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, 2021

OR

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

For the Transition Period From to

Commission file number: 001-38677

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	NYSE American

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 August 9, 2021, the registrant had 7,029,438 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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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, 2021	December 31, 2020
ASSETS		
Current Assets		
Cash and cash equivalents	$ 20,220	$ 23,906
Accounts receivable, net	228	238
Inventories	2,323	2,218
Prepaid expenses and other current assets	1,306	1,258
Total current assets	24,077	27,620
Property and equipment, net	2,661	3,211
Operating lease right-of-use-assets	2,300	2,484
Other non-current assets	121	123
TOTAL ASSETS	$ 29,159	$ 33,438
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 1,077	$ 571
Accrued expenses	2,021	4,348
Current portion of deferred revenue	1,787	1,801
Current portion of equipment financing	—	265
Current portion of promissory note	—	421
Current portion of operating lease liabilities	320	356
Total current liabilities	5,205	7,762
Deferred revenue	566	686
Promissory note	—	1,579
Operating lease liabilities	2,125	2,264
Total liabilities	7,896	12,291
Commitments and contingencies (Note 13)		
Stockholders' Equity		
Preferred stock, $0.0001 par value, 10,000,000 authorized; none issued	—	—
Common stock, $0.0001 par value, 300,000,000 shares authorized; 5,902,612 and 3,188,679 issued and outstanding at June 30, 2021 and December 31, 2020, respectively	7	7
Additional paid-in capital	186,943	174,342
Accumulated deficit	(165,687)	(153,202)
Total stockholders' equity	21,263	21,147
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 29,159	$ 33,438

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,	
	2021	2020	2021	2020
Net revenue				
Product sales	$ 318	$ 154	$ 724	$ 740
Service and other	687	746	1,399	1,534
Total net revenue	1,005	900	2,123	2,274
Cost of revenue				
Product sales	861	624	1,651	1,588
Service and other	627	543	1,210	1,163
Total cost of revenue	1,488	1,167	2,861	2,751
Gross loss	(483)	(267)	(738)	(477)
Operating expenses				
Selling, general and administrative	3,741	7,896	7,855	14,181
Research and development	3,018	1,953	5,834	3,248
Total operating expenses	6,759	9,849	13,689	17,429
Operating loss	(7,242)	(10,116)	(14,427)	(17,906)
Other income (expense), net				
Gain on extinguishment of debt	2,023	—	2,023	—
Interest income	1	10	2	124
Interest expense	(31)	(15)	(83)	(40)
Total other income (expense), net	1,993	(5)	1,942	84
Loss before income tax expense	(5,249)	(10,121)	(12,485)	(17,822)
Income tax expense	—	—	—	—
Net loss	$ (5,249)	$ (10,121)	$ (12,485)	$ (17,822)
Basic and diluted net loss per share	$ (1.28)	$ (10.71)	$ (3.56)	$ (23.83)
Basic and diluted weighted average common shares outstanding	4,089	945	3,506	748

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,	
	2021	2020	2021	2020
Net loss	$ (5,249)	$ (10,121)	$ (12,485)	$ (17,822)
Other comprehensive loss:				
Unrealized losses related to short-term investments	—	(4)	—	(26)
Total other comprehensive loss	$ —	$ (4)	$ —	$ (26)
Comprehensive loss	$ (5,249)	$ (10,125)	$ (12,485)	$ (17,848)

See notes to condensed financial statements.

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

	Six Months Ended June 30,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (12,485)	$ (17,822)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on extinguishment of debt (promissory note)	(2,023)	—
Depreciation and amortization	881	1,214
Provision for doubtful accounts	—	25
Stock-based compensation	1,865	2,080
Gain on sale of property and equipment	(493)	—
Changes in operating assets and liabilities:		
Accounts receivable	10	287
Inventories	(108)	33
Prepaid expenses and other assets	(46)	650
Accounts payable	368	107
Accrued expenses	(2,359)	1,295
Deferred revenue	(134)	(556)
Other liabilities	(175)	(156)
Net cash used in operating activities	(14,699)	(12,843)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from maturities of available-for-sale securities	—	16,000
Proceeds from sale of property and equipment	534	—
Purchases of property and equipment	(76)	(49)
Net cash provided by investing activities	458	15,951
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock and warrants, net of placement agent fees of $51 and $1,008, respectively	11,022	8,992
Proceeds from issuance of common stock in connection with the exercise of warrants	—	827
Proceeds from issuance of common stock in connection with the employee stock purchase plan	26	27
Proceeds from PPP promissory note	—	2,000
Payments on equipment financing	(265)	(145)
Payments of offering costs related to the issuance of common stock and warrants	(228)	(13)
Net cash provided by financing activities	10,555	11,688
NET CHANGE IN CASH AND CASH EQUIVALENTS	(3,686)	14,796
CASH AND CASH EQUIVALENTS, beginning of period	23,906	14,584
CASH AND CASH EQUIVALENTS, end of period	$ 20,220	$ 29,380
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Unpaid offering costs	$ 84	$ 231
Transfer from inventories to property and equipment for lasers	$ 3	$ 40
Unpaid property and equipment	$ 109	$ —
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash payments for interest	$ 2	$ 16
Cash payments for taxes	$ 2	$ —

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 (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balances at December 31, 2020	3,189	$ 7	$ 174,342	$ —	$ (153,202)	$ 21,147
Common stock issued, net	35	—	65	—	—	65
Stock-based compensation	35	—	1,169	—	—	1,169
Net loss	—	—	—	—	(7,236)	(7,236)
Balances at March 31, 2021	3,259	$ 7	$ 175,576	$ —	$ (160,438)	$ 15,145
Common stock issued, net	2,582	—	10,645	—	—	10,645
Common stock issued pursuant to the vesting of restricted stock units and ESPP	6	—	26	—	—	26
Stock-based compensation	56	—	696	—	—	696
Net loss	—	—	—	—	(5,249)	(5,249)
Balances at June 30, 2021	5,903	$ 7	$ 186,943	$ —	$ (165,687)	$ 21,263

	Common Stock Shares	Common Stock Amount	Additional Paid- in- Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balances at December 31, 2019	551	$ 1	$ 150,280	$ 26	$ (117,157)	$ 33,150
Common stock issued	5	—	—	—	—	—
Stock-based compensation	—	—	1,047	—	—	1,047
Other comprehensive loss	—	—	—	(22)	—	(22)
Net loss	—	—	—	—	(7,701)	(7,701)
Balances at March 31, 2020	556	$ 1	$ 151,327	$ 4	$ (124,858)	$ 26,474
Common stock issued, net	889	2	5,282	—	—	5,284
Warrants issued, net	—	—	3,464	—	—	3,464
Exercise of warrants	73	1	826	—	—	827
Common stock issued pursuant to the vesting of restricted stock units and ESPP	9	—	27	—	—	27
Stock-based compensation	—	—	1,033	—	—	1,033
Other comprehensive loss	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	(10,121)	(10,121)
Balances at June 30, 2020	1,527	$ 4	$ 161,959	$ —	$ (134,979)	$ 26,984

See notes to condensed financial statements.

Note 1—Organization and Nature of Operations

Ra Medical Systems, Inc. (the "Company") was formed on 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 and manufactures advanced excimer laser systems 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.

Reverse Stock Split—On November 16, 2020, the Company filed a certificate of amendment to the Certificate of Incorporation with the Secretary of State of the State of Delaware to effect a reverse stock split of the Company's common stock at a ratio of one-for-twenty-five ("Reverse Stock Split"). The Reverse Stock Split became effective as of 4:01 p.m. Eastern time on November 16, 2020, and the Company's common stock began trading on the New York Stock Exchange ("NYSE") on a post-split basis on November 17, 2020. Unless otherwise noted, all share and per share numbers contained in these financial statements are reflected on a post-split basis.

COVID-19—The global spread of the novel coronavirus (COVID-19) has created significant volatility, uncertainty and economic disruption. The ultimate effects of the COVID-19 on the Company's business, operations and financial condition are unknown at this time. In the near term, the Company expects that its revenue will continue to be adversely impacted and enrollment in its atherectomy clinical trial will continue to be delayed or slowed, as patients elect to postpone voluntary treatments and many physicians' offices have been either closed or operating at a reduced capacity. In addition, some customers are requesting more flexible payment terms on a temporary basis. The Company's manufacturing facility located in Carlsbad, California is currently operational. The Company has experienced delays in receiving shipments of certain parts, which has affected the timing of its key engineering efforts. To date, the delays have not materially impacted the Company's ability to support its atherectomy indication clinical trial. However, the extent to which COVID-19 impacts its business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain it or treat its impact, among others.

Going Concern —The Company has experienced recurring net losses from operations and negative cash flows from operating activities, has a significant accumulated deficit and expects to continue to incur net losses into the foreseeable future. The Company had an accumulated deficit of $165.7 million at June 30, 2021. For the year ended December 31, 2020 the Company used $28.3 million in cash for operating activities.

As of June 30, 2021, the Company had cash and cash equivalents of $20.2 million.

Management expects operating losses and negative cash flows to continue for the foreseeable future with the Company's reduced commercial footprint, and as the Company continues to incur costs related to its atherectomy clinical trial, engineering efforts to improve the shelf life of its catheters and develop next generation products and legal costs associated with ongoing litigation. In September 2020, the Company paused commercial sales of DABRA catheters not being used for the atherectomy clinical trial while it conducted further studies on the stability of its shelf life. The Company submitted additional test data with respect to the DABRA catheter shelf life in March 2021, which was cleared by the FDA in July 2021. Although eligible, the Company has not resumed commercial shipments and is evaluating its commercial catheter strategy. The Company also expects the COVID-19 pandemic to have a continued negative impact on its revenue and the timing of enrollment in its atherectomy clinical trial as well as the Company's ability to secure additional financing in a timely manner or on favorable terms, if at all.

Management believes that based on the Company's liquidity resources, there is substantial doubt about the Company's ability to continue as a going concern for a period of at least 12 months from the date of issuance of the financial statements.

