $37,000 in the six months ended June 30, 2019 under the ESPP. The number of shares of common stock that will be available for sale under the ESPP also includes an annual increase on the first day of each fiscal year beginning with our 2019 fiscal year, equal to the least of (1) 296,752 shares; (2) one and one quarter percent (1.25%) of the outstanding shares of our common stock as of the last day of the immediately preceding fiscal year; or (3) such other amount as the administrator may determine.

Note 11—Commitments and Contingencies

Securities Litigation

On June 7, 2019, a putative securities class action complaint captioned *Derr v. Ra Medical Systems, Inc., et. al.,* (Civil Action no. 19CV1079 LAB NLS) was filed in the United States District Court for the Southern District of California against the Company, certain current and former officers and directors, and certain underwriters of the Company's IPO. The complaint alleges that the defendants made material misstatements or omissions in the Company's registration statement that caused the stock price to drop. The court appointed a Lead Plaintiff on September 5, 2019, and on October 2, 2019, it ordered that Lead Plaintiff file an amended complaint within forty-five days after the Company files with the SEC its Form 10-Q for the period ended June 30, 2019. Management intends to vigorously defend the Company against this lawsuit. At this time, the Company cannot predict how a court or jury will rule on the merits of the claims and/or the scope of the potential loss in the event of an adverse outcome. Should the Company ultimately be found liable, the liability could have a material adverse effect on our financial condition and our results of operations for the period or periods in which it is incurred. The Company is unable to predict the ultimate outcome and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

On October 1, 2019, a shareholder derivative complaint captioned *Noel Borg v. Dean Irwin, et. al* (Civil Action no. 1:99-cm-09999) was filed in the United States District Court for the District of Delaware against certain current and former officers and directors, purportedly on behalf of the Company, which is named as a nominal defendant in the action. The complaint alleges breaches of fiduciary duty, unjust enrichment, waste, and violations of Section 14(a) of the Securities Exchange Act of 1934. On October 21, 2019, pursuant to the parties' stipulation, the court stayed the derivative lawsuit until the related class action is resolved.

Governmental Investigations

As previously announced in the Form 8-K filed on August 12, 2019, the Audit Committee of Ra Medical's Board of Directors (the "Audit Committee") was conducting an investigation of certain allegations raised by a former employee. The Company announced the Audit Committee's findings in the Form 8-K filed on October 31, 2019. The primary investigative findings were: (i) the DABRA catheter frequently failed to calibrate and occasionally overheated, posing a risk of injury to physicians and patients; (ii) our explanations regarding our fourth quarter 2018 and first quarter 2019 sales created a risk of confusion because they did not explicitly reference inconsistent DABRA catheter performance and catheter failures; (iii) we failed to timely make at least two Medical Device Reports, or MDRs, to the FDA; (iv) we, out of a concern for the DABRA catheters' performance, engaged in systematic efforts to replace product held by customers, which constituted product recalls, but were not documented as such, (v) we lack documentation of sufficient detail and specificity to support certain payments to physicians, ostensibly for training and consulting services, and as to three physicians did not accurately reflect the purpose and nature of approximately $300,000 of payments, which could be perceived as an improper attempt to obtain business or to gain special advantage, (vi) while the indication for use in the 510(k) clearance we obtained for the DABRA system is not for atherectomy, our salespeople were instructed to characterize DABRA as performing atherectomy and to encourage doctors to seek reimbursement using atherectomy codes, (vii) our determinations to direct potentially valuable benefits and opportunities to doctors were informed in part by sales prospects, and (viii) we received complaints regarding regulatory or compliance concerns that, because they implicated executive officers, should have been brought to the attention of the Board or the Audit Committee, but were not. The Audit Committee, in reviewing the allegations, identified certain behavior inconsistent with our Code of Ethics and Conduct and related policies.

As also previously announced, the Company voluntarily contacted the SEC's Enforcement Division regarding the Audit Committee's investigation and remains in discussion with such Agency.

In October 2019, the Department of Justice, or DOJ, served the Company with a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning whether the Company fraudulently obtained 510(k) marketing clearance for the Company's devices marketed under the trade name DABRA, whether the Company marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether the Company paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b. In response to the DOJ's CID, the Company reviewed the facts and circumstances of the clinical study used to support its 510(k) marketing clearance and has now completed such review. Following this review, the Company believes there is (i) adequate evidence to support the safety and efficacy reported in the study submitted with the 510(k) application, and (ii) no observations that would have a major impact on the reported results of the study. The Company is cooperating fully with the DOJ's request in connection with the Civil Investigative Demand. The Company is unable to predict the ultimate outcome and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

The Company received a letter on November 13, 2019, from the Los Angeles Office of the Division of Enforcement of the Securities and Exchange Commission (the "SEC"), in which the SEC notified the Company that it is conducting an investigation. The Company has been, and intends to continue, cooperating with the SEC in this investigation. The Company is unable to predict the ultimate outcome and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

On November 21, 2019, we became aware that the Criminal Division, Fraud Section of the U.S. Department of Justice has an open investigation related to the Company. At this time, it is unclear if the Company is a target in this investigation. The Company intends to cooperate with the DOJ criminal investigation.

Other Litigation

On August 30, 2018, Strata Skin Sciences, Inc. ("Strata") and Uri Geiger, a member of the board of directors of Strata Skin Sciences, Inc. filed an action against the Company in Pennsylvania State Court, Montgomery County (Civil Action No. 18-21421) (the "Pennsylvania Case"), requesting declaratory relief that: (1) Strata and Mr. Geiger are not liable for tortious interference, defamation, libel, or unfair competition based on an e-mail by Mr. Geiger to an investment bank (the "Geiger Email"); (2) Strata and Mr. Geiger made no actionable statements about the Company to such investment bank; (3) the Company cannot enforce the 2011 settlement and release agreement between the Company and PhotoMedex, Inc. ("Settlement Agreement") against Strata; and (4) that any dispute regarding the Geiger Email does not relate to the Settlement Agreement. The action filed by Strata and Mr. Geiger does not request any monetary damages. The Company believes that the action by Strata and Mr. Geiger was filed as a response to a letter that the Company sent to Strata on August 22, 2018 demanding that Strata and Mr. Geiger cease and desist from making statements about alleged patent infringement and affirmatively retract the statements made in the Geiger Email. The Company was served with the action on August 31, 2018, and responded with preliminary objections to the action on September 19, 2018. The court overruled the Company's preliminary arguments on April 29, 2019. The Company filed a motion for summary judgment on July 17, 2019 for the court to rule that the Company can enforce the Settlement Agreement against Strata. The Company believes that Strata's action in the Pennsylvania Case lacks merit, and plans to vigorously oppose the action on procedural and substantive grounds within the prescribed time limits. No loss is probable or reasonably possible as of June 30, 2019.

On May 16, 2019, the Company filed an action against Strata, Mr. Geiger and Accelmed Growth Partners, L.P. and its affiliates (collectively, the "Strata Parties") in the United States District Court for the Southern District of California (Civil Action No. 19-cv-0920-AJB-MSB (the "California Case")) alleging (1) violation of the Settlement Agreement, (2) tortious interference with economic advantage, and (3) trade libel based on the Geiger Email. In the lawsuit, the Company alleges, among other things, that the statements in the Geiger Email regarding alleged patent infringement constitute a breach of the Settlement Agreement, that the Strata Parties employed deceptive practices designed to delay the Company's initial public offering and reduce the amount of capital raised by the Company, and that statements in the Geiger Email regarding patent infringement, off label promotion and reimbursement constitute trade libel. The Company seeks an injunction barring the Strata Parties' alleged conduct, monetary damages, and other available legal and equitable relief. The Company amended its complaint on July 25, 2019 to allege violations of the Lanham Act's prohibition on false advertising. The Strata Parties filed motions to dismiss on August 25, 2019, and the Company responded with its oppositions to the motions to discuss on September 27, 2019. The Court has set a hearing date of December 19, 2019 on the motions to dismiss.

Note 12—Segment Information

The Company has organized its business into two operating segments based on the product specialties: the vascular segment and the dermatology segment.

In deciding how to allocate resources and assess performance, the Company's chief operating decision maker regularly evaluates the sales and gross profit of these segments. Amounts included within selling, general and administrative expense and research and development expense are general to the Company and not specific to a particular segment; therefore, these amounts are not evaluated by the Company's chief operating decision maker on a segmented basis.

The following tables summarize segment performance (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Vascular	$ 434	$ 94	$ 895	$ 184
Dermatology	1,719	1,142	3,006	2,021
Net revenue	$ 2,153	$ 1,236	$ 3,901	$ 2,205
Vascular	$ 1,423	$ 220	$ 2,590	$ 471
Dermatology	1,310	770	2,085	1,255
Cost of revenue	$ 2,733	$ 990	$ 4,675	$ 1,726
Vascular	$ (989)	$ (126)	$ (1,695)	$ (287)
Dermatology	409	372	921	766
Gross (loss) profit	$ (580)	$ 246	$ (774)	$ 479

Generally, all assets are common assets, except for lasers placed with customers, which are a subset of property and equipment. The net book value of demonstration lasers and lasers placed with customers aggregated in the vascular segment was $2.9 million and $2.2 million as of June 30, 2019 and December 31, 2018, respectively. The net book value of the demonstration lasers and lasers placed with customers aggregated in the dermatology segment was $0.9 million and $0.7 million as of June 30, 2019 and December 31, 2018, respectively.

No sales to an individual customer or country other than the United States accounted for more than 10% of net revenue for the three and six months ended June 30, 2019 and 2018. Net revenue, classified by the major geographic areas in which our customers are located, was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
United States	$ 1,949	$ 1,107	$ 3,601	$ 1,936
All other countries	204	129	300	269
Net revenue	$ 2,153	$ 1,236	$ 3,901	$ 2,205

ITEM 2. MANAGEMENT' S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Special Note Regarding Forward Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available. This section should be read in conjunction with our unaudited condensed financial statements and related notes included in Part I, Item 1 of this report. The statements contained in this Quarterly Report on Form 10-Q that are not historical facts are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended.

Forward-looking statements can be identified by words such as "believe," "anticipate," "may," "might," "can," "could," "continue," "depends," "expect," "expand," "forecast," "intend," "predict," "plan," "rely," "should," "will," "may," "seek," or the negative of these terms or and other similar expressions, although not all forward-looking statements contain these words. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements.

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including, but not limited to, those described in "Risk Factors". These forward-looking statements reflect our beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Quarterly Report on Form 10-Q and are subject to risks and uncertainties. We discuss many of these risks in greater detail in the section entitled "Risk Factors" included in Part II, Item 1A and elsewhere in this report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We qualify all of the forward-looking statements in this Quarterly Report on Form 10-Q by these cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources.

Filing Delay; Audit Committee Investigation

The filing of this quarterly report on Form 10-Q was delayed allowing the Audit Committee of our board of directors to conduct an investigation related to an initially anonymous complaint, as well as additional matters discovered during the course of the investigation. As a result of the findings from the investigation as described below, it was determined that that no adjustments to past financial statements were appropriate or required. With the filing of this report along with our Quarterly Report on Form 10-Q for the third quarter ended September 30, 2019 we are current with our SEC filing obligations.

The Audit Committee's primary investigative findings were: (i) the DABRA catheter frequently failed to calibrate and occasionally overheated, posing a risk of injury to physicians and patients; (ii) our explanations regarding our fourth quarter 2018 and first quarter 2019 sales created a risk of confusion because they did not explicitly reference inconsistent DABRA catheter performance and catheter failures; (iii) we failed to timely make at least two Medical Device Reports, or MDRs, to the FDA; (iv) we, out of a concern for the DABRA catheters' performance, engaged in systematic efforts to replace product held by customers, which constituted product recalls, but were not documented as such, (v) we lack documentation of sufficient detail and specificity to support certain payments to physicians, ostensibly for training and consulting services, and as to three physicians did not accurately reflect the purpose and nature of approximately $300,000 of payments, which could be perceived as an improper attempt to obtain business or to gain special advantage, (vi) while the indication for use in the 510(k) clearance we obtained for the DABRA system is not for atherectomy, our salespeople were instructed to characterize DABRA as performing atherectomy and to encourage doctors to seek reimbursement using atherectomy codes, (vii) our determinations to direct potentially valuable benefits and opportunities to doctors were informed in part by sales prospects, and (viii) we received complaints regarding regulatory or compliance concerns that, because they implicated executive officers, should have been brought to the attention of the Board or the Audit Committee, but were not.

The Audit Committee, in reviewing the allegations, identified certain behavior inconsistent withour Code of Ethics and Conduct and related policies involving certain of our former executive officers and employees. This resulted in material weaknesses in our control environment – see *Item 4. Controls and Procedures* for more detail.

The Audit Committee made a number of recommendations which the board of directors has adopted, including: separation of certain former executives and employees, implementing additional and enhanced policies and training, strengthening our quality regulatory systems, and adopting certain enhanced controls related to the matters investigated.

In addition, we have continued to take steps in an effort to remedy the inconsistencies in the Company's DABRA catheter performance, including hiring a VP, Quality, Regulatory and Clinical, conducting extensive internal and external audits of its quality systems, clinical trial data and manufacturing process, as well as initiating the previously announced voluntary recall of DABRA catheters.

The Company voluntarily contacted the SEC's Enforcement Division regarding the Audit Committee's investigation and learned on November 13, 2019 that the SEC is conducting an investigation . The Company intends to cooperate with the SEC's investigation. As previously reported, in October 2019, the Department of Justice ("DOJ") provided the Company with a Civil Investigative Demand ("CID") seeking information with respect to a False Claims Act investigation concerning, among other items, whether the Company fraudulently obtained 510(k) marketing clearance for its ablation devices marketed under the trade name DABRA (an item that had not been investigated by the Audit Committee). The Company intends to cooperate with the DOJ's civil investigation. In response to the DOJ's CID, the Company reviewed the facts and circumstances of the clinical study used to support its 510(k) marketing clearance and has now completed such review. Following this review, the Company believes there is (i) adequate evidence to support the safety and efficacy reported in the study submitted with the 510(k) application, and (ii) no observations that would have a major impact on the reported results of the study.

In November 2019, the Company also learned that the DOJ is conducting a criminal investigation.At this time, it is unclear if the Company is a target in this investigation. The Company intends to cooperate with the DOJ's criminal investigation.

Overview

We are a commercial-stage medical device company leveraging our advanced excimer laser-based platform for use in the treatment of vascular and dermatological immune-mediated inflammatory diseases. We believe our products enhance patients' quality of life by restoring blood-flow in arteries and clearing chronic skin conditions. Following the evaluation period for DABRA and once our customers decide to continue using DABRA in their facilities, we typically enter into DABRA laser commercial usage agreements or DABRA laser placement acknowledgements with each customer, which we refer to collectively as Usage Agreements. The terms of the Usage Agreements vary by customer, but each Usage Agreement provides for the specific terms of continued use of DABRA, including periodic maintenance fees and do not provide for a minimum purchase obligation. As of June 30, 2019, we had 83 lasers at customer sites under signed Usage Agreements with varying volumes of purchases.

DABRA is cleared by the U.S. Food and Drug Administration, or FDA, as a device for crossing chronic total occlusions, or CTOs, in patients with symptomatic infrainguinal lower extremity vascular disease and with an intended use for ablating a channel in occlusive peripheral vascular disease. DABRA is used as a tool in the treatment of peripheral artery disease, or PAD, a form of peripheral vascular disease, which commonly occurs in the legs. These procedures are typically referred to in the medical community as atherectomy procedures, which the medical community commonly defines as any removal by surgery or specialized catheterization of an atheroma, or blockage, in an artery. Even though the medical community refers to it as atherectomy, DABRA is not currently cleared by the FDA for atherectomy. Nevertheless, third-party health payers can reimburse a procedure performed by a device which is not cleared or approved for a specific indication or procedure, if the physician determines the device and procedure are medically appropriate for a particular patient. Payers and the medical community can take a broader view than FDA in recognizing the scope of appropriate device use. In order to more effectively market DABRA, we currently are pursuing expanded indications for use for DABRA to include an atherectomy indication for use, which the FDA currently defines to include a prespecified improvement in luminal patency, or a prespecified increase in the openness of the artery at a pre-defined time point. To satisfy the FDA's data requirements to support an atherectomy indication, we submitted an investigational device exemption, or IDE, designed to gather the clinical data necessary to determine substantial equivalence in support of the atherectomy indication. This IDE was approved in July 2019. However, as a result of our voluntary DABRA catheter recall, discussed below, we plan to submit updates to the IDE and enroll the first patient in the first quarter of 2020. We believe the incremental cost of obtaining the atherectomy indication will not be material.

In the fourth quarter of 2018, we announced the prospective long-term revascularization study of DABRA titled REvascularization RateS and Clinical OUtcomes with DABRA Laser. A Long-Term 2-year Study (RESULTS). This registry is being conducted to measure the benefit and the safety profile of DABRA over a longer time frame (two years) than our pivotal trial, which had a 180 day follow up. We have case reports of patients with extended freedom from restenosis even out to over four years, which prompted us to study longer-term outcomes more closely. We treated the first patient in the registry in the second quarter of 2019 and we intend to provide additional updates on a periodic basis throughout the study.

In the future, we intend to pursue additional uses for DABRA, including seeking regulatory clearance or approval for the use of DABRA as a tool for the treatment of vascular blockages associated with coronary artery disease, or CAD, in-stent restenosis, and other venous and arterial occlusions, or blockages in the veins or arteries, although we are not currently pursuing any of these additional uses at this time. There can be no assurance that DABRA will receive the necessary clearances for these additional indications. The DABRA laser system is based on the same core technology and utilizes a similar excimer laser as Pharos, a medical device that we have marketed as a tool for the treatment of proliferative skin conditions since October 2004. Pharos is designed for use in the treatment of inflammatory skin conditions and is FDA cleared as a tool used in the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma. Because DABRA and Pharos are both based on our core excimer laser technology platform and deploy similar mechanisms of action, we benefit from economies of scale in product development, manufacturing, quality assurance and distribution.

DABRA is our minimally-invasive excimer laser and single-use catheter system that is used by physicians as a tool in the endovascular treatment of vascular blockages resulting from lower extremity vascular disease, a form of PAD, both above- and below-the-knee, by breaking down plaque to its fundamental chemistry, such as proteins, lipids and other chemical compounds, eliminating blockages by essentially dissolving them without generating potentially harmful particulates. The accumulation of plaque in arteries, which is a result of lower extremity vascular disease, most commonly occurs in the pelvis and legs. Plaque accumulation, known as atherosclerosis, causes the narrowing of arteries, thereby reducing the flow of oxygenated blood to tissue and organs. If vascular blockages are left untreated, they can increase the risk of heart attack, stroke, amputation or death. In addition, studies have shown that older patients who undergo a major lower extremity amputation face a significant increased mortality risk. Major risk factors for PAD include age, smoking, diabetes and obesity. Despite its prevalence, PAD is underdiagnosed and undertreated relative to many other serious vascular conditions, including CAD, in part because up to half of the PAD population is asymptomatic, or shows no symptoms, and many dismiss symptoms as normal signs of aging. Recent analysis suggests that approximately 17.6 million people in the U.S. suffer from PAD. However, only 20-30% of PAD patients are actively being treated. We anticipate revenue from this recently commercialized business segment to grow over time. Our sales strategy includes either selling the DABRA laser with a transfer in title or placing it in high-volume practices for a nominal periodic fee while we retain title. We sell extended warranty service contracts for our lasers that have been purchased. Each vascular procedure requires the one-time use of our proprietary catheters which we expect to be the primary source of revenue for the vascular segment. Therefore, under both the sale and periodic fee options, we anticipate recurring revenue in catheter sales for each active laser in operation. We currently use our internal sales force in the U.S. and we utilize distributors outside the U.S.