Although the Company bolstered its liquidity resources in 2020 and 2021, it has an effective shelf registration statement and an "at the market" offering to allow it to raise additional capital when the opportunities permit and may receive additional funds from the exercise of its warrants depending on market conditions, management concluded that the aforementioned conditions, including the ongoing uncertainty related to the negative impacts of the COVID-19 pandemic, continue to raise substantial doubt about the Company's ability to continue as a going concern for a period of at least 12 months from the date of issuance of the financial statements. Management plans to address this uncertainty by raising additional funds, if necessary, through public

or private equity or debt financings as well as by engaging in regular and ongoing reviews of our business model and strategic options to help ensure that the Company is focusing its cash resources on advancing its key corporate initiatives. However, the Company may not be able to secure such financing in a timely manner or on favorable terms, if at all. Furthermore, if the Company issues equity securities to raise additional funds, its existing stockholders may experience dilution, and the new equity securities may have rights, preferences and privileges senior to those of the Company's existing stockholders.

The financial statements have been prepared on a going concern basis, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from the outcome of this uncertainty.

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 statements of stockholders' equity for the periods presented. The results of operations for the three and six months ended June 30, 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2021 or for any other future annual or interim period. The balance sheet as of December 31, 2020 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 17, 2021.

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 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, evaluation of impairment of assets, 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.

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 and 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 statements 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 statements of operations.

Revenue—The Company generates revenue from the sale of products and services. Product sales consist of the sale of Pharos laser systems, the sale of catheters for use with the DABRA laser, and the sale of consumables and replacement parts. The Company's vascular segment has paused selling commercial product and is only selling catheters for use in the Company's atherectomy clinical trial. 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.

Catheter Revenue
When engaged in commercial sales, 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 permitted 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 laser 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
Sales of laser systems are included in product sales in the statements 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 statements of operations. Deferred revenue at January 1, 2021 and 2020 was $2.5 million and $3.3 million, respectively. Revenue recognized in each of the three months ended June 30, 2021 and 2020 relating to amounts previously included in deferred revenue was $0.5 and $0.6 million, respectively. Revenue recognized in each of the six months ended June 30, 2021 and 2020 was $1.1 million and $1.3 million, respectively. The deferred revenue greater than one year will be recognized during the remaining service period through 2024. As of June 30, 2021 and 2020, deferred revenue greater than one year was $0.5 million and $0.8 million, respectively.

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.

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 $0.2 million capitalized at June 30, 2021 and December 31, 2020.

Rental Income

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 was $0.1 for each of the three months ended June 30, 2021 and 2020. Rental income from lease arrangements for each of the six months ended June 30, 2021 and 2020 was $0.3 million.

Note 3—Fair Value Measurements

The following table presents the hierarchy for assets measured at fair value on a recurring basis (in thousands):

	Total Fair Value	Quoted Market Prices for Identical Assets (Level 1)	Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
As of June 30, 2021				
Money market funds	$ 9,395	$ 9,395	$ —	$ —
As of December 31, 2020				
Money market funds	$ 18,394	$ 18,394	$ —	$ —

Note 4—Inventories

Inventories consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Raw materials	$ 1,918	$ 1,739
Work in process	306	270
Finished goods	99	209
Inventories	$ 2,323	$ 2,218

Note 5—Property and Equipment, net

Property and equipment consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Lasers	$ 4,407	$ 4,677
Machinery and equipment	950	866
Computer hardware and software	353	353
Automobiles	100	1,054
Leasehold improvements	119	119
Furniture and fixtures	48	48
Construction in progress	152	51
Property and equipment, gross	6,129	7,168
Accumulated depreciation	(3,468)	(3,957)
Property and equipment, net	$ 2,661	$ 3,211

Depreciation expense was $0.3 million and $0.5 million for the three months ended June 30, 2021 and 2020, respectively and $0.7 million and $1.0 million for the six months ended June 30, 2021 and 2020, respectively. During the six months ended June 30, 2021 automobiles were sold for a gain of $0.5 million. The gain is included in selling, general and administrative expenses in the accompanying condensed statements of operations.

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

	June 30, 2021	December 31, 2020
Compensation and related benefits	$ 725	$ 2,602
Accrued warranty (Note 7)	237	242
Accrued services	1,059	1,504
Accrued expenses	$ 2,021	$ 4,348

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

	Six Months Ended June 30, 2021	Year Ended December 31, 2020
Balance at beginning of period	$ 242	$ 338
Increase in warranty accrual	39	87
Change in liability for pre-existing warranties	—	(2)
Claims satisfied	(44)	(181)
Accrued warranty	$ 237	$ 242

Warranty expense was $15,000 and $8,000 for the three months ended June 30, 2021 and 2020, respectivelyand $39,000 and $40,000 for the six months ended June 30, 2021 and 2020, respectively. The accrued warranty balances at June 30, 2021 and December 31, 2020 each include $0.1 million relating to the voluntary recall of catheters, which occurred in September 2019. Warranty expense is included in cost of revenue in the accompanying condensed statements of operations.

Note 8—Paycheck Protection Program Promissory Note
In May 2020, the Company entered into a $2.0 million Paycheck Protection Program Promissory Note and Agreement ("PPP Promissory Note") with a commercial bank under the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act. The PPP Promissory Note bore an interest rate of 1.0% per annum. Under the terms of the PPP Promissory Note, payments would have been due monthly beginning November 1, 2020 and the principal amount of the PPP Promissory Note along with any unpaid interest would be due on May 3, 2022. On June 5, 2020, the Paycheck Protection Program Flexibility Act of 2020 (the "PPPFA") extended the deferral period for all loans to 10 months after the last day of the covered period. Under the revised terms, payments would have been due beginning August 2021 and the principal amount along with unpaid interest would be due in May 2022. The principal and interest may be forgiven if the proceeds are used for forgivable purposes as defined by the terms in the PPP Promissory Note. The Company applied for full forgiveness under the provisions of the CARES Act in March 2021 and received approval by the Small Business Administration on June 24, 2021. Gain on extinguishment of the PPP promissory note is recorded in other income on the condensed statements of operations. Interest expense for the three months ended June 30, 2021 and 2020 was approximately $5,000 and $3,000, respectively. Interest expense for the six months ended June 30, 2021 and 2020 was approximately $10,000 and $3,000, respectively.

Note 9—Leases
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 terms of the leases, which expire in 2027 and 2021.

At June 30, 2021, the weighted average remaining lease term was6.5 years. The operating leases are included in the balance sheets at the present value of the lease payments at a 7% discount rate, which approximates 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 each of the three months ended June 30, 2021 and 2020, operating lease expense and cash paid for leases were $0.1 million. For each of the six months ended June 30, 2021 and 2020, operating lease expense and cash paid was $0.3 million. Operating lease right-of-use assets amortization was $0.1 million and $0.2 million for each the three and six months ended June 30, 2021 and 2020, 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, 2021 (in thousands):

Years Ending December 31,		
2021 (remaining six months)	$	264
2022		432
2023		445
2024		459
2025		472
2026		486
Thereafter		501
Total operating lease payments	$	3,059
Less: imputed interest		(614)
Total operating lease liabilities	$	2,445

Note 10—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. A net loss cannot be diluted, so when the Company is in a net loss position, basic and diluted loss per common share are the same. If in the future the Company achieves profitability, the denominator of a diluted earnings per common share calculation will include both the weighted-average number of shares outstanding and the number of common stock equivalents, if the inclusion of such common stock equivalents would be dilutive. Dilutive common stock equivalents potentially include warrants, stock options and non-vested restricted stock awards and units using the treasury stock method, along with the effect, if any, from outstanding convertible securities.

The Company's outstanding warrants to purchase common stock have participation rights to any dividends that may be declared in the future and are therefore considered to be participating securities. Participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods of loss, no loss is allocated to the participating securities since the holders have no contractual obligation to share in the losses of the Company.

Anti-dilutive common share equivalents excluded from the computation of diluted net loss per share at June 30, 2021 consisted of warrants of 2,345,033, stock options of 132,477, restricted stock units of 54,924, restricted stock awards of 355,598 and Employee Stock Purchase Plan shares of 10,557.

Anti-dilutive common share equivalents excluded from the computation of diluted net loss per share at June 30, 2020 consisted of warrants of 877,604, stock options of 145,765 and restricted stock units of 7,876, restricted stock awards of 5,000 and Employee Stock Purchase Plan shares of 3,771.

Note 11—Equity Offerings

In February 2021, the Company completed an "at the market offering" of 35,768 shares of common stock, at a price of $8.3921 per share. The Company received approximately $0.3 million in net proceeds, after deducting placement agent's fees. The Company also incurred $0.2 million in offering and other expenses payable by it in association with filing the related Registration Statement on Form S-3 with the Securities and Exchange Commission.

On various dates in May and June 2021, the Company completed "at the market offerings" of 2,582,019 shares of common stock, at a weighted average price of $4.29 per share. The Company received approximately $10.7 million in net proceeds, after deducting placement agent's fees.

Note 12—Stock-Based Compensation

A summary of the activity and related information of the stock options issued under the 2018 Plan and the Compensation Plan is presented below:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2020	124,171	$ 363.31	6.42	$ —
Forfeited	(9,694)	82.61		
Outstanding at June 30, 2021	114,477	$ 387.08	5.85	$ —
Exercisable at June 30, 2021	95,116	$ 459.60	5.50	$ —
Vested and expected to vest at June 30, 2021	114,477	$ 387.08	5.85	$ —

A summary of the activity and related information of the restricted stock units issued under the 2018 Plan is presented below:

	Restricted Stock Units	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2020	33,548	$ 21.93
Granted	29,614	3.99
Vested and released	(1,845)	64.80
Forfeited	(6,393)	15.40
Outstanding at June 30, 2021	54,924	$ 11.58

A summary of the activity and related information of the restricted stock awards issued under the 2018 Plan is presented below:

	Restricted Stock Awards (in shares)	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2020	286,161	$ 4.77
Granted	103,939	4.82
Forfeited	(13,531)	6.40
Vested	(24,721)	6.92
Outstanding at June 30, 2021	351,848	$ 4.57

Stock options issued and outstanding under the 2020 Plan is 18,000 with a weighted average grant date fair value of $25.50 as of December 31, 2020 and June 30, 2021. Stock options aggregating 5,625 were exercisable as of June 30, 2021, under the 2020 Plan.

A summary of the activity and related information of the restricted stock awards issued under the 2020 Plan is presented below:

	Restricted Stock Awards (in shares)	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2020	4,375	$ 25.50
Vested	(625)	25.50
Outstanding at June 30, 2021	3,750	$ 25.50

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Selling, general and administrative	$ 541	$ 843	$ 1,503	$ 1,705
Research and development	95	103	224	202
Stock-based compensation in operating expenses	$ 636	$ 946	$ 1,727	$ 1,907

Stock-based compensation amounts of $0.1 million were capitalized to inventory and property and equipment during the three months ended June 30, 2021 and 2020.Stock-based compensation of $0.1 million and $0.2 million were capitalized to inventory and property and equipment during the six months ended June 30, 2021 and 2020, respectively.

Unrecognized compensation expense for stock options issued as of June 30, 2021 was $0.5 million and is expected to be recognized over a weighted-average period of2.0 years. Unrecognized compensation expense for the restricted stock units as of June 30, 2021 was $0.4 million and is expected to be recognized over a weighted-average period of2.0 years. Unrecognized compensation expense for the restricted stock awards as of June 30, 2021 was $1.3 million and is expected to be recognized over a weighted-average period of 2.2 years.

Note 13—Commitments and Contingencies

Legal—In the normal course of business, the Company is at times subject to pending and threatened legal actions. In management's opinion, any potential loss resulting from the resolution of these matters will not have a material effect on the results of operations, financial position or cash flows of the Company.

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. Following the appointment of a lead plaintiff and the filing of a subsequent amended complaint, the lawsuit alleges that the defendants made material misstatements or omissions in the Company's registration statement in violation of Sections 11 and 15 of the Securities Act of 1933 (the "Securities Act") and between September 27, 2018 and November 27, 2019, inclusive, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"). On March 11, 2020, lead plaintiffs voluntarily dismissed the underwriter defendants without prejudice. On March 13, 2020, defendants filed a motion to dismiss the amended complaint. On March 24, 2021, the court issued an order granting defendants' motion to dismiss claims under the Securities Act in full and certain claims under the Exchange Act, and denying defendants' motion to dismiss certain Exchange Act claims. Plaintiffs filed their second amended complaint on April 19, 2021, realleging the Securities Act claims and certain of the previously dismissed Exchange Act claims. On June 10, 2021 defendants moved to dismiss the second amended complaint. A hearing on the motion to dismiss is scheduled for October 12, 2021. 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 the Company's financial condition and its 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. While the Company has obligations to indemnify and/or advance the defendants' legal fees and costs in connection with this lawsuit, any monetary recovery from the defendants would be to the benefit of the Company. 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.

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") conducted 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) the Company's explanations regarding its 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) the Company failed to timely make at least two Medical Device Reports, or MDRs, to the FDA; (iv) the Company, 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) the Company 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 the Company obtained for the DABRA system is not for atherectomy, the Company's salespeople were instructed to characterize DABRA as performing atherectomy and to encourage doctors to seek reimbursement using atherectomy codes, (vii) the Company's determinations to direct potentially valuable benefits and opportunities to doctors were informed in part by sales prospects, and (viii) the Company 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 the Company's Code of Ethics and Conduct and related policies.

On December 28, 2020, the Company entered into a Settlement Agreement with the United States of America, acting through the DOJ and on behalf of the OIG, to resolve the pending DOJ investigation and a related civil action concerning our marketing of the DABRA laser system and DABRA-related remuneration to certain physicians. In connection with the Settlement Agreement, the Company also has reached agreements with the participating states that resolve previously disclosed related investigations conducted by certain state attorneys general.

The Settlement Agreement recites that a complaint filed by a former employee on behalf of the federal government in the United States District Court for the Eastern District of Michigan, and subsequently amended to assert claims on behalf of certain states, alleged, among other things, that the Company violated the False Claims Act, 31 U.S.C. § 3729, and certain state false claims acts by paying kickbacks to certain physicians in order to induce them to use the DABRA laser system, promoting off-label use of the DABRA laser system, failing to report adverse events to the United States Food and Drug Administration, marketing a device that does not work as advertised, and failing to adhere to Current Good Manufacturing Practices. The complaint, which was settled in connection with the Settlement Agreement, also alleged that we unlawfully retaliated against the former employee. Separate from the former employee's allegations in the civil action, the United States and the participating states contend that from May 1, 2017 through October 31, 2019, the Company (a) paid illegal remuneration to certain physicians to induce them to use the DABRA laser system in violation of the federal anti-kickback statute and (b) marketed the DABRA laser system for off-label use in atherectomy procedures despite product performance issues causing calibration and overheating problems, which posed a risk to physicians and patients (the "Covered Conduct"). The Company denies the allegations in the civil action and those asserted by the United States and the participating states, and the settlement does not constitute an admission of liability or wrongdoing by the Company.

Under the Settlement Agreement, and the agreements with the participating states, the Company is required to make an initial payment of $2.5 million, of which the Company paid $2.4 million in December 2020 and $0.1 million in April 2021. Pursuant to the terms of the Settlement Agreement, (a) if its revenue exceeds $10 million in any of the next four fiscal years (2021-2024), it also is required to pay an additional amount in settlement for the corresponding year: $500,000 for 2021, $750,000 for 2022, $1 million for 2023, and $1.25 million for 2024; (b) if it is acquired or is otherwise involved in a change in control transaction in the years 2020 through 2024, it is required to pay an additional settlement amount of $5 million, plus 4% of the value attributed to the Company in the transaction, so long as the attributed value is in excess of $100 million, with the total change in control payment never to exceed $28 million; and (c) if its obligations under the Settlement Agreement are avoided by bankruptcy, the United States may rescind the releases and bring an action against the Company in which the Company agrees is not subject to an automatic stay, is not subject to any statute of limitations, estoppel or laches defense, and is a valid claim in the amount of $56 million, minus any prior change in control payments. Under the Settlement Agreement, the Company also paid the former employee's reasonable expenses, costs and attorneys' fees, which amount to $0.2 million. The Company has expensed $2.7 million during the year ended December 31, 2020 and all amounts have been paid.

The OIG has agreed, conditioned upon full payment of amounts owed in the Settlement Agreement, and in consideration of the Company's obligations under a Corporate Integrity Agreement, to release its permissive exclusion rights and refrain from instituting any administrative action seeking to exclude it from participating in Medicare, Medicaid, or other federal health care programs as a result of the Covered Conduct. The Corporate Integrity Agreement has a five-year term and imposes monitoring, reporting, certification, documentation, oversight, screening, and training obligations on the Company, including the hiring of a compliance officer and independent review organization.

Pursuant to the terms of the Settlement Agreement, the United States and the former employee have dismissed the complaint against the Company withprejudice and have released the Company from any civil or administrative monetary liability arising under the Covered Conduct. The Settlement Agreement does not include a release for any conduct other than the Covered Conduct or any criminal liability related to the Covered Conduct. The Settlement Agreement does not release any claims under investigation by the SEC.

As also previously announced, the Company voluntarily contacted the SEC's Enforcement Division regarding the Audit Committee's investigation. Cn November 13, 2019, the SEC notified the Company that it was conducting an investigation. The Company cooperated fully with the SEC in this investigation. On August 3, 2021 the Company received notice that the SEC has concluded its investigation and does not intend to recommend an enforcement action by the SEC against the Company.

On November 21, 2019, the Company became aware that the Criminal Division, Fraud Section of the DOJ 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 has been, and intends to continue, cooperating with the DOJ in itsactive and ongoing 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.

Note 14—Segment Information

The Company has organized its business intotwo 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 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,	
	2021	2020	2021	2020
Vascular	$ 9	$ 78	$ 13	$ 191
Dermatology	996	822	2,110	2,083
Net revenue	$ 1,005	$ 900	$ 2,123	$ 2,274
Vascular	$ 466	$ 417	$ 865	$ 1,078
Dermatology	1,022	750	1,996	1,673
Cost of revenue	$ 1,488	$ 1,167	$ 2,861	$ 2,751
Vascular	$ (457)	$ (339)	$ (852)	$ (887)
Dermatology	(26)	72	114	410
Gross loss	$ (483)	$ (267)	$ (738)	$ (477)

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 the lasers in the vascular segment was $1.5 million and $1.9 million as of June 30, 2021 and December 31, 2020, respectively. The net book value of the lasers in the dermatology segment was $0.4 million and $0.7 million as of June 30, 2021 and December 31, 2020, respectively.

No sales to an individual customer or country other than the United States accounted for more than10% of revenue for the three and six months ended June 30, 2021 and 2020. 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,	
	2021	2020	2021	2020
United States	$ 994	$ 881	$ 2,057	$ 2,067
All other countries	11	19	66	207
Net revenue	$ 1,005	$ 900	$ 2,123	$ 2,274

Note 15—Subsequent Events

On August 3, 2021 the Company received notice that the SEC has concluded its investigation and does not intend to recommend an enforcement action by the SEC against the Company.

Between July 1, 2021 and August 2, 2021, the Company completed “at the market offerings” of1,139,306 shares of common stock and received approximately $4.4 million in net proceeds, after deducting placement agent’s fees.

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 Quarterly Report on Form 10-Q. 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.

Overview

Ra Medical Systems, Inc. is 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.

The DABRA laser and single-use catheter, together referred to as DABRA, is used as a tool in the treatment of peripheral artery disease, or PAD, which commonly occurs in the legs. 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 was also granted CE mark approval in Europe in September 2016 for the endovascular treatment of infrainguinal arteries via atherectomy and for crossing total occlusions.

Our vascular business strategy is focused on multiple engineering efforts to improve our catheter offering as well as conducting a clinical study to obtain an atherectomy "indication for use" in the United States. Key catheter engineering efforts currently underway include projects to:

- Extend our catheter's shelf life. During 2020, we identified the factors limiting our shelf life, including the introduction of unwanted elements in the catheter's fluid core and the degradation of the coating on the inner diameter, and are currently implementing multiple remediations to address these issues. Our internal real time aging test data supports shelf life for our catheter of at least six months;
- Increase the robustness of our catheter via a braided overjacket, or a similar design, to make the catheter more kink-resistant when navigating tortuous anatomy. We expect to complete the engineering work for this catheter and subsequently submit to the FDA for clearance in the first quarter of 2022; and

- Develop a version of the DABRA catheter that is compatible with a standard guidewire. We completed several guidewire-compatible catheter prototypes in the fourth quarter of 2020 and then conducted in vitro evaluations with several physicians. We expect to finalize the design for this catheter at the end of 2021 and subsequently submit to the FDA for clearance.