Pharos is our excimer laser device that emits highly concentrated ultraviolet light and is used as a tool in the treatment of dermatological skin disorders. Physicians use Pharos by applying 308 nanometer ultraviolet light to the skin. The FDA has granted 510(k) clearance to market Pharos in the U.S. for psoriasis, vitiligo, atopic dermatitis, and leukoderma. Pharos was granted CE mark approval in September of 2016 for use in the treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma by the application of UVB ultraviolet light. We have also received clearance to market Pharos from the China Food and Drug Administration, or CFDA and the Saudi Food and Drug Authority, or SFDA, in the applicable jurisdictions. Pharos was commercialized in 2004 and we have shipped over 1,000 systems to customers globally through June 30, 2019. Pharos is in use in nearly every U.S. state and in over 20 markets including several non-U.S. countries. While we have entered into periodic fee arrangements, our primary strategy is to sell Pharos. We recognize additional recurring revenue from the sale of extended warranty service contracts for Pharos. In July 2019, we announced updates to the design and performance of Pharos, including updated software designed to deliver faster treatments, as well as a more ergonomic handpiece.

We incurred net losses of $29.8 million and $30.8 million for the six months ended June 30, 2019 and the year ended December 31, 2018, respectively, and had an accumulated deficit of $90.0 million as of June 30, 2019. As of June 30, 2019, we had available cash and cash equivalents and short-term investments of approximately $48.4 million and had current liabilities of approximately $6.3 million and long-term liabilities of approximately $4.3 million, which includes operating lease liabilities relating to our building leases of $2.8 million and equipment financings of $0.5 million. Since inception, we have financed our operations primarily through sales of our products and services, the net proceeds from our initial public offering, and, to a lesser extent, private placements of our common stock and equipment financing arrangements. We expect to continue to incur net losses for the near term as we commercialize our products in the U.S., including remedying the inconsistencies in our DABRA catheter performance, optimizing our manufacturing facilities, continuing research and development efforts, and seeking regulatory clearance for new products and product enhancements, including new indications, both in the U.S. and in select non-U.S. markets. We may need additional funding to pay expenses relating to our operating activities, including selling, general and administrative expenses and research and development expenses. If needed, adequate funding may not be available to us on commercially acceptable terms, or at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, financial condition, and results of operations.

Recent Developments

In the fourth quarter of 2018 and first quarter of 2019, we experienced inconsistencies in our DABRA catheter performance. We believed at the time, that these inconsistencies related to controlling the temperature of the oven used in the manufacturing process, which we had previously referred to as production limitations. These inconsistencies led to an increase in the number of catheters that failed to calibrate at customer sites, despite calibrating successfully during our quality assurance steps. During that same period, our sales team noted higher rates of non-calibration of catheters at customer physician offices. The higher than anticipated rates of non-calibration resulted in customer dissatisfaction with the product, resulting in what we believe to be fewer purchases by our customers and therefore lower revenue during the fourth quarter of 2018 and in 2019, however, such amount is not determinable. In response, we upgraded our temperature control regulator and made certain changes in our production flow and validated the changes that we believed corrected the production limitations. After manufacturing several well-performing lots with this upgraded process, the percentage of catheters that failed to calibrate began to increase after decreasing during April and May 2019. After collecting field data and performing internal testing, we observed that while catheters can perform satisfactorily up to one year, catheters that were more than two months from sterilization, had a significantly higher rate of non-calibration than catheters that were within two months from sterilization. As a result, in September 2019, we initiated a recall of our catheters to relabel them from a 12 month to a two month shelf life, which we believe will significantly reduce the number of catheters that fail to calibrate. The product related costs associated with the recall are aggregated in cost of revenue in the accompanying condensed statements of operations and amounted to $0.2 million for the three and six months ended June 30, 2019. Until our DABRA catheters consistently calibrate in the field, DABRA sales may continue to be adversely impacted and we will continue to incur additional costs.

In addition, we implemented certain operational efficiency and cost-savings initiatives intended to align our resources with our product strategy, reduce our operating expenses, and manage our cash flows. These cost efficiency initiatives include targeted workforce reductions of our sales and marketing teams. We have reduced the size of our DABRA sales force from 34 employees as of June 30, 2019 to 6 employees as of November 11, 2019. In the near term, we intend to focus on servicing priority existing accounts while we prioritize remedying the inconsistencies in our DABRA catheter performance.

Initial Public Offering

On October 1, 2018, we closed on our initial public offering, or IPO, of 4,485,000 shares of common stock at an offering price of $17.00 per share, which included the full exercise of the underwriters' option to purchase 585,000 additional shares of our common stock. We raised a total of $76.2 million in gross proceeds from the IPO, or approximately $67.3 million in net proceeds after deducting underwriting discount and commissions of $5.3 million and offering costs of $3.6 million. Our registration statement on Form S-1 relating to our IPO was declared effective by the Securities and Exchange Commission on September 26, 2018.

Components of our Results of Operations

Net revenue

Product sales consist of the sale of DABRA and Pharos lasers, the sale of catheters for use with the DABRA laser and the sale of consumables and replacement parts.

Service and other revenue consists primarily of sales of extended warranty service contracts which we recognize over the contract period and billable services, including repair activity, which is recognized when the service is provided. It also includes income from the rental of our lasers.

We currently use our internal sales force in the U.S., and we utilize distributors outside the U.S. in markets where we have received regulatory approval. We expect to continue to seek regulatory approvals for our products in additional strategic markets.

Cost of revenue and gross margin

Cost of revenue for product sales consists primarily of costs of components for use in our products, the materials and labor that are used to produce our products, and the manufacturing overhead that directly support production.

Cost of revenue for service and other includes the cost of maintaining and servicing the warranties on our products.

We expect cost of revenue to increase to the extent our total revenue grows.

We calculate gross margin as gross profit divided by total net revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily production volumes, the cost of direct materials, discounting practices, manufacturing costs, product yields, headcount and cost-reduction strategies. We expect our gross margin to be negatively impacted in the near term as we focus on remedying the inconsistencies in our product performance. We intend to use our design, engineering and manufacturing capabilities to further advance and improve the efficiency of our manufacturing processes, which we believe will reduce costs and increase our gross margin over the longer term. Even with consistent product performance, gross margin will likely fluctuate from quarter to quarter as we continue to adopt new manufacturing processes and technologies.

Research and development expenses

Research and development, or R&D, expenses consist of applicable personnel, consulting, materials and clinical trial expenses. R&D expenses include:

- certain employee-related expenses, including salaries, benefits, travel expense and stock-based compensation expense;
- cost of outside consultants who assist with technology development, and clinical affairs;
- cost of clinical studies to support new products and product enhancements, including expanded indications; and
- supplies used for internal research and development and clinical activities.

We expense R&D costs as incurred. In the future, we expect R&D expenses to increase as we continue to develop new products, enhance existing products and technologies and perform activities related to obtaining additional regulatory approval. However, we expect R&D expenses as a percentage of total revenue to vary over time depending on the level and timing of our new product development efforts, as well as our clinical development, clinical trials and studies and other related activities.

Selling, general and administrative expenses

Selling, general and administrative, or SG&A, expenses consist of employee-related expenses, including salaries, benefits, travel expense, sales commissions and stock-based compensation expense. Other SG&A expenses include promotional activities, marketing, conferences and trade shows, professional services fees , including legal, audit and tax fees, insurance costs, general corporate expenses, allocated facilities-related expenses and shipping and handling costs. In August 2019, we began implementing certain operational efficiency and cost savings initiatives intended to align our resources with our product strategy, reduce our operating expenses, and manage our cash flows. These cost efficiency initiatives include targeted workforce reductions of our sales and marketing teams. We have reduced the size of our DABRA sales force from 34 employees as of June 30, 2019 to 6 employees as of November 11, 2019. In the near term, we intend to focus on servicing priority existing accounts while we prioritize remedying the inconsistencies in our DABRA catheter performance. We expect continued increases in legal, accounting, insurance and other expenses associated with the legal proceedings discussed in Note 11, “Commitments and Contingencies,” in the notes to the condensed financial statements and with being a public company, compared to the three and six months ended June 30, 2018 when we were privately held.

Results of Operations

The following table shows our results of operations (in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	Change $	2019	2018	Change $
Statements of operations data:						
Net revenue						
Product sales	$ 1,284	$ 475	$ 809	$ 2,178	$ 710	$ 1,468
Service and other	869	761	108	1,723	1,495	228
Total net revenue	2,153	1,236	917	3,901	2,205	1,696
Cost of revenue						
Product	1,935	647	1,288	3,330	989	2,341
Service and other	798	343	455	1,345	737	608
Total cost of revenue	2,733	990	1,743	4,675	1,726	2,949
Gross (loss) profit	(580)	246	(826)	(774)	479	(1,253)
Operating expenses:						
Selling, general and administrative	13,789	7,615	6,174	27,018	10,254	16,764
Research and development	979	1,022	(43)	2,510	1,308	1,202
Total operating expenses	14,768	8,637	6,131	29,528	11,562	17,966
Operating loss	(15,348)	(8,391)	(6,957)	(30,302)	(11,083)	(19,219)
Other income (expense), net	231	(1)	232	511	(2)	513
Loss before income taxes	(15,117)	(8,392)	(6,725)	(29,791)	(11,085)	(18,706)
Income tax expense	5	3	2	5	3	2
Net loss	$ (15,122)	$ (8,395)	$ (6,727)	$ (29,796)	$ (11,088)	$ (18,708)

By reportable segments

We organize our business into two operating segments based on the product specialties: the vascular segment and the dermatology segment. In deciding how to allocate resources and assess performance, we regularly evaluate the net revenue and gross profit of these segments. Amounts included within selling, general and administrative expense and research and development expense are general to us and not specific to a particular segment; therefore, these amounts are not evaluated by us on a segmented basis. Additional information on our reportable segments is contained in Note 12 to the interim condensed financial statements included in Part I, Item 1 in this Quarterly Report on Form 10-Q.

Net revenue

The following table shows our net revenue from our two segments (in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	Change $	2019	2018	Change $
Vascular	$ 434	$ 94	$ 340	$ 895	$ 184	$ 711
Dermatology	1,719	1,142	577	3,006	2,021	985
Total net revenue	$ 2,153	$ 1,236	$ 917	$ 3,901	$ 2,205	$ 1,696

Vascular

Net revenue was $0.4 million and $0.1 million for the three months ended June 30, 2019 and 2018, respectively. The $0.3 million increase was due to increased catheter sales following the completion of our initial 12-month commercial launch in June 2018 resulting in a full quarter of production revenue in the current period compared to nominal catheter sales in the same period in the prior year.

Net revenue was $0.9 million and $0.2 million for the six months ended June 30, 2019 and 2018, respectively. The $0.7 million increase was due to increased catheter sales following the completion of our 12-month commercial launch period in June 2018, resulting in a full six months of production revenue in the current period compared to nominal catheter sales in the same period in the prior year.

We expect our revenue to decrease in the near term with our reduced sales force as we focus on remedying theinconsistencies in our DABRA catheter performance. Over the longer term, if we are able to improve the consistency of our catheter performance and introduce design changes to the catheter, we believe we will be able to increase our vascular revenue.

Dermatology

Net revenue was $1.7 million and $1.1 million for the three months ended June 30, 2019 and 2018, respectively. The increase of $0.6 million was due primarily to increases of $0.5 million in direct unit product sales and $0.1 million from service revenue.

Net revenue was $3.0 million and $2.0 million for the six months ended June 30, 2019 and 2018, respectively. The increase of approximately $1.0 million was due primarily to an increase of $0.8 million in direct unit product sales and $0.2 million in service revenue.

Cost of revenue

The following table shows our cost of revenue from our two segments (in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	Change $	2019	2018	Change $
Vascular	$ 1,423	$ 220	$ 1,203	$ 2,590	$ 471	$ 2,119
Dermatology	1,310	770	540	2,085	1,255	830
Total cost of revenue	$ 2,733	$ 990	$ 1,743	$ 4,675	$ 1,726	$ 2,949

Vascular

Cost of revenue was $1.4 million and $0.2 million for the three months ended June 30, 2019 and 2018, respectively. The increase of $1.2 million was due to increased labor, material and overhead costs to support the increased sales of our products and maintenance costs and depreciation expense related to our lasers at our customer sites and continued efforts to remedy the inconsistencies in our DABRA catheter performance and warranty costs of replacement units, including $0.2 million relating to the recall of catheters.

Cost of revenue was $2.6 million and $0.5 million for the six months ended June 30, 2019 and 2018, respectively. The $2.1 million increase was due to (i) stock-based compensation expense due to continued expenses related to the modification accounting treatment of Replacement Awards that took place in the second quarter of 2018, (ii) increased labor, material and overhead costs to support the increased sales of our products (iii) continued efforts to remedy the inconsistencies in our DABRA catheter performance and warranty costs of replacement units, including $0.2 million relating to the recall of catheters (iv) maintenance costs and depreciation expense related to our lasers at our customer sites.

Dermatology

Cost of revenue was $1.3 million and $0.8 million for the three months ended June 30, 2019 and 2018, respectively. The increase of approximately $0.5 million was primarily due to an increase in direct unit product sales.

Cost of revenue was $2.1 million and $1.3 million for the six months ended June 30, 2019 and 2018, respectively. The increase of approximately $0.8 million was primarily due to a $0.6 million increase in direct unit product sales including and $0.2 million increase in service costs due to an increase in the number of machines under service agreements, including stock-based compensation expense due to continued expenses related to the modification accounting treatment of Replacement Awards that took place in the second quarter of 2018.

Gross profit (loss)

The following table shows our gross profit (loss) from our two segments (in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	Change $	2019	2018	Change $
Vascular	$ (989)	$ (126)	$ (863)	$ (1,695)	$ (287)	$ (1,408)
Dermatology	409	372	37	921	766	155
Total gross (loss) profit	$ (580)	$ 246	$ (826)	$ (774)	$ 479	$ (1,253)

Vascular

Gross loss was $1.0 million and $0.1 million for the three months ended June 30, 2019 and 2018, respectively. The $0.9 million increase in gross loss was primarily due to maintenance costs and depreciation expense related to our lasers at our customer sites and continued efforts to remedy the inconsistencies in our DABRA catheter performance and warranty costs of replacement units, including $0.2 million relating to the recall of catheters.

Gross loss was $1.7 million and $0.3 million for the six months ended June 30, 2019 and 2018, respectively. The $1.4 million increase in gross loss was primarily due to stock-based compensation expense due to continued expenses related to the modification accounting treatment of Replacement Awards that took place in the second quarter of 2018, continued efforts to remedy the inconsistencies in our DABRA catheter performance and warranty costs of replacement units, including $0.2 million relating to the recall of catheters and maintenance costs and depreciation expense related to our lasers at our customer sites.

We expect our gross profit (loss) to be negatively impacted in the short term with our reduced sales force and as we continue efforts to remedy the inconsistencies in our DABRA catheter performance.

Dermatology

Gross profit was $0.4 million for each of the three months ended June 30, 2019 and 2018, respectively.

Gross profit was $0.9 million and $0.8 million for the six months ended June 30, 2019 and 2018, respectively. The increase of $0.1 million was primarily due to the increase in revenue due to the number of laser units sold.

General

Selling, general and administrative expenses

SG&A expenses were $13.8 million and $7.6 million for the three months ended June 30, 2019 and 2018, respectively. The $6.2 million increase was primarily related to increases of (i) $2.8 million in stock-based compensation expense primarily due to continued expenses related to the modification accounting treatment of Replacement Awards that took place in the second quarter of 2018 and new grants, (ii) $1.9 million in salary, benefits, recruiting expenses and other personnel-related costs due to expanding our sales force and hiring administrative staff to operate as a public company, (iii) $0.4 million in travel and trade shows, (iv) $0.4 million in other costs including allowance for doubtful accounts and depreciation, (v) $0.3 million in outside services to operate as a public company, including legal, audit, consulting, board of directors and investor relations fees, (vi) $0.2 million in insurance due to being publicly traded and (vii) and $0.2 million in sales training related costs. Note 10 to the financial statements appearing elsewhere in this Quarterly Report on Form 10-Q more fully describes the accounting treatment for stock-based compensation awards.

SG&A expenses were $27.0 million and $10.3 million for the six months ended June 30, 2019 and 2018, respectively. The $16.7 million increase was primarily related to increases of (i) $8.7 million in stock-based compensation expense primarily due to continued expenses related to the modification accounting treatment of Replacement Awards that took place in the second quarter of 2018 and new grants, (ii) $4.4 million in salary, benefits, recruiting expenses and other personnel-related costs due to expanding our sales force and hiring administrative staff to operate as a public company, (iii) $1.0 million in outside services to operate as a public company, including legal, audit, consulting, board of directors and investor relations fees, (iv) $0.9 million in travel and trade shows, (v) $0.6 million in insurance due to being publicly traded, (vi) $0.6 million in other costs including marketing, freight, allowance for doubtful accounts and depreciation and (vii) $0.5 million in sales training related costs. Note 10 to the financial statements appearing elsewhere in this Quarterly Report on Form 10-Q more fully describes the accounting treatment for stock-based compensation awards.

We expect our legal expenses to increase in the near term as a result of the previously announced Audit Committee investigation and in connection with the legal proceedings discussed in Note 11, "Commitments and Contingencies," in the notes to the condensed financial statements.

Research and development expenses

R&D expenses were $1.0 million for each of the three months ended June 30, 2019 and 2018, respectively. There was a $0.6 million decrease in stock-based compensation expense primarily due to the full vesting of equity awards offset by increases of $0.2 million in clinical study costs and $0.4 million increase in payroll, consulting and supplies expenses.

R&D expenses were $2.5 million and $1.3 million for the six months ended June 30, 2019 and 2018, respectively. The $1.2 million increase was primarily due to increases of $0.3 million in stock-based compensation expense, $0.2 million in clinical study costs and $0.7 million in payroll, consulting and supplies expenses.

Other income (expense), net

Other income (expense), net was net other income of $0.2 million and $0.5 million for the three and six months ended June 30, 2019, respectively. Other expense was de minimis for the three months and six months ended June 30, 2018. In 2019, other income was primarily comprised of interest income on the net proceeds from the IPO that were received in October 2018. Other income is offset by interest expense primarily related to the significant financing component for multi-year warranty service contracts.

Non-GAAP Measures

EBITDA and Adjusted EBITDA are performance measures that provide supplemental information we believe is useful to analysts and investors to evaluate our ongoing results of operations, when considered alongside other GAAP measures. These Non-GAAP Measures exclude the financial impact of items management does not consider in assessing our ongoing operating performance, and thereby facilitate review of our operating performance on a period-to-period basis. Comparability to our results of operations to other companies may be impacted by our stock-based compensation which was classified as a liability and revalued at each reporting period with the change in fair value recorded to compensation expense in the statement of operations.

We believe that non-GAAP financial information, when taken collectively, may be helpful to investors because it provides consistency and comparability with past financial performance. However, non-GAAP financial information is presented for supplemental informational purposes only, has limitations as an analytical tool and should not be considered in isolation or as a substitute for financial information presented in accordance with U.S. GAAP. Some of these limitations are that:

- EBITDA excludes certain recurring, non-cash charges such as depreciation of fixed assets, although these are non-cash charges, the assets being depreciated may have to be replaced in the future; and
- Adjusted EBITDA further excludes stock-based compensation expense, which has been, and will continue to be for the foreseeable future, a significant recurring expense in our business and an important part of our compensation strategy.

In addition, other companies, including companies in our industry, may calculate similarly-titled non-GAAP measures differently or may use other measures to evaluate their performance, all of which could reduce the usefulness of our non-GAAP financial measures as tools for comparison.

A reconciliation for each non-GAAP financial measure to the most directly comparable financial measure stated in accordance with GAAP is included below. Investors are encouraged to review the related GAAP financial measures and the reconciliation of these non-GAAP financial measures to their most directly comparable GAAP financial measures, and not to rely on any single financial measure to evaluate our business. We define Adjusted EBITDA as our GAAP net loss as adjusted to exclude depreciation and amortization, interest income, interest expense, income tax expense and stock-based compensation.