As stated, we are currently pursuing an atherectomy indication for use, which the FDA defines to include a prespecified improvement in luminal patency. To satisfy the FDA's data requirements to support an atherectomy indication, we are performing a pivotal study designed to allow the FDA to evaluate the use of DABRA in atherectomy procedures. We received an Investigational Device Exemption, or IDE, approval in January 2020 and the study is approved for up to 10 clinical sites and 100 subjects.

We enrolled the first subject in February 2020. Throughout much of 2020 and 2021, the COVID-19 pandemic substantially impacted our ability to activate new sites and enroll additional subjects. Many sites or potential sites have been or are currently operating at a reduced capacity, and some have been closed from time to time. In addition, potential study subjects may voluntarily opt to postpone their procedures due to COVID-19 concerns. As of August 2, 2021, we have enrolled 69 subjects. Four sites are currently cleared to enroll subjects and the fifth site, previously cleared, has moved locations and is in the process of being reactivated. Due to the unpredictable impact the COVID-19 pandemic has had and will continue to have on enrollment in this study, we currently cannot estimate when enrollment will be completed.

We are continuing to supply catheters to those sites involved in our atherectomy clinical study. We paused shipments of catheters to commercial sites while we conducted further studies on the stability of our shelf life. We submitted additional test data with respect to the DABRA catheter shelf life in a traditional 510(k) in March 2021, which was cleared by the FDA in July 2021. Although eligible, we have not resumed commercial shipments and are evaluating our commercial catheter strategy.

Our Pharos laser is a medical device that we have marketed since October 2004 as a tool for the treatment of proliferative skin conditions including psoriasis, vitiligo, atopic dermatitis, and leukoderma. The COVID-19 pandemic is negatively impacting the dermatology business as many customers delay the acquisition or purchase of capital equipment such as our PHAROS laser. Because this business does not have a disposables component and we augment our capital equipment sales with recurring revenue derived from service and/or rental or lease agreements, we are experiencing less of an impact than business models that rely solely on capital equipment and/or disposables sales. We are evaluating multiple strategic options for the dermatology business, including, but not limited to, investments in the commercial organization, additional improvements to the Pharos laser system, commercial partnerships and alliances, or a divestiture of the business.

COVID-19

The global spread of the novel coronavirus (COVID-19) has created significant volatility, uncertainty and economic disruption. The ultimate effects of the COVID-19 on our business, operations and financial condition are unknown at this time. In the near term, we expect that our revenue will continue to be adversely impacted and enrollment in our atherectomy clinical trial will continue to be delayed or slowed, as patients elect to postpone voluntary treatments and physicians' offices are either closed or operating at a reduced capacity. In addition, some customers are requesting more flexible payment terms on a temporary basis. We also may not be able to secure additional financing in a timely manner or on favorable terms, if at all. Our manufacturing facility located in Carlsbad, California is currently operational. We have experienced delays in receiving shipments of certain parts, which has affected the timing of our key engineering efforts. To date, the shipment delays have not had a material impact on our ability to support our atherectomy indication trial. However, the extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain it or treat its impact, among others.

Components of our Results of Operations

Net revenue

Product sales consist of the sale of Pharos lasers, the sale of catheters for use with the DABRA laser and the sale of consumables and replacement parts. The Company's vascular segment is currently not selling commercial product and is only selling catheters for use in the Company's atherectomy clinical trial.

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

We currently use our commercial team to service the U.S. dermatology market, 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 profit (loss)

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

Cost of revenue for service and other includes the cost of maintaining and servicing the warranties on our products, including the depreciation on lasers we own.

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

We calculate gross profit (loss) as revenue less cost of revenue. Our gross profit (loss) 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. Our gross loss would be reduced if our production volume increased and certain costs remain fixed or increased at a slower rate. 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.

Research and development expenses

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

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

We expense R&D costs as incurred. In the future, we expect R&D expenses to increase if we continue to develop new products, enhance existing products and technologies or perform activities related to obtaining additional regulatory approval. However, we expect R&D expenses as a percentage of total expenses 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 primarily include professional services fees, including legal, audit and tax fees, insurance costs, general corporate expenses, facilities-related expenses and shipping and handling costs. We expect continued legal costs associated with ongoing litigation and government investigation.

Results of Operations

Comparison of the Three and Six Months Ended June 30, 2021 and 2020

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

	Three Months Ended June 30,			Six Months Ended June 30,		
	2021	2020	Change $	2021	2020	Change $
Statements of operations data:						
Net revenue						
Product sales	$ 318	$ 154	$ 164	$ 724	$ 740	$ (16)
Service and other	687	746	(59)	1,399	1,534	(135)
Total net revenue	1,005	900	105	2,123	2,274	(151)
Cost of revenue						
Product	861	624	237	1,651	1,588	63
Service and other	627	543	84	1,210	1,163	47
Total cost of revenue	1,488	1,167	321	2,861	2,751	110
Gross loss	(483)	(267)	(216)	(738)	(477)	(261)
Operating expenses:						
Selling, general and administrative	3,741	7,896	(4,155)	7,855	14,181	(6,326)
Research and development	3,018	1,953	1,065	5,834	3,248	2,586
Total operating expenses	6,759	9,849	(3,090)	13,689	17,429	(3,740)
Operating loss	(7,242)	(10,116)	2,874	(14,427)	(17,906)	3,479
Other income (expense), net	1,993	(5)	1,998	1,942	84	1,858
Loss before income taxes	(5,249)	(10,121)	4,872	(12,485)	(17,822)	5,337
Income tax expense	—	—	—	—	—	—
Net loss	$ (5,249)	$ (10,121)	$ 4,872	$ (12,485)	$ (17,822)	$ 5,337

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 (loss) of these segments. Amounts included within selling, general and administrative expense and research and development expense are not evaluated by us on a segmented basis. Additional information on our reportable segments is contained in Note 14 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,		
	2021	2020	Change $	2021	2020	Change $
Vascular	$ 9	$ 78	$ (69)	$ 13	$ 191	$ (178)
Dermatology	996	822	174	2,110	2,083	27
Total net revenue	$ 1,005	$ 900	$ 105	$ 2,123	$ 2,274	$ (151)

Vascular

Net revenue was $9,000 and $0.1 million for the three months ended June 30, 2021 and 2020, respectively. The $0.1 million decrease was due to decreased catheter unit sales as a result of pausing commercial shipments in 2021 while we conducted further studies on the stability of the catheter's shelf life. However, we continue to supply catheters to clinical trial sites.

Net revenue was $13,000 and $0.2 million for the six months ended June 30, 2021 and 2020, respectively. The $0.2 million decrease was due to decreased catheter unit sales as a result of pausing commercial shipments in 2021 while we conducted further studies on the stability of the catheter's shelf life. However, we continue to supply catheters to clinical trial sites.

We do not expect our net revenue to increase in the near term while we supply catheters only to a limited number of U.S. accounts involved in, our atherectomy clinical study and as we focus on remedying the inconsistencies in our DABRA catheter performance and obtaining an atherectomy indication. In addition, we expect net revenue to continue to be negatively impacted by the COVID-19 pandemic, as patients elect to postpone voluntary treatments and physicians' offices are either closed or operating at a reduced capacity. Over the longer term, we believe that we will be able to increase our vascular revenueif we can extend the catheter's shelf life, introduce design changes to the catheter and obtain an atherectomy indication.

Dermatology

Net revenue was $1.0 million and $0.8 million for the three months ended June 30, 2021 and 2020, respectively. The increase of approximately $0.2 million was due primarily to an increase in direct unit product sales.

Net revenue was $2.1 million for each of the six months ended June 30, 2021 and 2020.

We expect net revenue to continue to be negatively impacted by the COVID-19 pandemic,as patients elect to postpone voluntary treatments and physicians' offices are either closed or operating at a reduced capacity.

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,		
	2021	2020	Change $	2021	2020	Change $
Vascular	$ 466	$ 417	$ 49	$ 865	$ 1,078	$ (213)
Dermatology	1,022	750	272	1,996	1,673	323
Total cost of revenue	$ 1,488	$ 1,167	$ 321	$ 2,861	$ 2,751	$ 110

Vascular

Cost of revenue was $0.5 million and $0.4 million for the three months ended June 30, 2021 and 2020, respectively. The increase of $49,000 was primarily due to increased costs of repairs and maintenance of catheter manufacturing equipment.

Cost of revenue was $0.9 million and $1.1 million for the six months ended June 30, 2021 and 2020, respectively. The $0.2 million decrease was due to decrease in catheter unit sales, partially offset by increased costs of repairs and maintenance of catheter manufacturing equipment.

Dermatology

Cost of revenue was $1.0 million and $0.8 million for the three months ended June 30, 2021 and 2020, respectively. The increase of approximately $0.3 million was primarily due to an increase in direct unit product sales and an increase in the number of service calls and travel.

Cost of revenue was $2.0 million and $1.7 million for the six months ended June 30, 2021 and 2020, respectively. The increase of approximately $0.3 million was primarily due to an increase in direct unit product sales and an increase in the number of service calls and travel.

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,		
	2021	2020	Change $	2021	2020	Change $
Vascular	$ (457)	$ (339)	$ (118)	$ (852)	$ (887)	$ 35
Dermatology	(26)	72	(98)	114	410	(296)
Total gross loss	$ (483)	$ (267)	$ (216)	$ (738)	$ (477)	$ (261)

Vascular

Gross loss was $0.5 million and $0.3 million for the three months ended June 30, 2021 and 2020, respectively. The $0.2 million increase in gross loss was primarily due to decreased unit sales and increased costs of repairs and maintenance of catheter manufacturing equipment.

Gross loss was $0.9 million for each of the six months ended June 30, 2021 and 2020.

We expect our gross loss to be negatively impacted in the short term while we supply catheters only to a limited number of U.S. accounts involved in our atherectomy clinical study and as we continue efforts to remedy the inconsistencies in our DABRA catheter performance. In addition, we expect the gross loss to continue to be negatively impacted by the COVID-19 pandemic, as patients elect to postpone voluntary treatments and physicians' offices are either closed or operating at a reduced capacity.

Dermatology

Gross loss was $26,000 for the three months ended June 30, 2021 compared to gross profit $0.1 million for the three months ended June 30, 2020. The decrease of $0.1 million was primarily due to an increase in service costs as a result of an increase in service calls and travel.

Gross profit was $0.1 million and $0.4 million for the six months ended June 30, 2021 and 2020, respectively. The decrease of $0.3 million was primarily due to increased overhead as we are operating under capacity and increase in service costs as a result of an increase in service calls and travel.

We expect the gross profit to continue to be negatively impacted by the COVID-19 pandemic, as patients elect to postpone voluntary treatments and physicians' offices are either closed or operating at a reduced capacity.

General

Selling, general and administrative expenses

SG&A expenses were $3.7 million and $7.9 million for the three months ended June 30, 2021 and 2020, respectively. The $4.2 million decrease was primarily related to decreases of (i) $2.6 million in legal expense due to a decrease in legal services and legal settlement expenses,(ii) $0.7 million in salary, benefits, recruiting expenses and other personnel-related costs primarily due to continued cost reduction efforts,(iii) $0.3 million in insurance expenses due to a reduction in premiums, (iv) $0.3 million in stock-based compensation expense, (v) $0.2 million in public company expenses, (vi) $0.3 million in in other costs including sales related costs, travel and trade shows, marketing, and provisions for doubtful accounts, partially offset by a $0.2 million increase in consulting and professional expenses.

SG&A expenses were $7.9 million and $14.2 million for the six months ended June 30, 2021 and 2020, respectively. The $6.3 million decrease was primarily related to decreases of (i) $3.6 million in legal expense due to a decrease in legal services and legal settlement expenses,(ii) $1.0 million in salary, benefits, recruiting expenses and other personnel-related costs primarily due to continued cost reduction efforts, (iii) $0.6 in insurance expenses due to a reduction in premiums, (iv) $0.5 million due to gain on sale of vehicles that were purchased for the sales force to transport our laser equipment, (v) $0.4 million in public company expenses. (vi) $0.3 million in sales related costs, travel, trade shows and marketing costs, (vii) $0.4 million in other costs including provisions for doubtful accounts, (viii) $0.2 million in stock-based compensation expense, partially offset by a $0.6 million increase in consulting and professional expenses.

Research and development expenses

R&D expenses were $3.0 million and $2.0 million for the three months ended June 30, 2021 and 2020, respectively. The $1.0 million increase was due to increases of $0.6 million in personnel and consulting expenses, $0.3 million in supplies, and $0.1 in clinical study and other expenses. These increases are due to engineering efforts on our next-generation catheters, including increased shelf life and improved deliverability, and also progress on the atherectomy clinical study.

R&D expenses were $5.8 million and $3.2 million for the six months ended June 30, 2021 and 2020, respectively. The $2.6 million increase was primarily due to increases of $1.2 million in personnel and consulting expenses, $1.1 million in supplies, $0.1 million in clinical study expenses, $0.1 million in other expenses, and $0.1 million in stock-based compensation expense. These increases are due to engineering efforts on our next-generation catheters, including increased shelf life and improved deliverability, and also progress on the atherectomy clinical study.

Other income, net

Other income, net was $2.0 million for the three months ended June 30, 2021 and de minimis for the three months ended June 30, 2020, respectively. The increase of $2.0 million is due to the gain on forgiveness of the PPP loan.

Other income, net was $2.0 million and $0.1 million for the six months ended June 30, 2021 and 2020, respectively. The increase of $1.9 million is primarily due to $2.0 million gain from the forgiveness of the PPP loan, offset by $0.1 million decrease in interest expense 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.

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 and amortization of long-lived assets, although these are non-cash charges, the assets being depreciated and amortized 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 and gain on sale of property and equipment.

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 U.S. 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, stock-based compensation, gain on sale of property and equipment and gain on extinguishment of debt.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Statement of Operations Data:				
Net loss	$ (5,249)	$ (10,121)	$ (12,485)	$ (17,822)
Depreciation and amortization	426	636	881	1,214
Interest income	(1)	(10)	(2)	(124)
Interest expense	31	15	83	40
Income tax expense	—	—	—	—
EBITDA	(4,793)	(9,480)	(11,523)	(16,692)
Stock-based compensation	696	1,033	1,865	2,080
Gain on extinguishment of PPP promissory note	(2,023)	—	(2,023)	—
Loss (gain) on sale of property and equipment	8	—	(493)	—
Adjusted EBITDA	$ (6,112)	$ (8,447)	$ (12,174)	$ (14,612)

Adjusted EBITDA was negative $6.1 million compared to negative $8.4 million for the three months ended June 30, 2021 and 2020, respectivelyand a negative $12.2 million compared to a negative $14.6 million for the six months ended June 30, 2021 and 2020, respectively. The change in Adjusted EBITDA primarily reflects decreased selling, general and administrative costs, including legal expense. The decreased costs were partially offset by an increase in research and development.

Liquidity and Capital Resources

As of June 30, 2021, we had cash and cash equivalents of $20.2 million and accumulated deficit of $165.7 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, the net proceeds of $19.1 million from our 2020 public offerings, $11.0 million proceeds, net of placement agent fees, received from our “at the market” offering, $2.0 million received in the form of a Paycheck Protection Program loan under the CARES Act and, to a lesser extent, private placements of common stock and equipment financing arrangements.

Management expects operating losses and negative cash flows to continue for the foreseeable future with our reduced commercial footprint, and as we continue to incur costs related to our atherectomy clinical trial, engineering efforts to improve the shelf life of our catheters, development of our next generation products and legal costs associated with ongoing litigation. We also expect the COVID-19 pandemic to have a continued negative impact on our revenue and the timing of enrollment in our atherectomy clinical trial as well as our ability to secure additional financing in a timely manner or on favorable terms, if at all. In the third quarter of 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 included targeted workforce reductions of our sales and marketing teams. We continue to analyze opportunities for cost reductions. 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.

As a public company, we incur and will continue to incur significant legal, accounting, insurance, and other expenses. We expect legal and related expenses to remain high in the near term in connection with the legal proceedings discussed in Note 13, "Commitments and Contingencies," in the notes to the condensed financial statements

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

- our ability to complete our atherectomy trial in a timely manner or at all, which may be affected by reductions in voluntary medical procedures during the ongoing COVID-19 pandemic as well as by limitations in our DABRA catheter performance, as described above;
- the revenue generated by sales of our DABRA and Pharos products, related consumables, and other products that get 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; including extending shelf life and reducing non-calibrations, reducing kinking, and identifying other future issues, if any;
- our ability to develop a guidewire-compatible version of our DABRA catheter designed to allow physicians to navigate the vasculature more easily;
- our ability to develop a larger diameter catheter to facilitate treatment of larger vessels more commonly seen in above-the-knee procedures;
- following our voluntary 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 investigation in which we are involved;
- 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 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.

Although we bolstered our liquidity resources in 2020 and 2021, have an effective shelf registration statement and an "at the market" offering to allow us to raise additional capital when the opportunities permit, and may receive additional funds from the exercise of our warrants depending on market conditions, management concluded that the aforementioned conditions, including the ongoing uncertainty related to the negative impacts of the COVID-19 pandemic, continue to raise substantial doubt about our ability to continue as a going concern for a period of at least 12 months from the date of issuance of the financial statements. We plan to address this uncertainty by raising additional funds, if necessary, through public or private equity or debt financings as well as by engaging in regular and ongoing reviews of our business model and strategic options to help ensure that we are focusing our cash resources on advancing our key corporate initiatives. However, we may not be able to secure such financing in a timely manner or on favorable terms, if at all. Furthermore, if we issue equity securities to raise additional funds, our existing stockholders may experience dilution, and the new equity securities may have rights, preferences and privileges senior to those of our existing stockholders.

Our condensed financial statements include explanatory disclosures regarding substantial doubt about our ability to continue as a going concern. Future reports on our financial statements may also include explanatory disclosures with respect to our ability to continue as a going concern. Our condensed financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue our operations.

Cash Flows

	Six Months Ended June 30,	
	2021	2020
Net cash provided by (used in):		
Operating activities	$ (14,699)	$ (12,843)
Investing activities	458	15,951
Financing activities	10,555	11,688
Net change in cash and cash equivalents	$ (3,686)	$ 14,796

Net cash used in operating activities

Net cash used in operating activities was $14.7 million for the six months ended June 30, 2021, consisting of a net loss of $12.5 million and an increase in net operating assets and liabilities of $2.4 million, partially offset by non-cash charges of $0.2 million consisting of primarily stock-based compensation expense, and depreciation and amortization, partially offset by gain on sale of property and equipment and gain on extinguishment of the PPP promissory note.

Net cash used in operating activities was $12.8 million for the six months ended June 30, 2020, consisting of a net loss of $17.8 million and a decrease in net operating assets and liabilities of $1.7 million, and non-cash charges of $3.3 million consisting of primarily stock-based compensation expense and depreciation and amortization.

Net cash provided by investing activities

Net cash provided by investing activities was $0.5 million for the six months ended June 30, 2021, consisting primarily of $0.5 million from proceeds from sale of property and equipment.

Net cash provided by investing activities was $16.0 million for the six months ended June 30, 2020, consisting of $16.0 million from proceeds of maturities of investments.

Net cash provided by financing activities

Net cash provided by financing activities was $10.6 million for the six months ended June 30, 2021, was primarily from $11.0 million of proceeds, net of placement agent fees, received from our "at the market" offering proceeds of $0.1 million from the purchase of shares under our 2018 Employee Stock Purchase Plan, or ESPP, offset by payments on our financed equipment of $0.3 million. We also paid $0.2 million of offering costs for the Registration Statement on Form S-3 and the "at the market" offerings filed with the Securities and Exchange Commission.

Net cash provided by financing activities was $11.7 million for the six months ended June 30, 2020 was primarily due to $9.0 million of proceeds, net of placement agent fees, received from our May 2020 public offering, $2.0 million proceeds under the PPP Promissory Note and $0.8 million proceeds from the exercise of warrants associated with the May 2020 public

offering. The remaining $0.2 million offering costs associated with our May 2020 public financing were paid in July 2020.These proceeds were partially offset by 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 condensed financial statements included elsewhere in this Quarterly Report on 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. 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, 2020 filed with the SEC on March 17, 2021.