The following is a reconciliation of Net loss to Adjusted EBITDA:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Statement of Operations Data:				
Net loss	$ (15,122)	$ (8,395)	$ (29,796)	$ (11,088)
Depreciation and amortization	447	135	831	231
Interest income	(297)	—	(625)	—
Interest expense	66	1	114	2
Income tax expense	5	3	5	3
EBITDA	(14,901)	(8,256)	(29,471)	(10,852)
Stock-based compensation	7,132	4,680	14,877	5,204
Adjusted EBITDA	$ (7,769)	$ (3,576)	$ (14,594)	$ (5,648)

Adjusted EBITDA was negative $7.8 million compared to negative $3.6 million for the three months ended June 30, 2019 and 2018, respectively and a negative $14.6 million compared to a negative $5.6 million for the six months ended June 30, 2019 and 2018, respectively. The change in Adjusted EBITDA primarily reflects higher selling, general and administrative costs, including salary, benefits, travel, recruiting expenses, legal fees and consulting costs due to increased personnel and operating as a public company.

Liquidity and Capital Resources

As of June 30, 2019, we had cash and cash equivalents and short-term investments of $48.4 million and accumulated deficit of $90.0 million. Our primary sources of capital have been from the sale of our products and services, the net proceeds of $67.3 million from our initial public offering, and, to a lesser extent, private placements of common stock and equipment financing arrangements.

We believe that our cash and cash equivalentsand short-term investments as of June 30, 2019 will be sufficient to fund our operations for at least the next 12 months.In the near term, we expect our recurring costs to decrease as a result of our cost savings initiatives. In August 2019, we began implementing certain operational efficiency and cost savings initiatives intended to align our resources with our product strategy, reduce our operating expenses, and manage our cash flows. These cost efficiency initiatives include targeted workforce reductions of our sales and marketing teams. We have reduced the size of our DABRA sales force from 34 employees as of June 30, 2019 to 6 employees as of November 11, 2019. In addition, we may need to decrease or defer capital expenditures and development activities to further optimize our operations. Such measures may impair our ability to invest in developing, marketing and selling new and existing products. The efficiency and cost-savings initiatives are expected to reduce recurring operating expenses and enable us to efficiently align our resources in areaswe believe provide the greatest benefit, but if our efficiency and cost reduction efforts are unsuccessful, our cash position could be negatively impacted and we may, among other things, be required to seek other sources of financing.

We are incurring additional costs as a result of operating as a public company, including increases in legal, accounting, insurance and other expenses. Additionally, we expect legal and related expenses to increase in the near term as a result of the previously announced Audit Committee investigation and in connection with the legal proceedings discussed in Note 11, "Commitments and Contingencies," in the notes to the condensed financial statements

Our future capital requirements will depend on many factors, including:

- the revenue generated by sales of our DABRA and Pharos products, related consumables, and other products that may be approved in the U.S. and select non-U.S. markets, as well as the amount of sales personnel required to generate the revenue;
- our ability to remedy the inconsistencies in our DABRA catheter performance;
- following our product recall, our ability to achieve market acceptance of DABRA;
- matters arising out of our completed Audit Committee investigation;
- the cost, timing and outcomes of any litigation involving our company, products, and business activities, including securities class actions and derivative lawsuits, and government investigations in which we are involved in;
- the extent to which our products are adopted by the physician community;
- the ability of our customers to obtain adequate reimbursement from third-party payors for procedures performed using DABRA;
- the degree of success we experience in commercializing our excimer lasers and related consumables;
- the costs, timing and outcomes of any future clinical studies and regulatory reviews, including to seek and obtain approvals for new indications for our products;
- the costs and timing of developing variations of our excimer lasers, and, if necessary, obtaining FDA clearance to market such variations;
- the costs associated with any future expansion of our U.S. and international sales and marketing infrastructure and our manufacturing operations;
- the emergence of competing or complementary technologies;
- the number and types of future products we develop and commercialize;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the level of our selling, general and administrative expenses.

Cash Flows

	Six Months Ended June 30,		
	2019	**2018**	**Change $**
Net cash (used in) provided by:			
Operating activities	$ (15,747)	$ (5,966)	$ (9,781)
Investing activities	(36,657)	(251)	(36,406)
Financing activities	(124)	7,749	(7,873)
Net decrease in cash and cash equivalents	$ (52,528)	$ 1,532	$ (54,060)

Net cash used in operating activities

Net cash used in operating activities was $15.7 million for the six months ended June 30, 2019, consisting of a net loss of $29.8 million and an increase in net operating assets and liabilities of $1.9 million, primarily relating to an increase in inventory and payment of accrued expenses partially offset by non-cash charges of $16.0 million, consisting of stock-based compensation expense, depreciation and amortization and allowance for doubtful accounts.

Net cash used in operating activities was $6.0 million for the six months ended June 30, 2018, consisting of a net loss of $11.1 million and an increase in net operating assets of $0.4 million partially offset by non-cash charges of $5.5 million.

Net cash used in investing activities

Net cash used in investing activities was $36.7 million for the six months ended June 30, 2019, consisting $36.5 million to purchase short-term investments and $0.2 million for manufacturing equipment and vehicles for our sales force to transport our laser equipment.

Net cash used in investing activities was $0.3 million for the six months ended June 30, 2018, consisting primarily of purchases of manufacturing equipment, tenant improvements and vehicles for our sales force to transport our laser equipment.

Net cash (used in) provided by financing activities

Net cash used in financing activities was $0.1 million for the six months ended June 30, 2019 for payments on our financed equipment of $0.2 million, offset by proceeds from issuance of common stock related to the employee stock purchase plan of $37,000.

Net cash provided by financing activities was $7.7 million for the six months ended June 30, 2018, and was primarily a result of proceeds of $7.9 million from the issuance of common stock related to a private placement financing, partially offset by $0.1 million in payments related to our planned initial public offering and $21,000 of payments on our financed equipment.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial position and results of operations is based on our unaudited interim financial statements included elsewhere in this Form 10-Q, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. We believe certain of our accounting policies are critical to understanding our financial position and results of operations. Except for policy changes in accounting for revenues associated with our adoption of Topic 606 (see Note 2 “Revenue Recognition” in the Notes to Condensed Financial Statements in Item 1), there have been no significant changes to our critical accounting judgments, policies and estimates as described in our Annual Report on Form 10-K for the year ended December 31, 2018 filed with the SEC on March 15, 2019.

The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

Off-Balance Sheet Arrangements

We do not engage in transactions that generate relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, as a part of our ongoing business. Accordingly, we did not have any off-balance sheet arrangements during any of the periods presented.

Contractual Obligations

During the six months ended June 30, 2019, there have been no material changes outside the ordinary course of business to our contractual obligations disclosed in our “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of our Annual Report on Form 10-K for the year ended December 31, 2018.

ITEM 3. QUANTITATIVE AND QUALITATI VE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business, including the effects of interest rate changes and foreign currency fluctuations. Information relating to quantitative and qualitative disclosures about these market risks is described below.

Interest Rate Sensitivity

We had cash and cash equivalents of $11.8 million and short-term investments of $36.6 million as of June 30, 2019, which came from sales of our products and services, the net proceeds from our initial public offering and, to a lesser extent, private placements of common stock and equipment financing arrangements. The goals of our investment policy are liquidity and capital preservation; we do not enter into investments for trading or speculative purposes. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short-term nature of our cash and cash equivalents. A hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

Foreign Currency Exchange Risk

As we expand internationally our results of operations and cash flows may become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Our revenue is denominated in U.S. dollars. Our expenses are generally denominated in the currencies in which our operations are located, which is primarily in the United States. As of June 30, 2019, the effect of a 10% adverse change in exchange rates on foreign denominated cash, receivables and payables would not have been material for the periods presented. As our operations in countries outside of the United States grow, our results of operations and cash flows may be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. To date, we have not entered into any material foreign currency hedging contracts although we may do so in the future.

Inflation risk

We do not believe that inflation has had a material effect on our business, results of operations, or financial condition. Nonetheless, if our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs. Our inability or failure to do so could harm our business, results of operations, or financial condition.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Financial Officer, who is also serving as our Interim Chief Executive Officer, evaluated the effectiveness of our disclosure controls and procedures as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as of June 30, 2019. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives of ensuring that information we are required to disclose in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Financial Officer, who is also serving as our Interim Chief Executive Officer, to allow timely decisions regarding required disclosures, and is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms.

Based upon our evaluation, our Chief Financial Officer, who is also serving as our Interim Chief Executive Officer, concluded that, as of June 30, 2019, our disclosure controls and procedures were not effective, due to material weaknesses in internal control over financial reporting that are described below. Notwithstanding the material weaknesses, management has concluded that the Company's unaudited financial statements for the periods covered by and included in this quarterly report on Form 10-Q are fairly stated in all material respects in accordance with U.S. generally accepted accounting principles ("GAAP") for each of the periods presented herein.

In reviewing the allegations and findings from an Audit Committee investigation related to an initially anonymous complaint, as well as additional matters discovered during the course of the investigation, we have identified certain deficiencies in our internal controls which have been considered material weaknesses. Although no material misstatements or omissions in our financial statements or disclosures were identified, the material weaknesses in internal controls could have resulted in material misstatements or omissions to our financial statements or disclosures.

Control environment

We identified certain deficiencies in our internal controls, which aggregated to a material weakness in the control environment component of theCommittee of Sponsoring Organizations of the Treadway Commission in *Internal Control - Integrated Framework (the "COSO Framework*). The material weakness results from the aggregation of control deficiencies in the Company's control environment, in particular an inappropriate "tone at the top" set by certain members of senior management, including a failure to promote adherence to our Code of Ethics and Conduct, and the lack of sufficient competent resources in key roles at the organization The ineffective control environment resulted in the following:

- behavior that was inconsistent with our Code of Ethics and Conduct and related policies involving certain former executive officers and employees of the Company;
- explanations regarding the issues that had an impact on our fourth quarter 2018 and first quarter 2019 sales created a risk of confusion because the explanations did not explicitly reference the effect of inconsistent catheter performance and catheter failures;
- failure to timely make at least two Medical Device Reports, or MDRs, to the FDA;
- engagement in systematic efforts to replace product held by customers, which constituted product recalls, were not documented as such;
- lack of documentation of sufficient detail and specificity to support certain payments to physicians, ostensibly for training and consulting services, to three physicians did not accurately reflect the purpose and nature of approximately $300,000 of payments, which could be perceived as an improper attempt to obtain business or to gain special advantage;
- while the indication for use in the 510(k) clearance we obtained for the DABRA system is not for atherectomy, our salespeople were instructed to characterize DABRA as performing atherectomy and to encourage doctors to seek reimbursement using atherectomy codes;
- determinations to direct potentially valuable benefits and opportunities to doctors were informed in part by sales prospects.

The ineffective control environment contributed significantly to the material weakness described below.

Information and communication

We have identified a deficiency in the information and communication component of the COSO Framework that resulted in a material weakness. This deficiency related to the ineffective design of internal communication of information, including objectives and responsibilities for internal control, necessary to support the functioning of internal control. The deficiency resulted in the receipt of complaints regarding regulatory or compliance concerns that, because the complaints implicated executive officers, should have been brought to the attention of the board of directors or the Audit Committee, but were not.

Remediation Plan and Activities

We commenced measures to remediate the identified material weakness in the third quarter of 2019. Management, with the participation and input of the Audit Committee and the board of directors, is engaged in remedial activities to address the material weaknesses described above. The remedial activities we are taking include separation of certain former executives and employees, hiring qualified personnel including a VP Quality, Regulatory and Clinical, implementing additional and enhanced policies and training, including with respect to our Code of Business Ethics and Conduct, strengthening our quality and regulatory systems, bolstering documentation requirements for certain third-party consulting, advisory and training agreements, and adopting certain enhanced controls related to the matters investigated by the Audit Committee.

We are committed to maintaining a strong internal control environment, and we believe we are making progress toward achieving the effectiveness of our internal controls and disclosure controls. The actions that we are taking are subject to ongoing senior management review, as well as Audit Committee oversight. We will not be able to conclude whether the steps we are taking will fully remediate the material weaknesses in our internal control over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness. We may also conclude that additional measures may be required to remediate the material weaknesses in our internal control over financial reporting, which may necessitate additional implementation and evaluation time. We will continue to assess the effectiveness of our internal control over financial reporting and take steps to remediate the known material weakness expeditiously.

Changes in Internal Control over Financial Reporting

Other than the remediation steps taken above, there were no additional changes in our internal control over financial reporting during the six months ended June 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

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

PART II — OTHE R INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Securities Litigation

On June 7, 2019, a putative securities class action complaint captioned *Derr v. Ra Medical Systems, Inc., et. al.,* (Civil Action no. 19CV1079 LAB NLS) was filed in the United States District Court for the Southern District of California against the Company, certain current and former officers and directors, and certain underwriters of the Company's IPO. The complaint alleges that the defendants made material misstatements or omissions in the Company's registration statement that caused the stock price to drop. The court appointed a Lead Plaintiff on September 5, 2019, and on October 2, 2019, it ordered that Lead Plaintiff file an amended complaint within forty-five days after the Company files with the SEC its Form 10-Q for the period ended June 30, 2019. Management intends to vigorously defend the Company against this lawsuit. At this time, the Company cannot predict how a court or jury will rule on the merits of the claims and/or the scope of the potential loss in the event of an adverse outcome. Should the Company ultimately be found liable, the liability could have a material adverse effect on our financial condition and our results of operations for the period or periods in which it is incurred. The Company is unable to predict the ultimate outcome and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

On October 1, 2019, a shareholder derivative complaint captioned *Noel Borg v. Dean Irwin, et. al* (Civil Action no. 1:99-cm-09999) was filed in the United States District Court for the District of Delaware against certain current and former officers and directors, purportedly on behalf of the Company, which is named as a nominal defendant in the action. The complaint alleges breaches of fiduciary duty, unjust enrichment, waste, and violations of Section 14(a) of the Securities Exchange Act of 1934. On October 21, 2019, pursuant to the parties' stipulation, the court stayed the derivative lawsuit until the related class action is resolved.

Governmental Investigations

As previously announced in the Form 8-K filed on August 12, 2019, the Audit Committee of Ra Medical's Board of Directors (the "Audit Committee") was conducting an investigation of certain allegations raised by a former employee. The Company announced the Audit Committee's findings in the Form 8-K filed on October 31, 2019. The primary investigative findings were: (i) the DABRA catheter frequently failed to calibrate and occasionally overheated, posing a risk of injury to physicians and patients; (ii) our explanations regarding our fourth quarter 2018 and first quarter 2019 sales created a risk of confusion because they did not explicitly reference inconsistent DABRA catheter performance and catheter failures; (iii) we failed to timely make at least two Medical Device Reports, or MDRs, to the FDA; (iv) we, out of a concern for the DABRA catheters' performance, engaged in systematic efforts to replace product held by customers, which constituted product recalls, but were not documented as such, (v) we lack documentation of sufficient detail and specificity to support certain payments to physicians, ostensibly for training and consulting services, and as to three physicians did not accurately reflect the purpose and nature of approximately $300,000 of payments, which could be perceived as an improper attempt to obtain business or to gain special advantage, (vi) while the indication for use in the 510(k) clearance we obtained for the DABRA system is not for atherectomy, our salespeople were instructed to characterize DABRA as performing atherectomy and to encourage doctors to seek reimbursement using atherectomy codes, (vii) our determinations to direct potentially valuable benefits and opportunities to doctors were informed in part by sales prospects, and (viii) we received complaints regarding regulatory or compliance concerns that, because they implicated executive officers, should have been brought to the attention of the Board or the Audit Committee, but were not. The Audit Committee, in reviewing the allegations, identified certain behavior inconsistent with our Code of Ethics and Conduct and related policies.

In October 2019, the Department of Justice, or DOJ, served the Company with a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning whether the Company fraudulently obtained 510(k) marketing clearance for the Company's devices marketed under the trade name DABRA, whether the Company marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether the Company paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b. The Company is cooperating fully with the DOJ's request in connection with the Civil Investigative Demand. The Company is unable to predict the ultimate outcome and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

The Company received a letter on November 13, 2019, from the Los Angeles Office of the Division of Enforcement of the Securities and Exchange Commission (the "SEC"), in which the SEC notified the Company that it is conducting an investigation. The Company has been, and intends to continue, cooperating with the SEC in this investigation. The Company is unable to predict the ultimate outcome and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

On November 21, 2019, we became aware that the Criminal Division, Fraud Section of the U.S. Department of Justice has an open investigation related to the Company. At this time, it is unclear if the Company is a target in this investigation. The Company intends to cooperate with the DOJ criminal investigation.

Other Litigation

On August 30, 2018, Strata Skin Sciences, Inc. ("Strata") and Uri Geiger, a member of the board of directors of Strata Skin Sciences, Inc. filed an action against the Company in Pennsylvania State Court, Montgomery County (Civil Action No. 18-21421) (the "Pennsylvania Case"), requesting declaratory relief that: (1) Strata and Mr. Geiger are not liable for tortious interference, defamation, libel, or unfair competition based on an e-mail by Mr. Geiger to an investment bank (the "Geiger Email"); (2) Strata and Mr. Geiger made no actionable statements about the Company to such investment bank; (3) the Company cannot enforce the 2011 settlement and release agreement between the Company and PhotoMedex, Inc. ("Settlement Agreement") against Strata; and (4) that any dispute regarding the Geiger Email does not relate to the Settlement Agreement. The action filed by Strata and Mr. Geiger does not request any monetary damages. The Company believes that the action by Strata and Mr. Geiger was filed as a response to a letter that the Company sent to Strata on August 22, 2018 demanding that Strata and Mr. Geiger cease and desist from making statements about alleged patent infringement and affirmatively retract the statements made in the Geiger Email. The Company was served with the action on August 31, 2018, and responded with preliminary objections to the action on September 19, 2018. The court overruled the Company's preliminary arguments on April 29, 2019. The Company filed a motion for summary judgment on July 17, 2019 for the court to rule that the Company can enforce the Settlement Agreement against Strata. The Company believes that Strata's action in the Pennsylvania Case lacks merit, and plans to vigorously oppose the action on procedural and substantive grounds within the prescribed time limits.

On May 16, 2019, the Company filed an action against Strata, Mr. Geiger and Accelmed Growth Partners, L.P. and its affiliates (collectively, the "Strata Parties") in the United States District Court for the Southern District of California (Civil Action No. 19-cv-0920-AJB-MSB (the "California Case")) alleging (1) violation of the Settlement Agreement, (2) tortious interference with economic advantage, and (3) trade libel based on the Geiger Email. In the lawsuit, the Company alleges, among other things, that the statements in the Geiger Email regarding alleged patent infringement constitute a breach of the Settlement Agreement, that the Strata Parties employed deceptive practices designed to delay the Company's initial public offering and reduce the amount of capital raised by the Company, and that statements in the Geiger Email regarding patent infringement, off label promotion and reimbursement constitute trade libel. The Company seeks an injunction barring the Strata Parties' alleged conduct, monetary damages, and other available legal and equitable relief. The Company amended its complaint on July 25, 2019 to allege violations of the Lanham Act's prohibition on false advertising. The Strata Parties filed motions to dismiss on August 25, 2019, and the Company responded with its oppositions to the motions to discuss on September 27, 2019. The Court has set a hearing date of December 19, 2019 on the motions to dismiss.

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

ITEM 1A. RIS K FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q, before making an investment decision. The risks and uncertainties described below may not be the only ones we face. If any of the risks actually occur, our business, financial condition, operating results, cash flows and prospects could be materially and adversely affected. In that event, the market price of our common stock could decline, and you could lose part or all of your investment.

Risks Related to Our Business and Products

We may be unable to successfully remedy the performance and calibration issues associated with our DABRA catheters, achieve market acceptance of DABRA, or achieve revenue growth.

Our ability to grow our revenue in future periods will depend on our ability to successfully remedy the inconsistencies in our DABRA catheter performance, penetrate our target markets and increase sales of our products and any new product indications that we introduce, which will, in turn, depend in part on our success in growing our installed unit base and driving continued use of our systems, including long-term adoption by physicians. In the third quarter of 2019, we reduced the number of sales and marketing personnel in order to focus our efforts on key territories and accounts. We also initiated a recall of our DABRA catheters to relabel the shelf life from 12 months to two months. These actions will likely make it more difficult in the near term to achieve significant revenue growth. In addition, new product indications will also need to be approved or cleared by the FDA and comparable non-U.S. regulatory agencies to help drive revenue growth. If we cannot achieve revenue growth, it would have a material adverse effect on our business, financial condition, and results of operations.