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, 2021, 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, 2020.

ITEM 3. QUANTITATIVE AND QUALITATIVE 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 $20.2 million as of June 30, 2021. 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

Our revenue is denominated in U.S. dollars. Our expenses are generally denominated in the currencies in which our operations are located, which is in the United States. As of June 30, 2021, 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. If 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 Executive Officer and Chief Financial 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, 2021. 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 Executive Officer and Chief Financial Officer, as appropriate 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. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based upon our evaluation our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended June 30, 2021 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 — OTHER 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 us, certain current and former officers and directors, and certain underwriters of our IPO. Following the appointment of a lead plaintiff and the filing of a subsequent amended complaint, the lawsuit alleges that the defendants made material misstatements or omissions in our registration statement in violation of Sections 11 and 15 of the Securities Act of 1933 (the "Securities Act") and between September 27, 2018 and November 27, 2019, inclusive, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"). On March 11, 2020, lead plaintiffs voluntarily dismissed the underwriter defendants without prejudice. On March 13, 2020, defendants filed a motion to dismiss the amended complaint. On March 24, 2021, the court issued an order granting defendants' motion to dismiss claims under the Securities Act in full and certain claims under the Exchange Act and denying defendants' motion to dismiss certain Exchange Act claims. Plaintiffs filed their second amended complaint on April 19, 2021, realleging the Securities Act claims and certain of the previously dismissed Exchange Act claims. On June 10, 2021, defendants moved to dismiss the second amended complaint. A hearing on the motion to dismiss is scheduled for October 12, 2021. Management intends to vigorously defend against this lawsuit. At this time, we 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 we 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.

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. While we have obligations to indemnify and/or advance the defendants' legal fees and costs in connection with this lawsuit, any monetary recovery from the defendants would be to the benefit of us.

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") conducted an investigation of certain allegations raised by a former employee. We 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.

On December 28, 2020, we entered into a Settlement Agreement with the United States of America, acting through the DOJ and on behalf of the OIG, to resolve the pending DOJ investigation and a related civil action concerning our marketing of the DABRA laser system and DABRA-related remuneration to certain physicians. In connection with the Settlement Agreement, we also have reached agreements that resolve previously disclosed related investigations conducted by certain state attorneys general.

The Settlement Agreement recites that a complaint filed by a former employee on behalf of the federal government in the United States District Court for the Eastern District of Michigan, and subsequently amended to assert claims on behalf of certain states, alleged, among other things, that we violated the False Claims Act, 31 U.S.C. § 3729, and certain state false claims acts by paying kickbacks to certain physicians in order to induce them to use the DABRA laser system, promoting off-

label use of the DABRA laser system, failing to report adverse events to the United States Food and Drug Administration, marketing a device that does not work as advertised, and failing to adhere to Current Good Manufacturing Practices. The complaint, which was settled in connection with the Settlement Agreement, also alleged that we unlawfully retaliated against the former employee. Separate from the former employee's allegations in the civil action, the United States and the participating states contend that from May 1, 2017 through October 31, 2019, we (a) paid illegal remuneration to certain physicians to induce them to use the DABRA laser system in violation of the federal anti-kickback statute and (b) marketed the DABRA laser system for off-label use in atherectomy procedures despite product performance issues causing calibration and overheating problems, which posed a risk to physicians and patients (the "Covered Conduct"). We deny the allegations in the civil action and those asserted by the United States and the participating states, and the settlement does not constitute an admission of liability or wrongdoing by us.

Under the Settlement Agreement, and the agreements with the participating states, we are required to make an initial payment of $2.5 million, of which we paid $2.4 million in December 2020 and $0.1 million in April 2021. Pursuant to the terms of the Settlement Agreement, (a) if our revenue exceeds $10 million in any of the next four fiscal years (2021-2024), we also are required to pay an additional amount in settlement for the corresponding year: $500,000 for 2021, $750,000 for 2022, $1 million for 2023, and $1.25 million for 2024; (b) if we are acquired or are otherwise involved in a change in control transaction in the years 2020 through 2024, we are required to pay an additional settlement amount of $5 million, plus 4% of the value attributed to us in the transaction, so long as the attributed value is in excess of $100 million, with the total change in control payment never to exceed $28 million; and (c) if our obligations under the Settlement Agreement are avoided by bankruptcy, the United States may rescind the releases and bring an action against us in which we agree is not subject to an automatic stay, is not subject to any statute of limitations, estoppel or laches defense, and is a valid claim in the amount of $56 million, minus any prior change in control payments. Under the Settlement Agreement, we also paid the former employee's reasonable expenses, costs and attorneys' fees, which amount to $0.2 million.

The OIG has agreed, conditioned upon our full payment of amounts owed in the Settlement Agreement, and in consideration of our obligations under a Corporate Integrity Agreement, to release our permissive exclusion rights and refrain from instituting any administrative action seeking to exclude us from participating in Medicare, Medicaid, or other federal health care programs as a result of the Covered Conduct. The Corporate Integrity Agreement has a five-year term and imposes monitoring, reporting, certification, documentation, oversight, screening, and training obligations on us, including the hiring of a compliance officer and independent review organization.

Pursuant to the terms of the Settlement Agreement, the United States and the former employee have dismissed the complaint against us with prejudice and have released us from any civil or administrative monetary liability arising under the Covered Conduct. The Settlement Agreement does not include a release for any conduct other than the Covered Conduct or any criminal liability related to the Covered Conduct. The Settlement Agreement does not release any claims under investigation by the SEC.

As also previously announced, we voluntarily contacted the SEC's Enforcement Division regarding the Audit Committee's investigation. On November 13, 2019, the SEC notified us that it was conducting an investigation. We cooperated fully with the SEC in its investigation. On August 3, 2021 we received notice that the SEC has concluded its investigation and does not intend to recommend an enforcement action by the SEC against us.

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 us. At this time, it is unclear if we are a target in this investigation. We have been, and intend to continue, cooperating with the DOJ in its active and ongoing investigation. We are unable to predict the ultimate outcome and are unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

Other Litigation

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. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this 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.

Risk Factor Summary

Risks Related to Our Business and Products

- We have determined that there is substantial doubt about our ability to continue as a going concern, and we will need to undertake additional financings in order to execute our business plan and fund our operations.
- We may be unable to successfully remedy the performance, shelf life and calibration issues associated with our DABRA catheters, achieve market acceptance of DABRA, or achieve revenue growth.
- Our success depends in large part on DABRA. If we are unable to successfully manufacture, market and sell DABRA, our business prospects will be significantly harmed.
- Our ability to successfully complete our atherectomy trial may be hindered or delayed by the COVID-19 pandemic and DABRA catheter performance limitations that are currently being addressed by various engineering efforts.
- We anticipate requiring additional capital to finance our operations, which may not be available to us on acceptable terms or at all.
- We are required to devote significant resources to complying with the terms and conditions of our Settlement Agreement and Corporate Integrity Agreement and, if we fail to comply, we could be subject to penalties or, under certain circumstances, excluded from government healthcare programs, which would materially adversely affect our business.
- Physicians and staff may not commit enough time to sufficiently learn how to use our products.

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.
- Our medical device operations are subject to pervasive and continuing FDA regulatory requirements.
- Product clearances and approvals can often be denied or significantly delayed.
- 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.

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.
- 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.
- 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.
- We may not be able to protect our intellectual property and proprietary rights throughout the world.
- Changes in patent law in the U.S. or abroad could diminish the value of patents in general, thereby impairing our ability to protect our products.
- 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.

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.
- Our future operating results depend upon our ability to obtain components in sufficient quantities on commercially reasonable terms or according to schedules, prices, quality and volumes that are acceptable to us, and suppliers may fail to deliver components or we may be unable to manage these components effectively or obtain these components on such terms.

- 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.
- 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.

Risks Related to Ownership of Our Common Stock

- 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.
- 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.
- If we fail to comply with the continued listing standards of the NYSE American, our common stock could be delisted. If it is delisted, the market value and the liquidity of our common stock would be impacted.

Risks Related to Our Business and Products

We have determined that there is substantial doubt about our ability to continue as a going concern, and we will need additional financings to execute our business plan and to fund our operations.

We do not yet generate sufficient revenues from our operations to fund our activities and are therefore dependent upon external sources for financing our operations. As a result, our financial statements include disclosures expressing substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of the uncertainty regarding our ability to continue as a going concern. This disclosure with respect to our ability to continue as a going concern could materially limit our ability to raise additional funds through the issuance of equity or debt securities or otherwise. Future reports on our financial statements may continue to include such disclosures. If we cannot continue as a going concern, our stockholders may lose their entire investment in our common stock.

Historically, we have financed our operations through private and public placement of equity securities. Our ability to obtain financing is subject to multiple risks, many of which are beyond our control. We have and will continue seeking to reduce our recurring operation costs by engaging in regular and ongoing reviews of our business model and strategic options to help ensure that we are focusing our cash resources on advancing our key corporate initiatives. We also intend to raise additional capital in order to fund our operations and grow our business and have an effective shelf registration statement and "at the market" offering. However, no assurance can be provided that we will be able to do so on commercially reasonable terms, or at all. To the extent that we are unable to do so, we may need to curtail or cease our operations and implement a plan to extend payables or reduce overhead until sufficient additional capital is raised to support further operations.

We may be unable to successfully remedy the performance, shelf life 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. During the fourth quarter of 2018 and into 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. These 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. In the third quarter of 2019, we determined that catheters that were more than two months from sterilization had a significantly higher rate of non-calibration than catheters that were within two months of sterilization. As a result, in September 2019, we initiated a voluntary recall of our catheters to replace 12-month shelf life labeled catheters with two-month shelf life labeled catheters. Accordingly, we reduced the number of sales and marketing personnel in order to conserve cash and focus our efforts on key territories and accounts. We also initiated a voluntary recall of our DABRA catheters to replace 12-month shelf life labeled catheters with two-month shelf life labeled catheters and have paused commercial sales not related to our atherectomy clinical trial. 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 manufacture, 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 manufacture, 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, including extended shelf life and reduce non-calibrations, reduced kinking, and identify future issues;
- our ability to further enhance our DABRA catheter performance with an improved design to make the catheter more kink-resistant when navigating tortuous anatomy;
- our ability to develop a guidewire-compatible version of our DABRA catheter designed to allow physicians to navigate the vasculature more easily;
- our ability to develop a larger diameter catheter to facilitate treatment of larger vessels more commonly seen in above-the-knee procedures;
- our ability to upgrade the DABRA and Pharos laser's functionality and user interface, and maintain necessary regulatory clearances;
- our ability to continue commercializing DABRA for its cleared indications for use with a smaller sales force;
- our ability to complete our atherectomy trial in a timely manner or at all, which may be affected by reductions in voluntary medical procedures during the ongoing COVID-19 pandemic as well as by limitations in our DABRA catheter performance, as described above;
- our ability to receive FDA clearance for an atherectomy indication for use;
- our ability to successfully 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;
- our ability to improve and extend the shelf life of our DABRA catheters and obtain FDA clearance for the extended shelf life;
- any agreements or punitive actions that arise out of any adverse judgment or settlement of the active and ongoing investigation by governmental agencies;
- our ability to receive regulatory clearance or approval 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, manufacture and sell DABRA, we may not be able to achieve or maintain profitability, which will have a material adverse effect on our business, financial condition, and results of operations.

Our ability to successfully complete our atherectomy trial may be hindered or delayed by the COVID-19 pandemic and DABRA catheter performance limitations that are currently being addressed by various engineering efforts.

The current COVID-19 pandemic and the DABRA catheter performance limitations may impact our ability to complete our atherectomy study in a timely manner. For example, enrollment in our atherectomy clinical trial may be further delayed or slowed by continuing increases in COVID-19 cases, as patients elect, or are asked, to postpone voluntary treatments and physicians' offices are either closed or only performing procedures on patients with a more advanced disease state that may not meet the enrollment criteria for our atherectomy clinical trial. In addition, inconsistencies or limitations in our DABRA catheter performance, including a current two-month shelf life and a history of non-calibrations, may deter some clinical sites from participating in our atherectomy study. Other limitations in our DABRA catheter performance, such as the potential for kinking during certain clinical scenarios or the lack of a guidewire-compatible version of our DABRA catheter, may limit the number of cases in which the DABRA catheter will be used during the trial. We have recently experienced delays in our efforts to develop these design enhancements to the DABRA catheter as a result of delays in obtaining materials from a key supplier. Accordingly, we cannot predict whether or when we will be able to successfully complete our atherectomy indication trial. Any inability to complete our atherectomy indication trial could have an adverse impact on our ability to successfully manufacture, market and sell DABRA, which in turn could adversely impact our business, financial condition and results of operations.

We anticipate requiring additional capital to finance our operations, which may not be available to us on acceptable terms or at all.

Our operations have consumed substantial amounts of cash since inception, primarily due to our research and development and commercialization efforts. As of June 30, 2021, we had cash and cash equivalents of $20.2 million and an accumulated deficit of $165.7 million. For the years ended December 31, 2020 and 2019, we used $28.3 million and $33.2 million in cash for operating activities, respectively. We have experienced recurring net losses from operations, negative cash flows from operating activities, and a significant accumulated deficit and expect to continue to incur net losses into the foreseeable future. As a result, our financial statements include explanatory disclosures expressing substantial doubt about our ability to continue as a going concern.

In the near term, we expect our recurring operational costs to decrease as a result of our cost savings initiatives. In the third quarter of 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 included targeted workforce reductions of our sales and marketing teams. We have suspended sales of DABRA catheters not related to our atherectomy clinical trial. We submitted additional test data with respect to the DABRA catheter shelf life in March 2021, which was cleared by the FDA in July 2021. Further such actions 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. Until we are able to generate sufficient 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 legal and other costs related to our completed Audit Committee investigation, including the pending securities class action and derivative lawsuits and a pending DOJ criminal investigation as well as compliance with, and payments under, the terms of our Settlement Agreement and Corporate Integrity Agreement associated with our settlement of a DOJ civil investigation. Because of the numerous risks and uncertainties associated with our commercialization efforts and future product development and these lawsuits and ongoing government investigation, 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, including extended shelf life and reduced non-calibrations;
- whether we are able to further enhance our DABRA catheter performance with an improved design to reduce kinking and develop a guidewire-compatible version of our DABRA catheter designed to allow physicians to navigate the vasculature more easily;
- our ability to develop a larger diameter catheter to facilitate treatment of larger vessels more commonly seen in above-the-knee procedures;
- the timing of enrollment in our clinical trial for an atherectomy indication for use;
- 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;

- our ability to improve and extend the shelf life of our DABRA catheters and obtain FDA clearance for the extended shelf life;
- 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 use 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; and
- 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.

If we raise additional capital or develop and/or commercialize our products with third parties through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements, we may have to develop our products on a slower timeline or 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 also expect the continuing economic uncertainty resulting from the COVID-19 pandemic to have a negative impact on our ability to secure additional financing in a timely manner or on favorable terms, if at all.

We are required to devote significant resources to complying with the terms and conditions of our Corporate Integrity Agreement and, if we fail to comply, we could be subject to penalties or, under certain circumstances, excluded from government healthcare programs, which would materially adversely affect our business.

On December 28, 2020, we entered into a five-year Corporate Integrity Agreement with the OIG. The Corporate Integrity Agreement requires that we maintain our existing compliance programs, as well as expanding compliance-related requirements during the term of the Corporate Integrity Agreement. The Corporate Integrity Agreement requires us to establish specific procedures and requirements regarding consulting activities, marketing activities and other interactions with healthcare professionals and healthcare institutions and the sale and marketing of our products; ongoing monitoring, reporting, certification and training obligations; and the engagement of an independent review organization to perform certain auditing and reviews and prepare certain reports regarding our compliance with federal health care programs. Developing and maintaining these processes, policies and procedures necessary to comply with the Corporate Integrity Agreement will require a significant portion of management's attention and the application of significant resources. In addition, while we have developed and instituted a corporate compliance program, we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable U.S. federal and state regulations and/or laws, all potentially applicable foreign regulations and/or laws and/or all requirements of the Corporate Integrity Agreement. If we breach the Corporate Integrity Agreement, we could become liable for payment of certain stipulated penalties or could be excluded from participation in federal health care programs. The costs associated with compliance with the Corporate Integrity Agreement, or any liability or consequences associated with its breach, could have an adverse effect on 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 and familiarize themselves with our technology, we encourage physicians to attend structured training sessions. There are many nuances to successfully using our products. For example, the DABRA catheter is fragile and may be prone to bending, a problem known as kinking. In addition, the DABRA laser needs to be calibrated correctly for each use. During the fourth quarter of 2018 and into 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.Although we are instituting measures intended to improve calibration and decrease kinking in the future, physicians and their staff must utilize the technology on a regular basis to ensure they maintain the skill set necessary to use our products. This will depend on 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, including extending shelf life and reducing non-calibrations;
- whether physicians, catheterization laboratory owners and operators, patients, and others in the medical community consider our products to be safe, effective, and cost-effective treatment methods;
- our ability to improve and extend the shelf life of our DABRA catheters and obtain FDA clearance for the extended shelf life;
- our ability to further enhance our DABRA catheter performance with an improved design to reduce kinking when navigating tortuous anatomy;
- our ability to develop a guidewire-compatible version of our DABRA catheter designed to allow physicians to navigate the vasculature more easily;
- our ability to upgrade the DABRA and Pharos laser's functionality and user interface, and maintain necessary regulatory clearances;
- whether we are able to receive FDA clearance for an atherectomy indication for use;
- 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 action, derivative lawsuit and the active and ongoing government investigation, including the impact of any settlement or adverse judgment;
- 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 peripheral artery disease, or PAD, and the existence and proper use of our products, DABRA may not gain market acceptance, as many physicians do not routinely screen for PAD while screening for coronary artery disease, or 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 continued scrutiny by the OIG and the DOJ, for improper relationships with physicians. For example, on December 28, 2020, we entered into a Settlement Agreement and a related Corporate Integrity Agreement related to a resolution of a DOJ civil investigation concerning, among other things, whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b. Our failure to comply with the Corporate Integrity Agreement or 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 the reputational harm or negative publicity resulting from the settlement of the pending government investigation 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 have experienced inconsistencies in our DABRA catheter performance. This and any other development or manufacturing problems or delays could limit the potential growth of our revenue or increase our losses.

Beginning in the fourth quarter of 2018, we started experiencing inconsistencies in our DABRA catheter performance. We believed at the time that these inconsistencies were 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 into 2019, however, the decrease in purchases and the impact of such decrease on our revenues 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 at customer sites 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 voluntary recall of our catheters to replace 12-month shelf life labeled catheters with two-month shelf life labeled catheters. At the FDA's request, we engaged in additional shelf life testing as part of a special 510(k) and suspended commercial sales of catheters in order to remedy the shelf life issues. The FDA subsequently decided not to clear the special 510(k) and requested to see additional test data to confirm the stability of the shelf life before permitting us to resume commercial shipments. We submitted this additional test data with respect to the DABRA shelf life in March 2021 in a traditional 510(k) and received clearance by the FDA in July 2021.

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 timely 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 sole manufacturing facility in Carlsbad, California, 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, 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 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 replace 12-month shelf life labeled catheters with two-month shelf life labeled catheters, 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 the newly labeled DABRA catheters showed a significant decrease in non-calibrations, we have paused commercial sales of DABRA catheters not being used for the atherectomy clinical trial while we continue our engineering efforts to improve the shelf life of our catheters.

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

We incurred net losses of $36.0 million and $57.0 million for the years ended December 31, 2020 and 2019, respectively. As of June 30, 2021, we had an accumulated deficit of $165.7 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, to develop new products or add new features to our existing products, and to defend, cooperate and resolve pending lawsuits and government investigation, as applicable. In addition, our general and administrative expenses have increased following our initial public offering and we expect these costs to continue 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 completed Audit Committee investigation, including an active and ongoing government investigation 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 completed its internal investigation. In connection with the Audit Committee investigation, we voluntarily contacted the Enforcement Division of the SEC in August 2019 to advise them of the investigation and on November 13, 2019, the SEC notified us that it was conducting an investigation. On March 11, 2020, the SEC served us with document subpoenas. We cooperated fully with the SEC's investigation. On August 3, 2021 we received notice that the SEC has concluded its investigation and does not intend to recommend an enforcement action by the SEC against us. In November 2019, we learned that the DOJ opened a criminal investigation relating to us. We have been, and intend to continue, cooperating in the DOJ's investigation.