Our success depends in large part on DABRA. If we are unable to successfully market and sell DABRA, our business prospects will be significantly harmed.

Our future financial success will depend substantially on our ability to effectively and profitably market and sell DABRA. The commercial success of DABRA will depend on a number of factors, including the following:

- our ability to timely remedy the current inconsistencies in our DABRA catheter performance and identify future issues;
- our ability to continue commercializing DABRA for its indications for use with a smaller sales force;
- our ability to conduct the voluntary recall of our DABRA catheters and subsequently achieve market acceptance following the change in our labeling from a 12 month to two month shelf life;
- any agreements or punitive actions that arise out the settlement of the ongoing investigations by the governmental agencies;
- our ability to receive regulatory clearance for, and timely introduce, enhancements to the DABRA catheter design;
- the effectiveness of our and our distributors' marketing and sales efforts in the U.S. and abroad, including our efforts to build out and properly train our sales team;
- our ability to attract, motivate, train and retain experienced and qualified sales personnel;
- the availability, perceived advantages, relative cost, relative safety, and relative efficacy of alternative and competing treatments, including the time and expertise needed for training to effectively use the DABRA system as compared to competing treatments;
- our ability to properly support DABRA usage with our own qualified personnel or our ability to properly train and support our customers to use the DABRA system effectively on their own;
- the availability of coverage and adequate levels of reimbursement under private and governmental health insurance plans for DABRA-based procedures;
- our ability to obtain, maintain, and enforce our intellectual property rights in and to DABRA;
- our ability to achieve and maintain compliance with regulatory requirements applicable to DABRA;
- our ability to continue to develop, validate and maintain a commercially viable manufacturing process that is compliant with current Good Manufacturing Practices, or cGMP; and
- whether we are required by the FDA or comparable non-U.S. regulatory authorities to conduct additional clinical trials for future or current indications.

If we fail to successfully market and sell DABRA, we will not be able to achieve or maintain profitability, which will have a material adverse effect on our business, financial condition, and results of operations.

We may face additional issues associated with the voluntary recall of our DABRA catheters if we are unable to show that we initiated a timely recall and improved calibration rates in the use of our DABRA catheters.

In the third quarter of 2019 we initiated a voluntary recall of our DABRA catheters to relabel the catheters from a 12 month shelf life to a two month shelf life, as we observed through field data and internal testing that catheters more than two months from sterilization have a significantly higher rate of non-calibration. While we believe that the relabeling of our catheters to a two month shelf life will decrease the amount of non-calibrations, we cannot be certain that physicians will not continue to experience these issues. If the newly labeled DABRA catheters continue to experience high rates of non-calibration, that could lead to an expanded or additional recall which would harm our reputation with our existing physician customers, adversely affect our ability to generate revenue, and have an adverse effect on our financial condition and results of operations. Any future recall could cause further harm to our reputation, cause a decrease in revenue, and require us to devote financial resources from other aspects of our business.

Physicians and staff may not commit enough time to sufficiently learn how to use our products.

In order for physicians and staff to learn to use our products, we encourage physicians to attend structured training sessions in order to familiarize themselves with our technology. There are many nuances to successfully using our products. For example, the DABRA catheter is fragile and may be prone to bending at the entry of the artery, a problem known as kinking. In addition, the DABRA laser needs to be calibrated correctly for each use. In the first half of 2019, we saw an increase in calibration issues experienced by physicians. In addition, in reviewing the performance inconsistencies, we found that our catheters occasionally overheated, which could cause a risk of injury to patients and physicians. Further, physicians and their staff must utilize the technology on a regular basis to ensure they maintain the skill set necessary to use our products. Market acceptance of DABRA could be delayed by physician or staff experience with our product and their willingness to attend training sessions or sufficiently familiarize themselves with DABRA. An inability to train a sufficient number of physicians to generate adequate demand for our products could have a material adverse effect on our business, financial condition, and results of operations.

Our products may not gain or maintain market acceptance among physicians and patients and others in the medical community.

Our success will depend, in part, on the acceptance of our products as safe, useful and, with respect to physicians, cost effective and easy to use. We cannot predict how quickly, if at all, catheterization laboratories and physicians will accept our products or, if accepted, how frequently they will be used. Patients and their care providers must believe our products offer benefits over alternative treatment methods. Additional factors that will influence whether our products gain and maintain market acceptance, include:

- whether we are able to successfully and timely remedy the inconsistencies in our DABRA catheter performance;
- whether physicians, catheterization laboratory owners and operators, patients, and others in the medical community consider our products safe, effective, and cost-effective treatment methods;
- the potential and perceived advantages of our products over alternative treatment methods;
- the convenience, amount of training required, and ease of use of DABRA and Pharos relative to alternative treatment methods;
- matters arising out of our completed Audit Committee investigation, securities class actions, derivative lawsuits and government investigations;
- the prevalence and severity of any side effects associated with using our products;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling cleared or approved by the FDA or other authorities;
- the cost of treatment in relation to alternative treatments methods;
- pricing pressure, including from group purchasing organizations, or GPOs, seeking to obtain discounts on DABRA and Pharos based on the collective buying power of the GPO members;
- the availability of adequate coverage, reimbursement and pricing by third-party payors, including government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors, including government authorities;
- our ability to provide incremental clinical and economic data that shows the safety and clinical efficacy and cost effectiveness of, and patient benefits from, our products; and
- the effectiveness of our sales and marketing efforts for DABRA and Pharos.

If we do not adequately educate physicians about PAD and the existence and proper use and reimbursement of our products, DABRA may not gain market acceptance, as many physicians do not routinely screen for PAD while screening for CAD. Additionally, even if our products achieve market acceptance, they may not maintain that market acceptance over time if competing products or technologies are introduced that are received more favorably or are more cost effective. Failure to achieve or maintain market acceptance and/or market share would limit our ability to generate revenue and would have a material adverse effect on our business, financial condition, and results of operations.

The continuing development of our products depends upon our developing and maintaining strong working relationships with physicians.

The research, development, marketing and sale of our current products and any potential new and improved products or future product indications for which we receive regulatory clearance or approval depend upon our maintaining working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. Physicians assist us as researchers, marketing and product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations. At the same time, companies in the medical device industry are under increasing scrutiny by the U.S. Department of Health and Human Services Office of Inspector General, or OIG, and the DOJ for improper relationships with physicians. In October 2019, the DOJ provided us with a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning whether we fraudulently obtained 510(k) marketing clearance for our ablation devices marketed under the trade name DABRA, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b. In November 2019, we learned that the DOJ has opened a criminal investigation relating to the Company. We are complying and cooperating with the DOJ investigations and plan to timely file responses to the CID. Our failure to comply with requirements governing the industry's relationships with physicians, including the reporting of certain payments to physicians under the National Physician Payment Transparency Program (Open Payments) or an investigation into our compliance by the OIG or the DOJ, could impact physicians' willingness to conduct business with us, which would have a material adverse effect on our business, financial condition, and results of operations.

We are experiencing inconsistencies in our DABRA catheter performance. This and any other development or manufacturing problems or delays that could limit the potential growth of our revenue or increase our losses.

In the fourth quarter of 2018 and first quarter of 2019, we experienced inconsistencies in our DABRA catheter performance. We believed at the time, that these inconsistencies related to controlling the temperature of the oven used in the manufacturing process, which we had previously referred to as production limitations. These inconsistencies led to an increase in the number of catheters that failed to calibrate at customer sites, despite calibrating successfully during our quality assurance steps. During that same period, our sales team noted higher rates of non-calibration of catheters at customer physician offices. The higher than anticipated rates of non-calibration resulted in customer dissatisfaction with the product, resulting in what we believe to be fewer purchases by our customers and therefore lower revenue during the fourth quarter of 2018 and the first half of 2019, however, such amount is not determinable. In response, we upgraded our temperature control regulator and made certain changes in our production flow and validated the changes that we believed corrected the production limitations. After manufacturing several well-performing lots with this upgraded process, the percentage of catheters that fail to calibrate began to increase after decreasing during April and May 2019. After collecting field data and performing internal testing, we observed that while catheters can perform satisfactorily up to one year, catheters that were more than two months from sterilization, had a significantly higher rate of non-calibration than catheters that were within two months from sterilization. As a result, in September 2019, we initiated a recall of our catheters to relabel them from a 12 month to a two month shelf life, which we believe will significantly reduce the number of catheters that fail to calibrate. Until our DABRA catheters consistently calibrate in the field, DABRA sales may continue to be adversely impacted and we will continue to incur additional costs.

There can be no assurance that we will be able to timely correct the performance issues related to the DABRA catheters or that a premarket FDA submission would not be required for such changes. In addition, the manufacture of our products is subject to strict regulatory requirements as described in the risk factor entitled "Our medical device operations are subject to pervasive and continuing FDA regulatory requirements." Problems can arise during the manufacturing process for a number of reasons, including equipment malfunction, failure to maintain or follow necessary protocols and procedures, raw material problems or human error. If we are unable to remedy our inconsistencies in our DABRA catheter performance or if we otherwise fail to meet our internal quality standards or the quality system regulations enforced by the FDA or other applicable regulatory bodies, which include detailed manufacturing and quality obligations, our reputation could be damaged, we could be required to issue a safety alert to our customer or initiate a recall, we could incur product liability and other costs, product approvals could be delayed, suspended or revoked, enforcement action could be initiated by regulatory authorities, we could be required to cease commercialization of DABRA and our business could otherwise be adversely affected.

In addition, our production processes and assembly methods may require additional changes to accommodate any significant expansion of our manufacturing capacity, which may increase our manufacturing costs, delay production of our products, reduce our product margin, be subject to FDA approval and adversely impact our business. Conversely, if demand for our products shifts such that a manufacturing facility is operated below its capacity for an extended period, we may adjust our manufacturing operations to reduce fixed costs, which could lead to uncertainty and delays in manufacturing times and quality during any transition period.

Additionally, since our products are manufactured at our manufacturing facility in Carlsbad, any contamination of the controlled environment, equipment malfunction, or failure to strictly follow procedures can significantly reduce our yield. A drop in yield can increase our cost to manufacture our products or, in more severe cases, require us to halt the manufacture of our products until the problem is resolved. Identifying and resolving the cause of a drop in yield can require substantial time and resources.

If our manufacturing activities are adversely impacted, if we are unable to timely remedy the inconsistencies in our DABRA catheter performance by successfully manufacturing, assembling, testing, and shipping our products in a timely manner, our revenue could be impaired, market acceptance for our products could be adversely affected and our customers might instead purchase our competitors' products, which would have a material adverse effect on our business, financial condition, and results of operations.

We may require additional capital to finance our planned operations, which may not be available to us on acceptable terms or at all. As a result, we may not be able to continue our marketing efforts to increase the adoption of our products.

Our operations have consumed substantial amounts of cash since inception, primarily due to our research and development and commercialization efforts. We expect our sales and marketing expenses to increase over the long term in connection with our plan to continue our commercialization efforts of the DABRA system in the U.S. and internationally. These expenditures will also include costs associated with manufacturing and supply, sales and marketing costs, and general operations. In addition, other unanticipated costs may arise.

As of June 30, 2019, we had cash and cash equivalents and short-term investments of $48.4 million. On October 1, 2018, we completed our initial public offering, selling 4,485,000 shares of our common stock at $17.00 per share. Proceeds from our initial public offering, net of underwriting discounts and commissions and offering expenses, were $67.3 million. We believe that our existing cash and cash equivalents, will fund our projected operating expenses and capital expenditure requirements for at least the next 12 months.

In the near term, we expect our recurring costs to decrease as a result of our cost savings initiatives.In August 2019, we began implementing certain operational efficiency and cost savings initiatives intended to align our resources with our product strategy, reduce our operating expenses, and manage our cash flows. These cost efficiency initiatives include targeted workforce reductions of our sales and marketing teams. We have reduced the size of our DABRA sales force from 34 employees as of June 30, 2019 to 6 employees as of November 11, 2019. Further actions such as these may be required on an ongoing basis to optimize our organization. For example, we may need to decrease or defer capital expenditures and development activities or implement further operating expense reduction measures. Such measures may impair our ability to invest in developing, marketing and selling new and existing products. Furthermore, if our efficiency and cost reduction efforts are unsuccessful, our cash position could be negatively impacted and we may, among other things, be required to seek additional sources of financing. Until we are able to generate additional revenue to support our level of operating expenses, we will continue to incur operating and net losses and negative cash flow from operations. Additionally, we anticipate additional costs related to our Audit Committee investigation, securities class action and derivative lawsuits, and the Civil Investigative Demand issued by the DOJ and the DOJ's criminal investigation. Because of the numerous risks and uncertainties associated with our commercialization efforts and futureproduct development, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase our profitability.

The amount and timing of any expenditures needed to implement our commercial strategy will depend on numerous factors, including:

- whether we are able to successfully and timely remedy the inconsistencies in our DABRA catheter performance;
- our ability to achieve sufficient market acceptance, the ability for our customers to get coverage and adequate reimbursement from third-party payors and our ability to achieve acceptable market share for DABRA and Pharos;
- the cost to establish, maintain, expand, and defend the scope of our intellectual property portfolio, as well as any other action required in connection with licensing, preparing, filing, prosecuting, defending, and enforcing any patents or other intellectual property rights;
- the emergence of competing technologies and other adverse market developments;
- the costs associated with manufacturing, selling, and marketing DABRA and Pharos for their cleared or approved indications or any other indications for which we receive regulatory clearance or approval, including the cost and timing of expanding our manufacturing capabilities, as well as establishing our sales and marketing capabilities;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the timing, receipt, and amount of license fees and sales of, or royalties on, our future products or future improvements on our existing products, if any;
- the time and cost necessary to complete post-marketing studies that could be required by regulatory authorities or other studies required to obtain clearance for additional indications; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems, as a public company.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our products, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. If we are unable to obtain adequate financing on commercially reasonable terms when needed, we may have to delay, reduce the scope of or suspend our sales and marketing efforts, which would have a material adverse effect on our business, financial condition, and results of operations.

We have incurred losses in recent periods and may be unable to achieve profitability in the future.

We incurred net losses of $30.8 million and $17.8 million for the years ended December 31, 2018 and 2017, respectively, and a net loss of $29.8 million for the six months ended June 30, 2019. As of June 30, 2019, we had an accumulated deficit of $90.0 million. We expect to continue to incur significant manufacturing, product development, regulatory and other expenses as we continue to remedy the inconsistencies in our DABRA catheter performance, to obtain regulatory clearances or approvals for our products in additional jurisdictions and for additional indications, and to develop new products or add new features to our existing products. In addition, our general and administrative expenses have increased following our initial public offering and we expect these costs to continue to increase due to the additional costs associated with being a public company. The net losses that we incur may fluctuate significantly from period to period. We will need to generate significant additional revenue in order to achieve and sustain profitability and, even if we achieve profitability, we cannot be sure that we will remain profitable for an extended period of time. Our failure to achieve or maintain profitability would have a material adverse effect on our business, financial condition, and results of operations and could negatively impact the value of our common stock.

Matters relating to or arising from our Audit Committee investigation, including regulatory investigations and proceedings, litigation matters and potential additional expenses, may adversely affect our business and results of operations.

As previously disclosed in our public filings, the Audit Committee has recently substantially completed its internal investigation. In connection with the Audit Committee investigation, we voluntarily contacted the SEC Enforcement Division in August 2019 to advise them of the investigation of certain allegations made by a former employee. In October 2019, the Department of Justice, or DOJ, served the Company with a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning whether the Company fraudulently obtained 510(k) marketing clearance for the Company's ablation devices marketed under the trade name DABRA, whether the Company marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether the Company paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b. In November 2019, we learned that the DOJ has opened a criminal investigation relating to the Company. The Company intends to cooperate with the DOJ's civil and criminal investigations. We received a letter on November 13, 2019, from the Los Angeles Office of the Division of Enforcement of the Securities and Exchange Commission (the "SEC"), in which the SEC notified us that it is conducting an investigation. We have been, and intend to continue cooperating with the SEC in this investigation.

Furthermore, if the SEC or other government agency commences legal action, we could be required to pay significant penalties and become subject to injunctions, a cease and desist order and other equitable remedies. If our operations are found to violate federal law or regulations, or if we settle these investigations, we may be subject to civil and criminal penalties, damages, fines, disgorgement, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which would have a material adverse effect on our business, financial condition, and results of operations.

We have incurred, and may continue to incur, significant expenses related to legal, accounting, and other professional services in connection with the Audit Committee investigation and related legal matters. These expenses, the delay in timely filing our periodic reports, and the diversion of the attention of the management team that has occurred, and is expected to continue, has adversely affected, and could continue to adversely affect, our business, financial condition, and results of operations.

As a result of the matters reported above, we are exposed to greater risks associated with litigation, regulatory proceedings and government enforcement actions. In addition, securities class actions and other lawsuits have been filed against us, our directors and officers. Any future investigations or additional lawsuits could have a material adverse effect on our business, financial condition, and results of operations.

If our sole manufacturing facility becomes damaged or inoperable, or we are required to vacate the facility, our ability to manufacture and sell our products and to pursue our research and development efforts may be jeopardized.

We currently manufacture and assemble our products in our sole manufacturing facility in Carlsbad, California. Our products consist of components sourced from a variety of suppliers, with final assembly completed at our facility. Our facility and equipment, or those of our suppliers, could be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, fires, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, extreme weather conditions, medical epidemics, and other natural or man-made disasters or other business interruptions, for which we are predominantly self-insured. Any of these may render it difficult or impossible for us to manufacture products for an extended period of time. If our facility is inoperable for even a short period of time, the inability to manufacture our current products, and the interruption in research and development of any future products, may result in harm to our reputation, increased costs, lower revenue and the loss of customers, which would have a material adverse effect on our business, financial condition, and results of operations. Furthermore, it could be costly and time-consuming to repair or replace our facilities and the equipment we use to perform our research and development work and manufacture our products. We also rely on third-party component suppliers, and our ability to obtain commercial supplies of our products could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption, which would have a material adverse effect on our business, financial condition, and results of operations.

We are involved in pending securities litigation, and an adverse resolution of such litigation may adversely affect our business, financial condition, results of operations and cash flows.

In June 2019, we became the subject of a lawsuit alleging securities law violations based on alleged misstatements or omissions in our IPO Registration Statement. This type of litigation can be expensive and disruptive to normal business operations, and the outcome can be difficult to predict regardless of the facts involved. An unfavorable outcome with respect to this lawsuit could have a material adverse effect on our business, financial condition, results of operations or cash flows. For additional information regarding this lawsuit, see Note 11, "Commitments and Contingencies," in the notes to the condensed financial statements.

The delayed filing of some of our periodic SEC reports has made us currently ineligible to use a registration statement on Form S-3 to register the offer and sale of securities, which could adversely affect our ability to raise future capital or complete acquisitions.

As a result of the delayed filing of some of our periodic reports with the SEC, we are not currently eligible to register the offer and sale of our securities using a registration statement on Form S-3. To regain eligibility to use Form S-3, we must be timely and current in our public reporting for a period of twelve months preceding our S-3 filing. Should we wish to register the offer and sale of our securities to the public prior to the time we are eligible to use Form S-3, both our transaction costs and the amount of time required to complete the transaction could increase, making it more difficult to execute any such transaction successfully and potentially harming our financial condition.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our products and could result in recalls, delayed shipments and rejection of our products and damage to our reputation, and could expose us to regulatory or other legal action.

We face an inherent risk of product liability as a result of the marketing and sale of our products. For example, we may be sued if our products cause or are perceived to cause injury or are found to be otherwise unsuitable during manufacturing, marketing or sale. For example, in connection with the review of our performance inconsistencies, our catheters were found to occasionally overheat. Any product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or breach of warranty. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre-existing health of the patient. For example, we rely on physicians in connection with the use of our products on patients. If these physicians are not properly trained, including on the intended use, or are negligent, the capabilities of our products may be diminished or the patient may suffer critical injury. We may also be subject to claims that are caused by the activities of our suppliers, such as those who provide us with components and sub-assemblies.

There can be no assurance that we will be able to detect, remedy and report all defects in the products that we sell, including successfully remedying the issues with our catheters' performance. These issues with performance could result in the rejection of our products by physicians, damage to our reputation, lost sales, diverted development resources and increased customer service and support costs and warranty claims. Individuals could sustain injuries from our products, and we may be subject to claims or lawsuits resulting from such injuries. There is a risk that these claims or liabilities may exceed, or fall outside the scope of, our insurance coverage. Moreover, we may not be able to retain adequate liability insurance in the future.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit, delay or halt commercialization of our products. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- harm to our reputation;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- inability to market and sell our products; and
- a resulting decline in the price of our common stock.

We believe our product liability insurance is customary for similarly situated companies, but it may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise, if at all. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of products we develop. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would have a material adverse effect on our business, financial condition, and results of operations.

We face substantial competition, which may result in others discovering, developing or commercializing products more successfully than us.

The medical device industry is intensely competitive and subject to rapid and significant technological change. Many of our competitors have significantly greater financial, technical and human resources. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our competitors may also develop products that are more effective, more convenient, more widely used, less costly, have higher reimbursement coverage or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, as well as in acquiring technologies complementary to, or necessary for, our programs. Competition for these people in the medical device industry is intense and we may face challenges in retaining and recruiting such individuals if, for example, other companies may provide more generous compensation and benefits, more diverse opportunities, and better chances for career advancement than we do. Some of these advantages may be more appealing to high-quality candidates and employees than those we have to offer. In addition, the decline in our stock price has created additional challenges by reducing the retention value of our equity awards. Because of the complex and technical nature of our systems and the dynamic market in which we compete, any failure to attract and retain a sufficient number of qualified employees could materially harm our ability to develop and commercialize our technology, which would have a material adverse effect on our business, financial condition, and results of operations.

We may be unable to compete successfully with companies in our highly competitive industry, many of whom have substantially greater resources than we do.

The healthcare industry is highly competitive. There are numerous approved products for treating vascular and dermatological diseases in the indications in which we have received clearance or approval and those that we may pursue in the future. Many of these cleared or approved products are well-established and are widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may encourage the use of competitors' products. In addition, many companies are developing products, and we cannot predict what the standard of care will be in the future.

Our primary competitors for DABRA include Medtronic plc, Cardiovascular Systems Inc., Boston Scientific Corp., Avinger, Inc., Koninklijke Philips N.V., or Philips, including Volcano Corporation and Spectranetics Corporation, including products from the C.R. Bard acquisition, and Abbott Laboratories. These companies are manufacturers of products used in competing therapies within the peripheral arterial disease market such as:

- atherectomy, using mechanical methods to remove vascular blockages;
- balloon angioplasty and stents;
- specialty balloon angioplasty, such as scoring balloons, pillowing balloons, cutting balloons and drug-coated balloons; and
- amputation.

We also face competition from pharmaceutical companies that produce drugs which aim to destroy plaque or remove blockages in the bloodstream.

Our primary competitors for Pharos are Daavlin, National Biological, STRATA Skin Sciences and large pharmaceutical companies producing biologicals used in the treatment of chronic skin conditions.

Many of our competitors have substantially greater financial, manufacturing, commercial, and technical resources than we do. There has been consolidation in the industry, and we expect that to continue. Larger competitors may have substantially larger sales and marketing operations than we do. This may allow those competitors to spend more time with current and potential customers and to focus on a larger number of current and potential customers, which gives them a significant advantage over our sales and marketing team and our international distributors in making sales. In addition, we are often selling to customers who already utilize our competitors' products and who have established relationships with our competitors' sales representatives and familiarity with our competitors' products.

We are also aware that some of our competitors have been giving false and misleading information to our customers regarding reimbursement for procedures using DABRA, alleging without any factual basis that procedures performed using DABRA are not reimbursable under atherectomy coding. While we believe that these allegations are without merit, they may be successful in dissuading physicians from using the DABRA system out of concerns regarding reimbursement.

Larger competitors may also have broader product lines, which enables them to offer customers bundled purchase contracts and quantity discounts. These competitors may have more experience than we have in research and development, marketing, manufacturing, preclinical testing, conducting clinical trials, obtaining FDA and non-U.S. regulatory clearances or approvals and marketing cleared or approved products. Our competitors may discover technologies and techniques, or enter into partnerships and collaborations, to develop competing products that are more effective or less costly than our products or the products we may develop. This may render our technology or products obsolete or noncompetitive. Our competitors may also be better equipped than we are to respond to competitive pressures. If we are unable to compete successfully in our industry, it would have a material adverse effect on our business, financial condition, and results of operations.

If DABRA and Pharos are not approved for new indications, our commercial opportunity will be limited.

We market and sell DABRA for use as a tool in the treatment of vascular blockages resulting from lower extremity vascular disease and Pharos for use in the treatment of psoriasis, vitiligo, atopic dermatitis and leukoderma. Although physicians, in the practice of medicine, may prescribe or use marketed products for unapproved indications, manufacturers may promote their products only for the approved indications and in accordance with the provisions of the approved label. However, one of our strategies in the future is to pursue additional vascular indications for DABRA and additional dermatological indications for Pharos. Submitting the required applications for additional indications may require substantial additional funding beyond our cash and cash equivalents and short-term investments as of June 30, 2019. We cannot assure you that we will be able to successfully obtain approval for any of these additional product indications through the application process or that a premarket FDA submission may not be necessary.

Even if we obtain FDA clearance or approval to market our products for additional indications in the U.S., we cannot assure you that any such indications will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop our products for additional indications, our commercial opportunity will be limited, which would have a material adverse effect on our business, financial condition, and results of operations.

If we make acquisitions or divestitures, we could encounter difficulties that harm our business.

To date, the growth of our business has been organic, and we have no experience in acquiring other businesses, products or technologies. We may acquire companies, products or technologies that we believe to be complementary to the present or future direction of our business. If we engage in such acquisitions, we may have difficulty integrating the acquired personnel, financials, operations, products or technologies. Acquisitions may dilute our earnings per share, disrupt our ongoing business, distract our management and employees, increase our expenses, subject us to liabilities, and increase our risk of litigation, all of which could harm our business. If we use cash to acquire companies, products or technologies, it may divert resources otherwise available for other purposes. If we use our common stock to acquire companies, products or technologies, our stockholders may experience substantial dilution.

Technological change may adversely affect sales of our products and may cause our products to become obsolete.

The medical device market is characterized by extensive research and development and rapid technological change. Technological progress or new developments in our industry could adversely affect sales of our products. Our products could be rendered obsolete because of future innovations by our competitors or others in the treatment of vascular diseases and dermatological diseases, which would have a material adverse effect on our business, financial condition, and results of operations.

Consolidation in the medical device industry could have an adverse effect on our revenue and results of operations.

Many medical device industry companies are consolidating to create new companies with greater market power. For example, the Spectranetics Corporation was acquired by Koninklijke Philips N.V in 2017. As the medical device industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to negotiate price concessions or reductions for medical devices that incorporate components produced by us. If we reduce our prices because of consolidation in the healthcare industry, our revenue would decrease and our earnings, financial condition, or cash flows would suffer, which would have a material adverse effect on our business, financial condition, and results of operations.

We may be subject to enforcement actions, competitor lawsuits, or other claims if we engage or found to have engaged in the off-label promotion of our products.

Our promotional materials and training methods must comply with FDA regulations and other applicable laws, including restraints and prohibitions on the promotion of off-label, or uncleared use, of our products. Physicians may use our products for off-label use without regard to these prohibitions, as FDA regulations do not restrict or regulate a physician's choice of treatment within the practice of medicine. Although our policy is to follow published FDA guidance in order to avoid promoting our products improperly, the FDA or other regulatory agencies or third parties could disagree and conclude that we have engaged in off-label promotion. For example, our DABRA Laser System has been cleared by the FDA for crossing chronic total occlusions in patients with symptomatic infrainguinal lower extremity vascular disease and has an intended use for ablating a channel in occlusive peripheral vascular disease. We have not received FDA clearance or approval to market DABRA for an atherectomy indication, and we may not promote DABRA for an atherectomy indication. While our pivotal clinical study of the DABRA Laser System would not be sufficient to expand our FDA-cleared indication for use to an atherectomy indication for use, which the FDA currently defines to include a prespecified improvement in luminal patency, or prespecified increase in the openness of the artery at a pre-defined time point, such as six months following a DABRA procedure, using a consistent assessment tool, we believe that we can promote the device using the truthful and not misleading information from this study that is not inconsistent with our cleared indication.

During our initial public offering process, we received correspondence from a competitor claiming our promotion for DABRA as an atherectomy tool used by surgeons to treat peripheral vascular disease is off-label promotion for the product. We are also aware of similar claims being made to physicians by our competitors. We disagree with our competitors' claims and believe FDA's regulations and judicial case law allow companies to engage in certain forms of truthful, non-misleading and non-promotional speech concerning the off-label use of products, and we believe that we comply with these restrictions. We cannot predict the extent to which our competitors may be successful in dissuading physicians from using the DABRA system out of concerns regarding reimbursement. Furthermore, we may incur additional liability from claims initiated under the Lanham Act or other federal and state unfair competition laws with respect to how our products have been marketed and promoted.

In addition, we operate in an industry characterized by extensive litigation. However, the scope of potential liability with respect to any such claims, enforcement actions, or lawsuits is uncertain, and we cannot assure you that we will not receive claims from competitors or other third parties or be subject to enforcement actions in the future from regulatory agencies. For example, the FDA, FTC, the Office of the Inspector General of the Department of Health and Human Services ("HHS"), the DOJ and various state Attorneys General actively enforce laws and regulations that prohibit the promotion of off-label uses. In October 2019, the DOJ served us with a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning whether we fraudulently obtained 510(k) marketing clearance for our ablation devices marketed under the trade name DABRA, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether we paid imp roper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7bIn November 2019, we learned that the DOJ has opened a criminal investigation relating to the Company. We are cooperating fully with the DOJ's investigations. The False Claims Act, prohibits, among other things, making a fraudulent claim for payment of federal funds, causing such a fraudulent claim to be made, or making a false statement to get a false claim paid. The government may assert that a claim resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim under the False Claims Act. Many companies have faced government investigations or lawsuits by whistleblowers who bring a *qui tam* action under the False Claims Act on behalf of themselves and the government for a variety of alleged improper marketing activities, including providing free product to customers expecting that the customers would bill federal programs for the product, providing consulting fees, grants, free travel and other benefits to physicians to induce them to prescribe the company's products, and inflating prices reported to private price publication services, which are used to set drug reimbursement rates under government healthcare programs. In addition, the government and private whistleblowers have pursued False Claims Act cases against medical device companies for causing false claims to be submitted as a result of the marketing of their products for unapproved uses. Medical device and other healthcare companies also are subject to other federal false claim laws, including federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs. If we are found to have improperly promoted

off-label uses, we may be subject to significant liability, including civil fines, criminal fines and penalties, civil damages, exclusion from federal funded healthcare programs and potential liability under the federal False Claims Act and any applicable state false claims act. Due to the Civil Investigative Demand seeking information with respect to the False Claims Act investigation, we could incur substantial legal costs, including settlement costs, and business disruption responding to such investigation or suit, regardless of the outcome. If we are found to have violated the False Claims Act, it may result in significant financial penalties, on a per claim or statement basis, treble damages and exclusion from participation in federal health care programs. In addition, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials, which could negatively impact our marketing and decrease demand for our products. Conduct giving rise to such liability could also form the basis for private civil litigation by third-party payers, competitors, or other persons claiming to be harmed by such conduct. Notwithstanding the regulatory restrictions on off-label promotion, the FDA's regulations, guidance and judicial case law allow companies to engage in certain forms of truthful, non-misleading and non-promotional speech concerning the off-label use of products, for example FDA's June 2018 guidance document, "Medical Product Communications That Are Consistent With the FDA-Required Labeling - Questions and Answers." Nonetheless, the FDA, HHS, DOJ, and/or state Attorneys General, competitors, and other third parties may take the position that we are not in compliance with such requirements, and if such non-compliance is proven, it could harm our reputation, financial condition or divert financial and management resources from our core business, and would have a material adverse effect on our business, financial condition and results of operations. Moreover, any threatened or actual government enforcement actions or lawsuits by third parties could also generate adverse publicity, which could decrease demand for our products and require that we devote substantial resources that could be used productively on other aspects of our business.

Litigation and other legal proceedings may adversely affect our business.

From time to time we are involved in and may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal regulatory investigations, securities class action, and other legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. For example, we are currently a party to securities litigation and other litigation as set forth in Part II, Item 1 "Legal Proceedings." Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could have a material adverse effect on our business, financial condition, and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers' confidence and reduce long-term demand for our products, even if the regulatory or legal action is unfounded or not material to our operations.

We must indemnify officers and directors, including, in certain circumstances, former employees and directors, against all losses, including expenses, incurred by them in legal proceedings and advance their reasonable legal defense expenses, unless certain conditions apply. A prolonged uninsured expense and indemnification obligation could have a material adverse effect on our business, financial condition, and results of operations.

We are subject to numerous laws and regulations related to healthcare fraud and abuse, false claims, anti-bribery and anti-corruption laws, such as the U.S. Anti-Kickback Statute and Foreign Corrupt Practices Act of 1977, in which violations of these laws could result in substantial penalties, exclusion and prosecution.

In the United States, we are subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. There are similar laws in other countries. These laws may impact, among other things, the sales, marketing and education programs for our products. The federal Anti-Kickback Statute prohibits persons from knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program. The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Any allegation, investigation, or violation of domestic healthcare fraud and abuse laws could result in government or internal investigations, significant diversion of resources, exclusion from government healthcare programs and the curtailment or restructuring of our operations, significant fines, penalties, or other financial consequences, any of which may ultimately have a material adverse effect on our business, financial condition, and results of operations. For example, our Audit Committee identified potential healthcare compliance risk areas relating to the previous sales, marketing and education programs for our products such as lacking documentation of sufficient detail and specificity regarding payments that could be perceived as overpayments to obtain business from certain physicians, salespeople being instructed to provide potentially improper reimbursement information by characterizing treatment with DABRA as atherectomy and encouraging doctors to seek reimbursement under Medicare using atherectomy codes, and that determinations to direct potentially valuable benefits and opportunities to doctors were informed by sales prospects.

In October 2019, the DOJ served us with a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning whether we fraudulently obtained 510(k) marketing clearance for our ablation devices marketed under the trade name DABRA, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b. In November 2019, we learned that the DOJ has opened a criminal investigation relating to the Company We are cooperating fully with the DOJ's investigations.

For our sales and operations outside the United States, we are similarly subject to various heavily-enforced anti-bribery and anti-corruption laws, such as the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, U.K. Bribery Act, and similar laws around the world. These laws generally prohibit U.S. companies and their employees and intermediaries from offering, promising, authorizing or making improper payments to foreign government officials for the purpose of obtaining or retaining business or gaining any advantage. We face significant risks if we, which includes our third parties, fail to comply with the FCPA and other anti-corruption and anti-bribery laws.

We leverage various third parties to sell our products and conduct our business abroad, including to government owned universities and hospitals. We, our distributors and channel partners, and our other third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities (such as in the context of obtaining government approvals, registrations, or licenses or sales to government owned or controlled healthcare facilities, universities, institutes, clinics, etc.) and may be held liable for the corrupt or other illegal activities of these third-party business partners and intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize such activities. In many foreign countries, particularly in countries with developing economies, it may be a local custom that businesses engage in practices that are prohibited by the FCPA or other applicable laws and regulations. To that end, while we have adopted and implemented internal control policies and procedures and employee training and compliance programs to deter prohibited practices, such compliance measures ultimately may not be effective in prohibiting our employees, contractors, third parties, intermediaries or agents from violating or circumventing our policies and/or the law.

Responding to any enforcement action or related investigation, such as the current CID, may result in a materially significant diversion of managements attention and resources and significant defense costs and other professional fees. Any violation of the FCPA, other applicable anti-bribery, anti-corruption laws, healthcare laws, and anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could have a material and adverse effect on our reputation, business, financial condition, and results of operations.

Governmental export or import controls could limit our ability to compete in foreign markets and subject us to liability if we violate them.

Our products may be subject to U.S. export controls. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, we may be fined or other penalties could be imposed, including a denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or technologies targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell access to our products would likely materially and adversely affect our business, financial condition, and results of operations.

A variety of risks associated with marketing our products internationally could materially adversely affect our business.

In addition to selling our products in the U.S., we sell DABRA and Pharos outside of the U.S. We are subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- differing reimbursement regimes in foreign countries, including price controls and lower payment;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.;
- product shortages resulting from any events affecting raw material or finished good supply or distribution or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations, which would have a material adverse effect on our business, financial condition, and results of operations.

We face additional credit and compliance risks related to our international sales using foreign distributors.

We partner with distributors for DABRA and Pharos in select geographies outside of the U.S. For the six months ended June 30, 2019, approximately 8% of our sales were outside of the U.S. We may not be able to collect all of the funds owed to us by our foreign distributors. Some foreign distributors may experience financial difficulties, including bankruptcy, which may hinder our collection of accounts receivable. Where we extend credit terms to distributors, we periodically review the collectability and creditworthiness when determining the payment terms for such distributors. If our uncollectible accounts exceed our expectations, this could adversely impact our operating results. In addition, failure by our foreign distributors to comply with the Foreign Corrupt Practices Act or similar laws, insurance requirements, or other contract terms could have a negative impact on our business. Failure to manage the risks related to our foreign distributors would have a material adverse effect on our business, financial condition, and results of operations.

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive medical devices industry depends upon our ability to attract and retain highly qualified managerial, scientific, sales and medical personnel. We are highly dependent on our senior management team. The loss of the services of any of our executive officers and other key employees, and our inability to find suitable replacements could result in delays in product development and harm our business.

For example, we terminated our Chief Executive Officer on August 11, 2019 and are searching for a permanent chief executive officer.We face intense competition for executive-level talent from a variety of sources, including from current and potential competitors in the medical device and healthcare industries, and it may be difficult to find a new chief executive officer on a timely basis. Our continued success is dependent, in part, upon our ability to attract and retain superior executive officers, including a permanent chief executive officer.

Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have issued stock options and restricted stock units that vest over time. The value to employees of stock options and restricted stock units that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. The decline in our stock price may create additional challenges by reducing the retention value of our equity awards to these employees. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel. If we are not successful in attracting and retaining highly qualified personnel, it would have a material adverse effect on our business, financial condition, and results of operations.

If we experience significant disruptions in our information technology systems, our business may be adversely affected.

We depend on our information technology systems for the efficient functioning of our business, including the manufacture, distribution and maintenance of DABRA and Pharos, as well as for accounting, data storage, compliance, purchasing and inventory management. We do not have redundant information technology systems at this time. Our information technology systems may be subject to computer viruses, ransomware or other malware, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures and user errors, among other malfunctions. In addition, a variety of our software systems are cloud-based data management applications hosted by third-party service providers whose security and information technology systems are subject to similar risks. Technological interruptions would impact our business operations would disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers or disrupt our customers' ability use our products for treatments. In the event we experience significant disruptions, we may be unable to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our business, financial condition, and results of operations. Currently, we carry business interruption coverage to mitigate certain potential losses, but this insurance is limited in amount, subject to deductibles, and we cannot be certain that such potential losses will not exceed our policy limits. We are increasingly dependent on complex information technology to manage our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance our existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a material adverse effect on our business, financial condition, and results of operations.

We have identified material weaknesses in our internal control over financial reporting. If we do not remediate the material weaknesses in our internal control over financial reporting, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our stock.

In connection with our Audit Committee investigation as more fully described in Item 4, "*Controls and Procedures*", we identified material weaknesses in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses that we identified related to the aggregation of control deficiencies in the Company's control environment, in particular an inappropriate "tone at the top" set by certain members of senior management, a failure to promote adherence to our Code of Ethics and Conduct, and the lack of sufficient competent resources in key roles at the organization.

Additionally, we will be required, pursuant to Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting beginning with our annual report filed on Form 10-K for the year ending December 31, 2019. We will need to disclose any material weaknesses identified by our management in our internal control over financial reporting. As an "emerging growth company," we will avail ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. However, we may no longer avail ourselves of this exemption when we cease to be an "emerging growth company." When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the U.S. Securities and Exchange Commission, or SEC, or other regulatory authorities, which would require additional financial and management resources.

In prior periods we identified certain material weaknesses in our internal controls related to revenue recognition and lack of staffing in the accounting and finance organization. In connection with these prior material weaknesses we implemented remediation measures including training of accounting personnel as well as hiring additional personnel with experience in the ongoing identification, design and implementation of internal control over financial reporting. In connection with our 2017 audit, as part of the restatement to the 2016 financial statements, we identified a material weakness in the design of our internal controls related to the administration of capital stock transactions, including stock issuances and a reverse stock split which were not effected in accordance with the requirements of applicable law and the communication of stock option awards which were not validly authorized.

We have incurred significant costs to remediate these prior period weaknesses, primarily personnel costs, external consulting and legal fees, system implementation costs, and related indirect costs including the use of facilities and technology. However, completion of remediation does not provide assurance that our controls will operate properly or that our financial statements will be free from error, which may undermine our ability to provide accurate, timely and reliable reports on our financial and operating results. There may be additional undetected material weaknesses in our internal control over financial reporting, as a result of which we may not detect financial statement errors on a timely basis. Further, to the extent we identify additional material weaknesses, we will not be able to fully assess whether corrective measures will remediate the material weakness in our internal control over financial reporting until we have completed our implementation efforts and sufficient time passes in order to evaluate their effectiveness. In addition, if we identify additional errors that result in material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. Moreover, in the future we may engage in business transactions, such as acquisitions, reorganizations or implementation of new information systems that could negatively affect our internal control over financial reporting and result in material weaknesses.

If we identify additional material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, we may be late with the filing of our periodic reports, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected. As a result of such failures, we could also become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation, financial condition or divert financial and management resources from our core business, and would have a material adverse effect on our business, financial condition and results of operations.

We could be subject to claims based on defects with respect to certain corporate transactions that were not authorized in accordance with applicable law.

We have determined that due to the material weakness in our internal controls related to the administration of capital stock transactions, there have been defects with respect to certain corporate transactions, including (i) stock issuances that were not or may not have been properly approved by our board of directors and/or adequately documented, (ii) a reverse stock split for which we failed to file the amendment to our articles of incorporation, and (iii) the communication of option awards that were not validly authorized by our board of directors as a result of non-existent or defective board approvals, in each case in accordance with applicable law.

To remediate these defects, we have taken a number of actions. Our board of directors has ratified the defective stock issuances; we obtained agreements from holders of the vast majority of our common stock which include a confirmation of the securities each stockholder holds, a release of potential claims with respect to issuance of securities to such stockholders, and a surrender specifically of any claims to the equity of the Delaware corporation except for the shares of the Delaware corporation that such stockholder has received in the reincorporation merger pursuant to the merger agreement; we confirmed with the vast majority of the applicable stockholders that the appropriate number of shares of common stock outstanding immediately prior to the time of the intended reverse stock split were contributed to the capital of the Company effective as of the intended time of, and to give effect to, the intended reverse stock split; and we have approved compensation to and obtained releases from our impacted employees and other service providers to resolve potential claims, if any, related to the communicated grants of option awards and to promote retention and align their interests with the long-term interests of our stockholders. While we have attempted to narrow potential future claims by taking certain remedial corporate actions, the scope of liability with respect to such defects is uncertain and we cannot assure that these actions will entirely remediate these defects or that we will not receive claims in the future from other persons asserting rights to shares of our capital stock or to stock options or other equity. To the extent any such claims are successful, they could have a material adverse effect on our business, financial condition and results of operations.

Under certain authority, common law ratification by our board of directors of prior stock issuances may have caused such issuances to be valid stock issuances by us at the time of the respective issuances. However, there is uncertainty under applicable law as to whether such common law ratification may be effective under all circumstances. There can be no assurance that stockholders will not assert claims that a defective corporate act or putative stock issuance ratified by us is void or voidable due to the identified failure of proper authorization by our board of directors, as well as other claims related thereto, and, if asserted, that any such claims will not be successful. If such ratification is deemed not to be effective, then the issuances of certain shares of our stock and other attempted corporate actions would be invalid and we could have liability to grantees of our common stock, which may have a material adverse effect on our business and results of operations.

We have also confirmed that the vast majority of the applicable stockholders as of the time of the intended reverse stock split contributed a number of shares of common stock sufficient to give effect to the recapitalization intended by the reverse stock split. However, a holder of our common stock could argue that this process does not represent an adequate remedy for a potential failure to properly implement the reverse stock split. If the contribution of shares to the capital of the Company was not effective, then we could have liability to certain holders of our common stock, which may have a material adverse effect on our business and results of operations.

Additionally, we may have potential liability to certain of our employees, directors, consultants, and other service providers for communicated grants of option awards that were not authorized in compliance with applicable law. With respect to the communicated grants of option awards that were not validly authorized, we approved compensation and obtained a release of potential claims from such persons. We approved compensation to our impacted employees, directors, consultants, and other service providers to mitigate potential claims related to the communicated grants of option awards, if any. However, an impacted individual could argue that such compensation is not an adequate remedy for prior invalid option awards and, if a court were to impose a greater remedy, our financial exposure could be greater and have a material adverse effect on our business and results of operations. The foregoing could also result in tax withholding, employment taxes or other tax liabilities, including penalties and interest, all of which could have a material adverse effect on our business, financial condition and results of operations.

In order to increase our revenue over the longer term, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

At June 30, 2019, we had 123 full-time employees. In August 2019, we began implementing certain operational efficiency and cost savings initiatives intended to align our resources with our product strategy, reduce our operating expenses, and manage our cash flows. These cost efficiency initiatives include targeted workforce reductions of our sales and marketing teams. We have reduced the size of our DABRA sales force from 34 employees as of June 30, 2019 to 6 employees as of November 11, 2019.

Over the longer term, we intend to hire and train additional skilled sales personnel. At such time, we would expect to need additional managerial, operational, sales, marketing, financial, and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees, including additional members of our sales force;
- managing our internal development efforts effectively, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully market and sell our products will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our products and, accordingly, may not achieve our research, sales and marketing goals, which would have a material adverse effect on our business, financial condition, and results of operations.

We actively employ social media as part of our marketing strategy, which could give rise to regulatory violations, liability, fines, breaches of data security or reputational damage.

Despite our efforts to monitor evolving social media communication guidelines and comply with applicable rules, there is risk that the use of social media by us, our employees or our customers to communicate about our products or business may cause us to be found in violation of applicable requirements, including requirements of regulatory bodies such as the FDA and Federal Trade Commission. For example, promotional communications and endorsements on social media that, among other things, promote our products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label uses"), do not contain a fair balance of information about risks associated with using our products, make comparative or other claims about our products that are not supported by sufficient evidence, and/or do not contain required disclosures could result in an enforcement actions against us. In addition, adverse events, product complaints, off-label usage by physicians, unapproved marketing or other unintended messages posted on social media could require an active response from us, which may not be completed in a timely manner and could result in regulatory action by a governing body. Further, our employees may knowingly or inadvertently make use of social media in ways that may not comply with our corporate policies or other legal or contractual requirements, which may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers and others. Furthermore, negative posts or comments about us or our products in social media could seriously damage our reputation, brand image and goodwill, which would have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Regulatory Approval and our Industry

Regulatory compliance is expensive, complex and uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business.

The FDA and similar agencies regulate our products as medical devices. Complying with these regulations is costly, time consuming, complex and uncertain. FDA regulations and regulations of similar agencies are wide-ranging and include, among other things, oversight of:

- product design, development, manufacture (including suppliers) and testing;
- pre-clinical and clinical studies;
- product safety and effectiveness;
- product labeling;
- product storage and shipping;
- record keeping;
- pre-market clearance or approval;
- marketing, advertising and promotion;
- product sales and distribution;
- product changes;
- product recalls; and
- post-market surveillance and reporting of deaths or serious injuries and certain malfunctions.

Our current products are subject to extensive regulation by the FDA and non-U.S. regulatory agencies. Further, all of our potential products and improvements of our current products will be subject to extensive regulation and will likely require permission from regulatory agencies and ethics boards to conduct clinical trials, and clearance or approval from the FDA and non-U.S. regulatory agencies prior to commercial sale and distribution. Failure to comply with applicable U.S. requirements regarding, for example, promoting, manufacturing or labeling our products, may subject us to a variety of administrative or judicial actions and sanctions, such as Form 483 observations, warning letters, untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution. The FDA can also refuse to clear or approve pending applications. Any enforcement action by the FDA and other comparable non-U.S. regulatory agencies could have a material adverse effect on our business, financial condition, and results of operations.

Our medical device operations are subject to pervasive and continuing FDA regulatory requirements.

Medical devices regulated by the FDA are subject to"general controls" which include: registration with the FDA; listing commercially distributed products with the FDA; complying with cGMPs under the Quality System Regulations, or QSR; filing reports with the FDA of and keeping records relative to certain types of adverse events associated with devices under the medical device reporting regulation; assuring that device labeling complies with device labeling requirements; reporting certain device field removals and corrections to the FDA; and obtaining premarket notification 510(k) clearance for devices prior to marketing. Some devices known as "510(k)-exempt" devices can be marketed without prior marketing clearance or approval from the FDA. In addition to the "general controls," some Class II medical devices are also subject to"special controls," including adherence to a particular guidance document and compliance with the performance standard. As Class II, 510(k)-cleared devices, our products are subject to both general and special controls. Instead of obtaining 510(k) clearance, most Class III devices are subject to premarket approval, or PMA. None of our current products are Class III devices, but future products could be, which would subject them to the PMA process.

Many medical devices, such as medical lasers, are also regulated by the FDA as"electronic products." In general, manufacturers and marketers of"electronic products" are subject to certain FDA regulatory requirements intended to ensure the radiological safety of the products. These requirements include, but are not limited to, filing certain reports with the FDA about the products and defects/safety issues related to the products as well as complying with radiological performance standards.

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, or MDR, requirements, including the reporting of adverse events and malfunctions related to our products. We are required to file MDRs if our products may have caused or contributed to a serious injury or death or malfunctioned in a way that could likely cause or contribute to a serious injury or death if it were to recur. Any such MDR that reports a significant adverse event could result in negative publicity, which could harm our reputation and future sales. For example, the Audit Committee found that we failed to timely make at least two MDRs, to the FDA, which have since been reported.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 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 clearances or approvals, product seizures, injunctions or the imposition of civil or criminal penalties which may have a material adverse effect on our business, financial condition, and results of operations.

The medical device industry is now experiencing greater scrutiny and regulation by federal, state and foreign governmental authorities. Companies in our industry are subject to more frequent and more intensive reviews and investigations, often involving the marketing, business practices, and product quality management. Such reviews and investigations may result in the civil and criminal proceedings; the imposition of substantial fines and penalties; the receipt of warning letters, untitled letters, demands for recalls or the seizure of our products; the requirement to enter into corporate integrity agreements, stipulated judgments or other administrative remedies, and result in our incurring substantial unanticipated costs and the diversion of key personnel and management's attention from their regular duties, any of which may have an adverse effect on our financial condition, results of operations and liquidity, and may result in greater and continuing governmental scrutiny of our business in the future.

Additionally, federal, state and foreign governments and entities have enacted laws and issued regulations and other standards requiring increased visibility and transparency of our interactions with healthcare providers. For example, the U.S. Physician Payment Sunshine Act, now known as Open Payments, requires us to report to the Centers for Medicare & Medicaid Services, or CMS, payments and other transfers of value to all U.S. physicians and U.S. teaching hospitals, with the reported information made publicly available on a searchable website. Effective January 2022, we will also be required to collect and report information on payments or transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives. Failure to comply with these legal and regulatory requirements could impact our business, and we have had and will continue to spend substantial time and financial resources to develop and implement enhanced structures, policies, systems and processes to comply with these legal and regulatory requirements, which may also impact our business and which could have a material adverse effect on our business, financial condition, and results of operations.

Product clearances and approvals can often be denied or significantly delayed.

Under FDA regulations, unless exempt, a new medical device may only be commercially distributed after it has received 510(k) clearance, is authorized through the de novo classification process, or is the subject of an approved PMA. The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to another legally marketed product not subject to a PMA. Sometimes, a 510(k) clearance must be supported by preclinical and clinical data.

The PMA process typically is more costly, lengthy and stringent than the 510(k) process. Unlike a 510(k) review which determines "substantial equivalence," a PMA requires that the applicant demonstrate reasonable assurance that the device is safe and effective by producing valid scientific evidence, including data from preclinical studies and human clinical trials. Therefore, to obtain regulatory clearance or approvals, we typically must, among other requirements, provide the FDA and similar foreign regulatory authorities with preclinical and clinical data that demonstrate to their satisfaction that our products satisfy the criteria for approval. Preclinical testing and clinical trials must comply with the regulations of the FDA and other government authorities in the U.S. and similar agencies in other countries.

We may be required to obtain PMAs, PMA supplements or additional 510(k) premarket clearances to market modifications to our existing products. The FDA requires device manufacturers to make and document a determination of whether a modification requires approval or clearance; however, the FDA can review a manufacturer's decision. The FDA may not agree with our decisions not to seek approvals or clearances for particular device modifications. If the FDA requires us to obtain PMAs, PMA supplements or pre-market clearances for any modification to a previously cleared or approved device, we may be required to cease manufacturing and marketing the modified device and perhaps also to recall such modified device until we obtain FDA clearance or approval. We may also be subject to significant regulatory fines or penalties.

The FDA may not approve our current or future PMA applications or supplements or clear our 510(k) applications on a timely basis or at all. Such delays or refusals could have a material adverse effect on our business, financial condition, and results of operations.

The FDA may also change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. Any of these actions could have a material adverse effect on our business, financial condition, and results of operations.

International regulatory approval processes may take more or less time than the FDA clearance or approval process. If we fail to comply with applicable FDA and comparable non-U.S. regulatory requirements, we may not receive regulatory clearances or approvals or may be subject to FDA or comparable non-U.S. enforcement actions. We may be unable to obtain future regulatory clearance or approval in a timely manner, or at all, especially if existing regulations are changed or new regulations are adopted. For example, the FDA clearance or approval process can take longer than anticipated due to requests for additional clinical data and changes in regulatory requirements. A failure or delay in obtaining necessary regulatory clearances or approvals would materially adversely affect our business, financial condition, and results of operations.

Although we have obtained regulatory clearance for our products in the U.S. and certain non-U.S. jurisdictions, they will remain subject to extensive regulatory scrutiny.

Although our products have obtained regulatory clearance in the U.S. and certain non-U.S. jurisdictions, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, effectiveness, and other post-market information, including both federal and state requirements in the U.S. and requirements of comparable non-U.S. regulatory authorities.

Our manufacturing facility is required to comply with extensive requirements imposed by the FDA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to the QSR or similar regulations set by foreign regulatory authorities. Following our recall and given our Audit Committee findings, we have a heightened potential for an FDA inspection. As such, we will be subject to continual review and inspections to assess compliance with the QSR and adherence to commitments made in any 510(k) application. Accordingly, we continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

Any regulatory clearances or approvals that we have received for our products will be subject to limitations on the cleared or approved indicated uses for which the product may be marketed and promoted or to the conditions of approval, or contain requirements for potentially costly post-marketing testing. We are required to report certain adverse events and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing product safety issues could result in increased costs to assure compliance. The FDA and other agencies, including the DOJ, closely regulate and monitor the post-clearance or approval marketing and promotion of products to ensure that they are marketed and distributed only for the cleared or approved indications and in accordance with the provisions of the cleared or approved labeling. We have to comply with requirements concerning advertising and promotion for our products.

Promotional communications with respect to devices are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's cleared or approved labeling. As such, we may not promote our products for indications or uses for which they do not have clearance or approval. However, physicians can use their independent and professional judgment and use our products for off-label purposes, as FDA regulations do not restrict a physician's choice of treatment with the practice of medicine. For certain changes to a cleared product, including certain changes to product labeling, the holder of a cleared 510(k) application may be required to submit a new application and obtain clearance or approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with our facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- subject our manufacturing facility to an adverse inspectional finding or Form 483, or other compliance or enforcement notice, communication, or correspondence;
- issue warning or untitled letters that would result in adverse publicity or may require corrective advertising;
- impose civil or criminal penalties;
- suspend or withdraw regulatory clearances or approvals;
- refuse to clear or approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our sub-assembly suppliers' facilities;
- seize or detain products; or
- require a product recall.

In addition, violations of the Federal Food, Drug, and Cosmetic Act, or FDCA, relating to the promotion of approved products may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory clearance or approval is withdrawn, it would have a material adverse effect on our business, financial condition, and results of operations.

Our products may be subject to additional recalls, revocations or suspensions after receiving FDA or foreign approval or clearance, which could divert managerial and financial resources, harm our reputation, and adversely affect our business.

The FDA and similar foreign governmental authorities have the authority to order the recall of our products because of any failure to comply with applicable laws and regulations, or defects in design or manufacture. A government mandated or voluntary product recall by us could occur because of, for example, component failures, device malfunctions, or other adverse events, such as serious injuries or deaths, or quality-related issues such as manufacturing errors or design or labeling defects. For example, in the third quarter of 2019, we initiated a voluntary recall of DABRA catheters due to inconsistent performance caused by catheters that failed to calibrate and relabeled the catheters with two-month expiration, replacing its previous twelve-month shelf life expiration. Any government-mandated recall or additional voluntary recall by us could occur as a result of component failures, manufacturing errors, design or labeling defects or other issues. This recall and any future recalls of our products could divert managerial and financial resources, harm our reputation and adversely affect our business.

Depending on the corrective action we take to address a product's deficiencies or defects, the FDA may require, or we may voluntarily decide, that we will need to seek and obtain new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including adverse inspection finding, FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our products in the future.

As part of our investigation into the DABRA device performance, we conducted an internal audit of the clinical study that was used to support the device's 510(k) application. The audit consisted of review of clinical study documentation that was retained by the study sponsor and found adequate evidence to support the safety and efficacy reported in the clinical study report submitted with the 510(k) application. The other observations identified by the audit were found to not have a major impact on the reported results of the study. If FDA were to disagree with the outcome of the audit and take the position that the issues with the clinical trial were reportable to the FDA, we could be required to issue a safety alert to our customers or initiate a recall, we could incur product liability and other costs, product approvals could be delayed, suspended or revoked, enforcement action could be initiated by regulatory authorities, we could be required to cease commercialization of DABRA and our business could otherwise be adversely affected.

In addition, we are subject to medical device reporting regulations that require us to report to the FDA or similar foreign governmental authorities if one of our products may have caused or contributed to a death or serious injury or if we become aware that it has malfunctioned in a way that would be likely to cause or contribute to a death or serious injury if the malfunction recurred. After a May 2018 inspection, the FDA issued to us a Form 483 that included observations for failure to properly evaluate whether certain complaints related to Pharos and DABRA that we have received rose to a level required to be reported to the FDA. In response, we informed the FDA that we have modified our complaint review procedures and we completed a retrospective evaluation and have not found any complaints which require a submission to the FDA. In connection with our Audit Committee investigation, the Audit Committee also found failures to properly identify reportable events or to file timely reports, as well as failure to address each of the observations to FDA's satisfaction. These failures can subject us to sanctions and penalties, including warning letters and recalls. Physicians, hospitals and other healthcare providers may make similar reports to regulatory authorities. Any such reports may trigger an investigation by the FDA or similar foreign regulatory bodies, which could divert managerial and financial resources, harm our reputation and have a material adverse effect on our business, financial condition, and results of operations.

Material modifications to our devices may require new 510(k) clearances or premarket approvals or may require us to recall or cease marketing our devices until clearances or approvals are obtained.

Material modifications to the intended use or technological characteristics of our devices will require new 510(k) clearances or premarket approvals, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on FDA published guidelines, the FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement, or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA-cleared device that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would constitute a material modification and 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 devices or for modifications to, additional indications for, our devices in a timely fashion, or at all. Delays in obtaining required future clearances would harm our ability to introduce new or enhanced devices in a timely manner, which in turn would harm our future growth. We have made modifications to our devices in the past and will 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 selling or marketing our devices as modified, which could harm our operating results and require us to redesign our platform devices. In these circumstances, we may also be subject to significant enforcement actions such as significant regulatory fines or penalties. Furthermore, the FDA's ongoing review of the 510(k) program may make it more difficult for us to modify our previously cleared products, either by imposing stricter requirements on when a new 510(k) for a modification to a previously cleared product must be submitted, or applying more onerous review criteria to such submissions. Specifically, on July 9, 2012, the FDA Safety and Innovation Act of 2012 was enacted which, among other requirements, obligates the FDA to prepare a report for Congress on the FDA's approach for determining when a new 510(k) will be required for modifications or changes to a previously cleared device. The FDA recently submitted this report and suggested that manufacturers continue to adhere to the FDA's 1997 Guidance on this topic when making a determination as to whether or not a new 510(k) is required for a change or modification to a device. However, the practical impact of the FDA's continuing scrutiny of these issues remains unclear.

If we fail to comply with the FDA's Quality System Regulation or any applicable state equivalent, our operations could be interrupted and our potential product sales and operating results could suffer.

We are required to comply with the FDA's QSR, which delineates, among other things, the design controls, document controls, purchasing controls, identification and traceability, production and process controls, acceptance activities, nonconforming product requirements, corrective and preventive action requirements, labeling and packaging controls, handling, storage, distribution and installation requirements, complaint handling, records requirements, servicing requirements, and statistical techniques potentially applicable to the production of our medical devices. We and our suppliers are also subject to the regulations of foreign jurisdictions regarding the manufacturing process if we market products overseas. The FDA enforces the QSR through periodic and announced or unannounced inspections of manufacturing facilities. Our facilities have been inspected by the FDA and other regulatory authorities, and we anticipate that we and certain of our third-party component suppliers will be subject to additional future inspections. If our facilities and manufacturing processes are found to be in non-compliance or fail to take satisfactory corrective action in response to adverse QSR inspectional findings, FDA could take legal or regulatory enforcement actions against us and/or our products, including but not limited to the cessation of sales or the initiation of a recall of distributed products, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

Current regulations depend heavily on administrative interpretation. If the FDA does not believe that we are in compliance with applicable FDA regulations, the agency could take legal or regulatory enforcement actions against us and/or our products. We are also subject to periodic inspections by the FDA, other governmental regulatory agencies, as well as certain third-party regulatory groups. Future interpretations made by the FDA or other regulatory bodies made during the course of these inspections may vary from current interpretations and may adversely affect our business and prospects. The FDA's and other comparable non-U.S. regulatory agencies' statutes, regulations, or policies may change, and additional government regulation or statutes may be enacted, which could increase post-approval regulatory requirements, or delay, suspend, prevent marketing of any cleared or approved products or necessitate the recall of distributed products. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

The medical device industry has been under heightened FDA scrutiny as the subject of government investigations and enforcement actions. If our operations and activities are found to be in violation of any FDA laws or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and other legal and/or agency enforcement actions. Any penalties, damages, fines, or curtailment or restructuring of our operations or activities could adversely affect our ability to operate our business and our financial results. The risk of us being found in violation of FDA laws is increased by the fact that many of these laws are broad and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend ourselves against that action and its underlying allegations, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Where there is a dispute with a federal or state governmental agency that cannot be resolved to the mutual satisfaction of all relevant parties, we may determine that the costs, both real and contingent, are not justified by the commercial returns to us from maintaining the dispute or the product.

Various claims, design features or performance characteristics of our medical devices, that we regarded as permitted by the FDA without marketing clearance or approval, may be challenged by the FDA or state or foreign regulators. The FDA or state or foreign regulatory authorities may find that certain claims, design features or performance characteristics, in order to be made or included in the products, may have to be supported by further studies and marketing clearances or approvals, which could be lengthy, costly and possibly unobtainable.

If any of our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be required to report under applicable medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, or MDR 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 likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. For example, in 2015 we submitted to the FDA an MDR for an event that involved a patient who experienced significant erythema, or skin reddening, and transient blistering after treatment with Pharos. The patient was treated with topical antibiotics and subsequently continued treatment. For DABRA, the most frequent complication reported to us as a result of post-market surveillance is clinically non-significant vessel perforation. In connection with an internal audit of our regulatory reporting systems and our Audit Committee investigation, we are revising our internal operating procedures for complaint handling and adverse event classifications. We reviewed all adverse medical events that have been reported to us and retrospectively filed three MDRs with the FDA.

If we fail to report events required to be reported to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require our time and capital, distract management from operating our business, and may harm our reputation and have a material adverse effect on our business, financial condition, and results of operations.

Healthcare reform initiatives and other administrative and legislative proposals may adversely affect our business, financial condition, results of operations and cash flows in our key markets.

There have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control or manage the increasing costs of healthcare and, more generally, to reform the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the coverage and reimbursement available for our products and could limit the acceptance and availability of our products on the market. The adoption of proposals to control costs could have a material adverse effect on our business, financial condition, and results of operations.

For example, in the U.S., in March 2010, the Patient Protection and Affordable Care Act,or ACA, was passed. The ACA has made significant changes to the way healthcare is financed by both federal and state governments and private insurers, and has directly impacted the medical device industry. Among other provisions that may affect our business, including provisions that are meant to contain healthcare costs, improve quality and/or expand access, the ACA implemented, with limited exceptions, a deductible excise tax of 2.3% on sales of medical devices by entities, including us, which manufacture or import certain medical devices offered for sale in the U.S., including many of our products. The tax was to become effective January 1, 2013, but is currently suspended until January 1, 2020. Revenue from many of our products will be subject to that excise tax.

There have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA and we expect such challenges and amendments to continue. For example, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the 2.3% excise tax imposed on manufacturers and importers for certain sales of medical devices, the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, and the annual fee imposed on certain health insurance providers based on market share. Congress may consider additional legislation to repeal or repeal and replace all or certain elements of the ACA, including the medical device excise tax. We continue to evaluate the impact of the ACA and its possible repeal or replacement on our business.

In addition, other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will remain in effect through 2027 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control product costs. Additionally, individual states in the U.S. have also become increasingly active in passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, Medicare, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their healthcare programs. Adoption of price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue, attain profitability.

Various new healthcare reform proposals are emerging at the federal and state level. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federal and state governments will pay for healthcare products and services, and could have a material adverse effect on our business, financial condition, and results of operations.

Healthcare cost containment pressures and legislative or administrative reforms resulting in restrictive coverage and reimbursement practices of third-party payors could decrease the demand for our products and the number of procedures performed using our devices, which could have an adverse effect on our business.

Our products are purchased principally by catheterization laboratories, which typically bill various third-party payors, including governmental programs, such as Medicare and Medicaid, private insurance plans and managed care plans, for the healthcare services provided to their patients. The ability of our customers to obtain reimbursement for procedures that are performed using our products from government and private third-party payors is critical to our success. The availability of coverage and reimbursement for procedures performed using our products affects which products customers purchase and the prices they are able to pay to us.

Reimbursement can vary based on geographical location, type of provider/customer, and third-party payor and can significantly influence the acceptance of new products and services. Third-party payors may view some procedures performed using our products as experimental and may not provide coverage. Third-party payors may not cover and reimburse our customers for certain procedures performed using our products in whole or in part in the future, or payment rates may decline and not be adequate, or both. Further, coverage and reimbursement by third-party payors to our customers is also related to billing codes to describe procedures performed using our products. Hospitals and physicians use several billing codes to bill for such procedures. Third-party payors may not continue to recognize the current CPT codes available for use by our customers. The CPT codes may change undermining our customer's ability to use those codes and reimbursement may be interrupted. Furthermore, some payors may not accept these new or revised codes for payment. If payors do not cover atherectomy, physicians may not perform as many DABRA treatments as they otherwise would perform. Consequently, we may not be able to sell as many catheters for DABRA treatments as projected.

Reimbursement rates are unpredictable, and we cannot project how our business may be affected by future legislative and regulatory developments. Future legislation or regulation, or changing payment methodologies, may have a material adverse effect on our business, financial condition, and results of operations, and reimbursement may not be adequate for all customers. From time to time, typically on an annual basis, payment amounts are updated and revised by third-party payors. Because the cost of our products generally is recovered by the healthcare provider as part of the payment for performing a procedure and not separately reimbursed, these updates, especially lower payments could directly impact the demand for our products. For example, in July 2013, the CMS proposed reimbursement changes that would have decreased reimbursement for procedures in an outpatient based facility, such as a catheterization lab. Although CMS chose not to implement those changes in 2013, we cannot assure you that CMS will not take similar actions in the future.

After we develop new products or seek to market our products for new approved or cleared indications, we may find limited demand for the product unless government and private third-party payors provide adequate coverage and reimbursement to our customers. Obtaining codes and reimbursement for new products may require an extended, multi-year effort. Even with reimbursement approval and coverage by government and private payors, providers submitting reimbursement claims for new products or existing products with new approved or cleared indications may face delay in payment if there is confusion by providers or payors regarding the appropriate codes to use in seeking reimbursement. Such delays may create an unfavorable impression within the marketplace regarding the level of reimbursement or coverage available for our products.

Demand for our products or new approved indications for our existing products may fluctuate over time if federal or state legislative or administrative policy changes affect coverage or reimbursement levels for our products or the services related to our products. In the U.S., there have been and we expect there will continue to be legislative and regulatory proposals to change the healthcare system, such as the potential repeal of the ACA, some of which could significantly affect our business. It is uncertain what impact the current U.S. presidential administration will have on healthcare spending including a campaign promise to repeal the ACA. If enacted and implemented, any measures to restrict healthcare spending could result in decreased revenue from the sale of our products and decreased potential returns from our research and development initiatives. Other legislative or administrative reforms to the U.S. or international reimbursement systems in a manner that significantly reduces reimbursement for procedures performed using our products or denies coverage for those procedures could have a material adverse effect on our business, financial condition, and results of operations.

Our employees, independent contractors, consultants, commercial partners, distributors, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial partners, distributors, and vendors and other individuals or entities with whom we have arrangements may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the laws of the FDA and other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws in the U.S. and similar foreign fraudulent misconduct laws; or (iv) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing, and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, waste, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

We have adopted a code of ethics and business conduct, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If such actions are instituted against us, in connection with the Audit Committee investigation or otherwise, and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, additional integrity reporting and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business, financial condition, and results of operations.

Environmental and health safety laws may result in liabilities, expenses and restrictions on our operations.

Federal, state, local and foreign laws regarding environmental protection, hazardous substances and human health and safety may adversely affect our business. Using hazardous substances in our operations exposes us to the risk of accidental injury, contamination or other liability from the use, storage, importation, handling, or disposal of hazardous materials. If our or our suppliers' operations result in the contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and fines, and any liability could significantly exceed our insurance coverage and have a material adverse effect on our on our business, financial condition, and results of operations. Future changes to environmental and health and safety laws could cause us to incur additional expenses or restrict our operations, which could have a material adverse effect on our business, financial condition, and results of operations.

Our operations and relationships with customers and third-party payors are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties including criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation of our cleared devices and any future cleared or approved devices. Our current and future arrangements with providers, third-party payors and customers may be materially limited because of broadly applicable fraud and abuse and other healthcare laws and regulations. The business or financial arrangements and relationships through which we market, sell and distribute our cleared devices could also be constrained.

Restrictions under applicable U.S. federal and state healthcare laws and regulations may include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- federal false claims laws, including the federal False Claims Act, imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Persons and entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, established new statutes imposing criminal healthcare fraud liability and increased civil monetary penalties for, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of the healthcare fraud statutes HIPAA established or specific intent to violate them in order to have a liability;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health, or HITECH, Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, on covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information. We believe we are not a covered entity for purposes of HIPAA, and we believe that we generally do not conduct our business in a manner that would cause us to be a business associate under HIPAA;
- the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members. Effective January 2022, we will also be required to collect and report information on payments or transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales ormarketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require medical device companies to comply with the medical device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. In addition, we may be subject to state and non-U.S. laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Our Audit Committee identified certain conduct that may implicate healthcare laws and FDA regulatory requirements, and we have undertaken efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations. Such efforts may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of product candidates from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the above occurs, it could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs, which could have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to our Intellectual Property

If we are unable to obtain and maintain patent protection for our products, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our existing products and any products we may develop, and our technology may be adversely affected.

As with other medical device companies, our ability to maintain and solidify a proprietary position for our products will depend upon our success in obtaining effective patent claims that cover such products, their manufacturing processes and their intended methods of use, and enforcing those claims once granted. Furthermore, in some cases, we may not be able to obtain issued claims covering DABRA and Pharos, as well as other technologies that are important to our business, which are sufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to DABRA and Pharos could have a material adverse effect on our business, financial condition, and results of operations.

Changes in either the patent laws or their interpretation in the U.S. and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our issued patents. Additionally, we cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, suppliers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of

patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are therefore reliant on our licensors or licensees. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship, and the like, although we are unaware of any such defects that we believe are of material importance. If we or any future licensors or licensees, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If any future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation or prosecution of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

In addition, if any patents are issued in the future, they may not provide us with any competitive advantages, or may be successfully challenged by third parties. Agreement terms that address non-competition are difficult to enforce in many jurisdictions and may not be enforceable in any particular case. To the extent that our intellectual property and other proprietary rights are not adequately protected, third parties might gain access to our proprietary information, develop and market products or services similar to ours, or use trademarks similar to ours, each of which could materially harm our business. Existing United States federal and state intellectual property laws offer only limited protection. Moreover, the laws of other countries in which we now, or may in the future, conduct operations or contract for services may afford little or no effective protection of our intellectual property. The failure to adequately protect our intellectual property and other proprietary rights could materially harm our business.

The strength of patent rights involves complex legal and scientific questions and can be uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents. The patent applications that we own may fail to result in issued patents in the United States or foreign countries with claims that cover our products or services. Even if patents do successfully issue from the patent applications that we own, third parties may challenge the validity, enforceability or scope of such patents, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful challenge to our patents could deprive us of exclusive rights necessary for the successful commercialization of our products and services. Furthermore, even if they are unchallenged, our patents may not adequately protect our products and services, provide exclusivity for our products and services, or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our products and services is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our products and services.

Patents have a limited lifespan. In the United States, the natural expiration of a utility patent is generally 20 years after its effective filing date and the natural expiration of a design patent is generally 14 years after its issue date, unless the filing date occurred on or after May 13, 2015, in which case the natural expiration of a design patent is generally 15 years after its issue date. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our products and services, we may be open to competition. Further, if we encounter delays in our development efforts, the period of time during which we could market our products and services under patent protection would be reduced.

In addition to the protection afforded by patents, we also rely on trade secret protection to protect proprietary know-how that may not be patentable or that we elect not to patent, processes for which patents may be difficult to obtain or enforce, and any other elements of our products and services that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. If the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secrets. Misappropriation or unauthorized disclosure of our trade secrets could significantly affect our competitive position and may have a material adverse effect on our business. Furthermore, trade secret protection does not prevent competitors from independently developing substantially equivalent.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and products would be adversely affected.

The patent position of medical device companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our products or which effectively prevent others from commercializing competitive technologies and products.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether DABRA and Pharos will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the U.S. and abroad. We may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of DABRA and Pharos. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us, which would have a material adverse effect on our business, financial condition, and results of operations.

Obtaining and maintaining our patent protection depends on compliance with various procedural measures, document submissions, fee payments and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the U.S. over the lifetime of our patents and applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, and results of operations.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Third parties may attempt to commercialize competitive products or services in foreign countries where we do not have any patents or patent applications where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations.

Filing, prosecuting, and defending patents on our products in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the U.S. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. Thelegal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the U.S. could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the U.S. transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (i) file any patent application related to our products or (ii) invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, and results of operations.

Issued patents covering our products could be found invalid or unenforceable if challenged in court or before administrative bodies in the U.S. or abroad.

If we initiated legal proceedings against a third party to enforce a patent covering our products, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of our patents before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes review*, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products. Such a loss of patent protection would have a material adverse effect on our business, financial condition, and results of operations.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our products, we rely upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain a competitive position. We seek to protect our proprietary information, in part, through confidentiality agreements with our employees, collaborators, contractors, advisors, consultants, and other third parties, and invention assignment agreements with our employees. We also have agreements with some of our consultants that require them to assign to us any inventions created as a result of their working with us. The confidentiality agreements are designed to protect our proprietary information and, in the case of agreements or clauses requiring invention assignment, to grant us ownership of technologies that are developed through a relationship with a third party.

Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed. Furthermore, we expect these trade secrets, know-how and proprietary information to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel from academic to industry scientific positions.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions, which could have a material adverse effect on our business, financial condition, and results of operations.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our products. Litigation may be necessary to defend against these and other claims challenging inventorship or our patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our products. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, and results of operations.

We may become involved in intellectual property litigation either due to claims by others that we are infringing their intellectual property rights or due to our own assertions that others are infringing upon our intellectual property rights.

The medical device industry in general has been characterized by extensive litigation and administrative proceedings regarding patent infringement and intellectual property rights. Our competitors hold a significant number of patents relating to medical laser technology. From time to time, we may commence litigation to enforce our intellectual property rights. An adverse decision in these actions or in any other legal action could limit our ability to assert our intellectual property rights, limit the value of our technology or otherwise negatively impact our business, financial condition and results of operations.

Monitoring unauthorized use of our intellectual property is difficult and costly. Unauthorized use of our intellectual property may have occurred or may occur in the future. Although we have taken steps to minimize the risk of this occurring, any such failure to identify unauthorized use and otherwise adequately protect our intellectual property would adversely affect our business. Moreover, if we are required to commence litigation, whether as a plaintiff or defendant, not only will this be time-consuming, but we will also be forced to incur significant costs and divert our attention and efforts of our employees, which could, in turn, result in lower revenue and higher expenses.

We cannot provide assurance that our products or methods do not infringe the patents or other intellectual property rights of third parties. Additionally, if our business is successful, the possibility may increase that others will assert infringement claims against us.

Determining whether a product infringes a patent involves complex legal and factual issues, and the outcome of a patent litigation action is often uncertain. We have not conducted an extensive search of patents issued or assigned to other parties, including our competitors, and no assurance can be given that patents containing claims covering our products, parts of our products, technology or methods do not exist, have not been filed or could not be filed or issued. Because of the number of patents issued and patent applications filed in our technical areas, our competitors or other parties may assert that our products and the methods we employ in the use of our products are covered by U.S. or foreign patents held by them. In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. There could also be existing patents that one or more of our products or parts may infringe and of which we are unaware. As the number of competitors in the market for medical lasers and as the number of patents issued in this area grows, the possibility of patent infringement claims against us increases. In certain situations, we may determine that it is in our best interests or their best interests to voluntarily challenge a party's products or patents in litigation or other proceedings, including patent interferences or re-examinations. As a result, we may become involved in unwanted litigation that could be costly, result in diversion of management's attention, require us to pay damages and force us to discontinue selling our products.

Infringement and other intellectual property claims and proceedings brought against us, whether successful or not, could result in substantial costs and harm to our reputation. Such claims and proceedings can also distract and divert management and key personnel from other tasks important to the success of the business. We cannot be certain that we will successfully defend against allegations of infringement of patents and intellectual property rights of others. In the event that we become subject to a patent infringement or other intellectual property lawsuit and if the other party's patents or other intellectual property were upheld as valid and enforceable and we were found to infringe the other party's patents or violate the terms of a license to which we are a party, we could be required to do one or more of the following:

- cease selling or using any of our products that incorporate the asserted intellectual property, which would adversely affect our revenue;
- pay substantial damages for past use of the asserted intellectual property;

- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all, and which could reduce profitability; and
- redesign or rename, in the case of trademark claims, our products to avoid violating or infringing the intellectual property rights of third parties, which may not be possible and could be costly and time-consuming if it is possible to do so.

Third-party claims of intellectual property infringement, misappropriation or other violation against us or our collaborators may prevent or delay the sale and marketing of our products.

The medical devices industry is highly competitive and dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, there may be significant intellectual property related litigation and proceedings relating to our, and other third party, intellectual property and proprietary rights in the future.

Our commercial success depends in part on our and any potential future collaborators' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. It is uncertain whether the issuance of any third-party patent would require us or any licensee to alter our development or commercial strategies, obtain licenses, or cease certain activities. The medical device industry is characterized by extensive litigation regarding patents and other intellectual property rights, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, recently, due to changes in U.S. law referred to as patent reform, new procedures including *inter partes* review and post-grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future.

Third parties may currently have patents or obtain patents in the future and claim that the manufacture, use or sale of our products infringes upon these patents. In the event that any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by our products. In this case, the holders of such patents may be able to block our ability to commercialize the applicable products or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our products, or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

For example, in December of 2017, we were contacted by a third party suggesting that we should consider licensing three U.S. patents directed to the treatment of vitiligo, U.S. Pat. No. 6,979,327 ("'327 patent"), U.S. Pat. No. 7,261,729 ("'729 patent"), and U.S. Pat. No. 8,387,621 ("'621 patent"). In addition, we were also previously contacted in 2006 by the same third party suggesting that we should consider licensing the '327 patent as well as the then pending application that became the '729 patent. We believe that we will be meritorious if a claim of infringement of the '327 patent, the '729 patent, or the '621 patent is asserted against us in a legal proceeding by this or any other third party. However, although we believe that we do not infringe the claims of the '327 patent, the '729 patent, or the '621 patent, nor do we believe that we need a license to the '327 patent, the '729 patent, or the '621 patent in order to freely commercialize our products, there is a possibility that a suit claiming infringement of the '327 patent, the '729 patent, or the '621 patent will be brought against us, and we cannot assure that a court or an administrative agency will agree with our assessment with regard to non-infringement of the '327 patent, the '729 patent, or the '621 patent. If it was necessary to obtain a license to the '327 patent, the '729 patent, or the '621 patent and a license was not available on commercially reasonable terms or available at all, that could affect our ability to commercialize our products and materially and adversely affect our business.

If a third party commences a patent infringement action against us it could consume significant financial and management resources, regardless of the merit of the claims or the outcome of the litigation. Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing our infringing products. In addition, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our products, which could harm our business significantly.

Engaging in litigation to defend against third parties alleging that we have infringed their patents or otherintellectual property rights is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because they may have greater financial resources. Patent litigation and other proceedings may also consume significant management time. Uncertainties resulting from the initiation or continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents, or we may be required to defend against claims of infringement. In addition, our patents also may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time consuming. In an infringement proceeding, a court may decide that a patent owned by us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants and scientific advisors are currently or were previously employed at universities or healthcare companies, including our competitors and potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we have been and may in the future become subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. For example, in 2018, we received letters from a competitor concerning one of their former employees who is currently working for us. The letters allege, among other things, that the employee is in violation of the employee's continuing obligations to the employee's prior employer. While we dispute the validity of the claims and would vigorously defend against them and assert appropriate defenses, litigation may be necessary to defend against these claims. If we fail in defending any such claims, it could have a material adverse effect on our business, financial condition, and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs to us and be a distraction to management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, and results of operations.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be violating or infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement or dilution claims brought by owners of other trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, and results of operations.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our products or utilize similar technology but that are not covered by the claims of the patents that we may own or that incorporate certain technology in our products that is in the public domain;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we own now or in the future;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our current or future pending patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Our Reliance on Third Parties

We depend on third-party suppliers for key components and sub-assemblies used in our manufacturing processes, and the loss of these third-party suppliers or their inability to supply us with adequate components and sub-assemblies could harm our business.

We are currently experiencing inconsistencies in our DABRA catheter performance as more fully described in the risk factor entitled "*We are experiencing inconsistencies in our DABRA catheter performance. This and any other development or manufacturing problems or delays that could limit the potential growth of our revenue or increase our losses.*" In addition to the inconsistencies and risks described in the foregoing risk factor, we may encounter unforeseen situations that would result in delays or shortfalls in manufacturing. Key components and sub-assemblies of DABRA and Pharos are currently provided by a limited number of suppliers, and we do not maintain large inventory levels of these components and sub-assemblies. For example, we rely on a limited number of suppliers for the Thyratron used to manufacture our lasers. If we experience a shortage in any of these components or sub-assemblies, we would need to identify and qualify new supply sources, which could increase our costs, result in manufacturing delays, and cause delays in the delivery of our products. We may also experience a delay in completing validation and verification testing or sterility audits for controlled-environment rooms at our manufacturing facility.

We also depend on limited source suppliers for some of our product components and sub-assemblies, and if any of those suppliers are unable or unwilling to produce these components or sub-assemblies or supply them in the quantities that we need, and at acceptable prices, we would experience manufacturing delays and may not be able to deliver our products on a timely or cost-effective basis to our customers, or at all, which could reduce our product sales, increase our costs, and harm our business. While we believe that we could obtain replacement components from alternative suppliers, we may be unable to do so. Losing any of these suppliers could cause a disruption in our production. Our suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction and environmental factors. Establishing additional or replacement suppliers for these materials may take significant time, as certain of these suppliers must be approved by regulatory authorities, which could disrupt our production. As a result, we could experience significant delays in manufacturing and delivering our products to customers. We cannot assure you we can continue obtaining required materials, components, and sub-assemblies that are in short supply within the time frames we require at an affordable cost, if at all. If we cannot secure on a timely basis sufficient quantities of the materials we depend on to manufacture our products, if we encounter delays or contractual or other difficulties in our relationships with these suppliers, or if we cannot find replacement suppliers at an acceptable cost, then manufacturing our products may be disrupted, which could increase our costs, prevent or impair our development or commercialization efforts, and have a material adverse effect on our business, financial condition, and results of operations.

We and our component suppliers may not meet regulatory quality standards applicable to our manufacturing processes, which could have an adverse effect on our business, financial condition, and results of operations.

As a medical device manufacturer, we must register with the FDA and non-U.S. regulatory agencies, and we are subject to periodic inspection by the FDA and foreign regulatory agencies, for compliance with certain good manufacturing practices, including design controls, product validation and verification, in process testing, quality control and documentation procedures. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA and foreign regulatory agencies. Our component suppliers are also required to meet certain standards applicable to their manufacturing processes.

We cannot assure you that we or our component suppliers comply or can continue to comply with all regulatory requirements. A failure by us or one of our component suppliers to achieve or maintain compliance with these requirements or quality standards may disrupt our ability to supply products sufficient to meet demand until compliance is achieved or, with a component supplier, until a new supplier has been identified and evaluated. Our or any of our component supplier's failure to comply with applicable regulations could cause sanctions to be imposed on us, including warning letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals or clearances, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, which could harm our business. We cannot assure you that if we need to engage new suppliers to satisfy our business requirements, we will be able to locate new suppliers in compliance with regulatory requirements at a reasonable cost and in an acceptable timeframe. Our failure to do so could have a material adverse effect on our business, financial condition, and results of operations.

In the European Union, we must maintain certain International Organization for Standardization, or ISO, certifications to sell our products and must undergo periodic inspections by notified bodies, including the British Standards Institution, to obtain and maintain these certifications. If we fail these inspections or fail to meet these regulatory standards, it could have a material adverse effect on our business, financial condition, and results of operations.

We may form or seek strategic alliances or enter into licensing arrangements in the future, and we may not realize the benefits or costs of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our sales and marketing efforts with respect to our products and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our products. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our products could delay the commercialization of our products in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

Risks Related to Ownership of Our Common Stock

We must comply with the New York Stock Exchange's requirements for the continued listing of our common stock on the NYSE.

Our common stock is listed on the New York Stock Exchange ("NYSE"). We received a deficiency notice on August 20, 2019, indicating that the we are not in compliance with the NYSE's continued listing requirements under the timely filing criteria established in Section 802.01E of the NYSE Listed Company Manual as a result of our failure to timely file this Quarterly Report on Form 10-Q for the quarter ended June 30, 2019. However, we must also continue to meet other NYSE listing standards, including requirements that our average market capitalization over a consecutive 30 trading-day period not be less than $50 million at the same time shareholders' equity is less than $50 million, that our average market capitalization over a consecutive 30 trading-day period not be less than $15 million and that the common stock not trade at an "abnormally low" value. As of November 20, 2019, our market capitalization is $19.6 million. There can be no assurance that we will be able to successfully implement the necessary actions to maintain or regain compliance with NYSE listing requirements or that any appeal of a decision to delist the Company's common stock would be successful.

Failure to maintain our NYSE listing could negatively impact us and our stockholders by reducing the willingness of investors to hold our common stock because of the resulting decreased price, liquidity and trading of our common stock, limited availability of price quotations, and reduced news and analyst coverage. These developments may also require brokers trading in our common stock to adhere to more stringent rules and may limit our ability to raise capital by issuing additional shares in the future. Delisting may adversely impact the perception of our financial condition, and cause reputational harm with investors and parties conducting business with us.

The price of our stock may be volatile, which could result in substantial losses for investors. Further, an active, liquid and orderly trading market for our common stock may not be sustained and we do not know what the market price of our common stock will be, and as a result it may be difficult for you to sell your shares of our common stock.

Prior to our listing on the NYSE in September 2018, there was no public market for shares of our common stock. Although our common stock is listed on the NYSE, the market for our shares has demonstrated varying levels of trading activity. Furthermore, an active trading market for our shares may not be sustained in the future. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using shares of our common stock as consideration, which could have a material adverse effect on our business, financial condition, and results of operations. In addition, the trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "*Risk factors*" section and elsewhere in this Quarterly Report on Form 10-Q, these factors include:

- increased expenses from remedying the performance of our catheters;
- our failure to increase the sales of our products, specifically DABRA and remedy the performance issues associated with our DABRA catheters;
- the failure by our customers to obtain adequate reimbursements or reimbursement levels that would be sufficient to support product sales to our customers and pricing of our products to support revenue projections;
- unanticipated serious safety concerns related to the use of our products;
- changes in our organization and our search for a permanent chief executive officer;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our future growth;
- the size and growth of our target markets;
- actual or anticipated variations in quarterly operating results;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including stockholder litigation, government actions or litigation related to intellectual property;
- our cash position;

- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- any delay in any regulatory filings for our future products and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such products;
- adverse regulatory decisions, including failure to receive regulatory approval of our future products, failure to maintain regulatory approval for our existing products or failure to obtain regulatory approval for additional indications for our existing products;
- changes in laws or regulations applicable to our products;
- adverse developments concerning our suppliers or distributors;
- our inability to obtain adequate supplies and components for our products or inability to do so at acceptable prices;
- our inability to establish and maintain collaborations if needed;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of large blocks of our common stock including sales by our executive officers and directors;
- trading volume of our common stock;
- limited "public float" in the hands of a small number of persons whose sales or lack of sales of our common stock could result in positive or negative pricing pressure on the market price for our common stock;
- additions or departures of key scientific or management personnel;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of managements attention and resources, which could have a material adverse effect on our business, financial condition, and results of operations.

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

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

- increased expenses from remedying the performance of our catheters;
- the timing and cost of, and level of investment in, research and development activities relating to our current and any future products, which will change from time to time;
- the cost of manufacturing our current and any future products, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with suppliers;
- the degree and rate of market acceptance for DABRA and Pharos, including the ability of our customers to receive adequate reimbursement for procedures performed using our products;
- expenditures that we will or may incur to acquire or develop additional products and technologies;
- competition from existing and potential future products that compete with our products, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;

- the level of demand for our current and future products, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our products, and existing and potential future products that compete with our products;
- our ability to commercialize additional products, if approved, inside and outside of the U.S., either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing, or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- changes in FDA regulations and comparable foreign regulations;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

From time to time, we may also enter into license or collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend in part on any potential future license and collaboration agreements and sales of our products. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

We do not intend to pay dividends on our common stock so any returns will be limited to increases, if any, in our stock's value.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on, among other factors, our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. Any return to stockholders will therefore be limited to the appreciation in the value of their stock, if any.

Our ability to use our net operating loss carryforwards may be limited.

As of December 31, 2018, we had net operating loss, or NOL, carryforwards of approximately $27.7 million for federal income tax purposes, and $23.6 million for state income tax purposes. These federal and state NOL carryforwards begin expiring in 2029. Utilization of these NOLs depends on many factors, including our future income, which cannot be assured. These NOLs could expire unused and be unavailable to offset our future income tax liabilities. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership by 5% stockholders over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change income may be limited. We have determined that we have not experienced Section 382 ownership changes in the past and therefore our NOLs are not subject to an annual limitation under Section 382. In addition, we may experience ownership changes in the future as a result of subsequent changes in our stock ownership, some of which may be outside of our control. If we determine that an ownership change has occurred and our ability to use our historical NOLs is materially limited, it could harm our future operating results by effectively increasing our future tax obligations. In addition, under the Tax Cuts and Jobs Act of 2017, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely and the deductibility of such federal NOLs is limited.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, on December 22, 2017, President Trump signed tax legislation into law, commonly referred to as the Tax Cuts and Jobs Act of 2017, that contains many significant changes to the U.S. tax laws, the consequences of which have not yet been fully determined. Changes in corporate tax rates, the realization of net deferred tax assets relating to our U.S. operations, the taxation of foreign earnings, and the deductibility of expenses contained in the Tax Cuts and Jobs Act of 2017 or other tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges in the current or future taxable years, and could increase our future U.S. tax expense. The foregoing items could have a material adverse effect on our business, cash flow, financial condition or results of operations. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax legislation. The impact of this tax legislation on holders of our common stock is also uncertain and could be adverse. We urge our stockholders and investors to consult with our legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of June 30, 2019, our executive officers, directors, and 10% stockholders owned approximately 38% of the outstanding shares of our common stock. In addition, as of June 30, 2019, our officers, directors, 10% stockholders, and their affiliates held (i) options to purchase an aggregate of 1,221,000 shares of our common stock at exercise prices of $28.94 per share; and (ii) 1,076,992 restricted stock units, which would give our officers, directors, and 10% stockholders ownership of approximately 43% of our outstanding common stock if such awards are fully vested and are exercised in full. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders, which could have a material adverse effect on our business, financial condition, and results of operations.

We are an emerging growth company and a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we completed our initial public offering, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a“smaller reporting company” which may allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we are not subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

We have incurred and will continue to incur significant increased costs as a result of operating as a public company, and our management has devoted and will continue to devote substantial time to new compliance initiatives, including maintaining an effective system of internal controls over financing reporting.

As a public company, we have incurred and will continue to incur significant legal, accounting, insurance, and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the New York Stock Exchange to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Emerging growth companies are permitted to implement many of these requirements over a longer period and up to five years from the completion of our initial public offering. We intend to take advantage of this legislation but cannot guarantee that we will not be required to implement these requirements sooner than anticipated or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

These rules and regulations applicable to public companies have increased and will continue to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Future sales and issuances of a substantial number of shares of our common stock or rights to purchase common stock by our stockholders in the public market could result in additional dilution of the percentage ownership of our stockholders and cause our stock price to fall.

If our stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of June 30, 2019, we had outstanding 13,220,951 shares of our common stock.

In addition, pursuant to our 2018 Equity Incentive Plan, or 2018 Plan, equity incentive awards representing up to an aggregate of 1,918,439 shares of our common stock were available for issuance to our employees, directors and consultants as of June 30, 2019. The 2018 Plan includes an annual increase in the number of shares available for future grant each year pursuant to the "evergreen" provision of our 2018 Plan. Additionally, pursuant to our 2018 Employee Stock Purchase Plan, or ESPP a total of 446,160 shares were available for sale under our ESPP as of June 30, 2019. The ESPP also includes an annual increase in the number of shares available for sale under our ESPP each year pursuant to the "evergreen" provision of our ESPP. If these additional shares of common stock are issued and sold, or if it is perceived that they will be sold, in the public market, this could result in additional dilution and the trading price of our common stock could decline.

Further, additional capital may be needed in the future to continue our planned operations, including commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business.

If one or more of the analysts covering us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. In addition, if one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove members of our board of directors or our current management and may adversely affect the market price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- our board of directors is divided into three classes serving staggered three-year terms, such that not all members of the board is elected at one time, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at an annual or special meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairperson of the board of directors, the chief executive officer or president (in the absence of a chief executive officer) or a majority vote of our board of directors, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66 2/3% of the voting power of all of the then outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation relating to the issuance of preferred stock and management of our business or our amended and restated bylaws, which may inhibit the ability of an acquirer to affect such amendments to facilitate an unsolicited takeover attempt;
- the ability of our board of directors, by majority vote, to amend our amended and restated bylaws, which may allow our board of directors to take additional actions to prevent an unsolicited takeover and inhibit the ability of an acquirer to amend our amended and restated bylaws to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

In addition, because we are now incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the Stateof Delaware and the federal district courts of the United States are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; and any action asserting a claim against us that is governed by the internal affairs doctrine. Our amended and restated certificate of incorporation further provides that the federal district courts of the United States is the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material adverse effect on our business, financial condition, and results of operations.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Sales of Unregistered Securities

None.

Recent Repurchases of Equity Securities

None.

Use of Proceeds

On September 26, 2018, our Registration Statement on Form S-1 (File No. 333-226191) relating to our initial public offering was declared effective by the SEC. Pursuant to such Registration Statement, we sold an aggregate of 4,485,000 shares of our common stock, including 585,000 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares, at a price of $17.00 per share. The aggregate offering price for shares sold in the offering was approximately $76.2 million. Piper Jaffray & Co. and Cantor Fitzgerald & Co. acted as lead joint book-running managers for the offering. SunTrust Robinson Humphrey, Inc. acted as lead manager and Nomura Securities International, Inc. and Maxim Group LLC acted as co-managers for the offering. On October 1, 2018, we closed the sale of such shares, resulting in aggregate cash proceeds to us of approximately $67.3 million, net of $5.3 million of underwriting discounts and commissions and $3.6 million of offering expenses paid or payable by us. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

We stated, in our Registration Statement for our initial public offering, that we intend to use the net proceeds as follows:

- approximately $21 million for the expansion of our direct sales force and marketing of our products;
- approximately $14 million to support clinical studies for new products and product enhancements including for expanded indications; and
- the balance of the proceeds may be used to support other research and development activities, working capital, and general corporate purposes.

As discussed elsewhere in this Form 10-Q, we are currently focusing on servicing priority existing accounts while we prioritize remedying the inconsistencies in our DABRA catheter performance. Accordingly, we intend to use the remainder of the net proceeds for these and other general corporate purposes, including our clinical studies.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Exhibit Title
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on October 1, 2018 (File No. 001-38677).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed on October 1, 2018 (File No. 001-38677).
31	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32(*)	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

(*) In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished pursuant to this item will not be deemed "filed" for purposes of Section 18 of the Exchange Act (15 U.S.C. 78r), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

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.

RA MEDICAL SYSTEMS, INC.

(Registrant)

Date: November 27, 2019

By: /s/ Andrew Jackson
Andrew Jackson
Interim Chief Executive Officer and Chief Financial Officer

Exhibit 31

CERTIFICATION OF PRINCIPAL EXECUTIVE AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Andrew Jackson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ra Medical Systems,Inc.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures(as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report ourconclusions 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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control overfinancial 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 financialreporting 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 theregistrant's internal control over financial reporting.

Date: November 27, 2019

By: /s/ Andrew Jackson
Andrew Jackson
Interim Chief Executive Officer and Chief Financial Officer (Principal Executive Officer and Principal Financial Officer)

Exhibit 32

CERTIFICATION OF PRINCIPAL EXECUTIVE AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, Andrew Jackson, hereby certify that, to my knowledge:

(i) the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019 to which this Certification isattached as Exhibit 32 (the "Report") fully complies with the requirements of section 13(a) or 15(d) of the Exchange Act, and

(ii) that the information contained in the Report fairly presents, in all material respects, the financial condition and resultsof operations of Ra Medical Systems, Inc.

Date: November 27, 2019

By: /s/ Andrew Jackson
Andrew Jackson
Interim Chief Executive Officer and Chief Financial Officer (Principal executive officer and principal financial officer)

This certification accompanies the Quarterly Report on Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Ra Medical Systems, Inc. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.