As disclosed above, on December 28, 2020, we entered into a Settlement Agreement with the DOJ to resolve a civil False Claims Act investigation and a related civil action, and in connection with the Settlement Agreement, reached agreements that resolve previously disclosed related civil investigations conducted by certain state attorneys general. Under the Settlement Agreement, and the agreements with the participating states, we are required to make an initial payment of $2.5 million, of which we paid $2.4 million in December 2020 and $0.1 million in April 2021. In addition, if our revenue exceeds $10 million in any of the next four fiscal years, we also are required to pay an additional amount in settlement for the corresponding year: $500,000 for 2021, $750,000 for 2022, $1 million for 2023, and $1.25 million for 2024. If we are acquired or are otherwise involved in a change-in-control transaction prior to December 31, 2024, we also are required to pay an additional settlement amount of $5 million, plus 4% of the value of the transaction if the value of the transaction is in excess of $100 million, with

the total change-in-control payment not to exceed $28 million. Under the Settlement Agreement, we also paid the former employee's reasonable expenses, costs and attorneys' fees, which amounted to $0.2 million. We also have additional obligations under a related Corporate Integrity Agreement, which has a five-year term and imposes monitoring, reporting, certification, documentation, oversight, screening, and training obligations on us, including the hiring of a compliance officer and independent review organization.

If one or more government agencies, including those conducting the pending investigation identified above, commences legal action and we are found to have violated state or federal laws or regulations, we may be subject to criminal damages, penalties, fines, disgorgement, injunctions, cease and desist orders, other equitable remedies, 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 for years. Regardless of whether actions are commenced, if we were to settle with one or more government agencies or state governments, including those conducting the ongoing investigation identified above, such settlements could include an agreement to pay civil or criminal damages, deferred prosecution agreements, or other equitable remedies, exclusion form 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 for years after any settlement is reached. In light of the ongoing nature of the investigation, whether actions will be commenced, whether this investigation can be settled before or after actions are commenced, and the terms on which this investigation can be resolved is not certain.

We have incurred, and may continue to incur, significant expenses related to legal, accounting, and other professional services in connection with the completed Audit Committee investigation and related legal matters, including the securities class action, shareholder derivative lawsuit, and government investigation, as well as costs related to compliance under, and payments made pursuant to, the Settlement Agreement and Corporate Integrity Agreement. These expenses 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. 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, pandemics, epidemics, 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.

The emergence and effects related to a pandemic, epidemic or outbreak of an infectious disease, including the current COVID-19 pandemic could adversely affect our operations.

If a disaster such as a pandemic, epidemic, outbreak of an infectious disease or other public health crisis were to occur in an area in which we operate, our operations could be adversely affected. For example, COVID-19 has now been characterized as a global pandemic and how long and how extensive the economic effects will last, has not been determined. The extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain it or treat its impact, among others. A further spread of the pandemic could cause include the temporary closure of our manufacturing facilities and those used in our supply chain processes, restrictions on the export or shipment of our products, business closures in impacted areas, and further restrictions on our employees' and consultants' ability to travel and to meet with customers. The pandemic has, and will likely continue, to cause delays in enrollment in our atherectomy indication trial. In

addition, we have experienced minor delays in receiving shipments of parts, which has not had a material impact on the timing of our key engineering efforts, nor our ability to support our atherectomy indication clinical trial. The pandemic could also adversely affect our ability to secure additional financing in a timely manner or on favorable terms, if at all.

We are involved in 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 the Registration Statement for our IPO and in subsequent public statements. 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 13, "Commitments and Contingencies," in the notes to the condensed financial statements included elsewhere in this Quarterly Report on Form 10-Q.

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. 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., including Volcano Corporation and Spectranetics Corporation, Becton Dickinson and Company, including products from the C.R. Bard acquisition, AngioDynamics and Abbott Laboratories. These companies are manufacturers of products used in competing therapies within the peripheral arterial disease market such as:

- atherectomy, using mechanical and laser ablation 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 The Daavlin Company, National Biological Corp., 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.

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. For example, our competitors with laser-based products may develop upgrades to their lasers that make them easier to use, more efficient or more functional and they may more quickly obtain necessary FDA and non-U.S. regulatory clearances and approvals for such improvements. 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 cleared or 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 uncleared or unapproved indications, manufacturers may promote their products only for the cleared or approved indications and in accordance with the provisions of the cleared or 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 as of June 30, 2021. We cannot assure you that we will be able to successfully obtain clearance or 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 are 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. As previously disclosed, the DOJ served us with a Civil Investigative Demand seeking information with respect to a False Claims Act investigation concerning, among other things, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs. Without admitting any liability or wrongdoing, on December 28, 2020 we entered into a Settlement Agreement and related Corporate Integrity Agreement that resolved this civil investigation. Our pivotal clinical study of the DABRA Laser System completed in 2017 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 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, or HHS, the DOJ and various state Attorneys General actively enforce laws and regulations that prohibit the promotion of off-label uses. As disclosed above, on December 28, 2020, we entered into a Settlement Agreement and the related Corporate Integrity Agreement to resolve a DOJ civil investigation into, among other things, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs, and in connection with the Settlement Agreement, we also have reached agreements that resolve previously disclosed related investigations conducted by certain state attorneys general. The Settlement Agreement does not include a release for any conduct other than the Covered Conduct or any criminal liability related to the Covered Conduct. We have been, and intend to continue, cooperating with the DOJ's ongoing criminal investigation.

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 Settlement Agreement and the Corporate Integrity Agreement, the concluded SEC investigation and ongoing DOJ criminal investigation, we have incurred, and will continue to incur, substantial legal costs, including settlement costs, costs of compliance with such agreements, and payments made pursuant to such agreements, and business disruption, including from ongoing and future compliance with such agreements. In the future, 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.

The FDA, HHS, DOJ, and/or state Attorneys General, competitors, and other third parties may take the position that we have violated or are not in compliance with such guidelines, 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, threatened or actual government enforcement actions or lawsuits by third parties have and could continue to 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.

Regardless of whether actions are commenced, if we were to settle with one or more government agencies, including those conducting the ongoing and unresolved investigation identified above, such settlements could include an agreement to pay civil or criminal damages, injunctions, cease and desist orders, deferred prosecution agreements, or other equitable remedies, 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 for years after any settlement is reached. In light of the ongoing nature of the investigation, whether actions will be commenced, whether this investigation can be settled before or after actions are commenced, and the terms on which this investigation can be resolved is not certain.

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 the "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 or advance reasonable legal expenses for officers and directors, including, in certain circumstances, former employees and directors, in their defense against legal proceedings, 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. In particular, the Audit Committee found that we lacked documentation of sufficient detail and specificity regarding certain payments to physicians, ostensibly for training and consulting services, and did not accurately reflect the purpose and nature of approximately $300,000 of payments to three physicians, which could be perceived as an improper attempt to obtain business or to gain special advantage. The Audit Committee also found that our salespeople were instructed to characterize DABRA as performing atherectomy and to encourage doctors to seek reimbursement using atherectomy codes.

In November 2019, we learned that the DOJ opened a criminal investigation relating to us. We have been, and intend to continue, cooperating with the DOJ in its ongoing investigation described above. On December 28, 2020, we entered into a Settlement Agreement and a related Corporate Integrity Agreement that resolved a DOJ civil investigation and related lawsuit that concerned, among other things whether we paid improper remuneration to physicians and other healthcare providers in violation of the Anti-Kickback Statute, 42 U.S.C. §1320a-7b.

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 currently ongoing DOJ investigation, may result in a materially significant diversion of management's 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 for years after these investigations are resolved.

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 Pharos, and in the past have sold DABRA, 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;
- the impact of the current situation relating to trade with China and tariffs and other trade barriers that may be implemented by governmental authorities;
- the impact of public health epidemics on the global economy, such as the new coronavirus currently impacting the United States, Europe, China and elsewhere; 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 have partnered with distributors for DABRA and Pharos in select geographies outside of the U.S. For the six months ended June 30, 2021, approximately 3% of our sales were outside of the U.S. We are not currently distributing DABRA outside the U.S. and will likely not be able to do so until we extend the shelf life of the DABRA catheter. 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.

Changes in trade policies among the U.S. and other countries, in particular the imposition of new or higher tariffs, could place pressure on our average selling prices as our customers seek to offset the impact of increased tariffs on their own products. Increased tariffs or the imposition of other barriers to international trade could have a material adverse effect on our revenues and operating results.

The U.S. has imposed or proposed new or higher tariffs on certain products exported by a number of U.S. trading partners, including China, Europe, Canada, and Mexico. In response, many of those trading partners, including China, have imposed or proposed new or higher tariffs on American products. Continuing changes in government trade policies create a heightened risk of further increased tariffs that impose barriers to international trade. For the six months ended June 30, 2021. approximately 3% of our revenue came from international markets.

Tariffs on our customers' products may adversely affect our gross profit margins in the future due to the potential for increased pressure on our selling prices by customers seeking to offset the impact of tariffs on their own products. We believe that increases in tariffs on imported goods or the failure to resolve current international trade disputes could have a material adverse effect on our business and operating results.

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.

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. Our continued success is dependent, in part, upon our ability to attract and retain superior executive officers.

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, financial reporting, 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.

Failure to maintain effective internal controls could cause our investors to lose confidence in us and adversely affect the market price of our common stock. If our internal controls are not effective, we may not be able to accurately report our financial results or prevent fraud.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of 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" unless at that time we are still a "smaller reporting 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 SEC or other regulatory authorities, which would require additional financial and management resources.

In reviewing the allegations and findings from an Audit Committee investigation related to an initially anonymous complaint in 2019, as well as additional matters discovered during the course of the investigation, 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 our 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.

The material weaknesses discussed were remediated as of December 31, 2019. We incurred significant costs to remediate those 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.

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, 2021, we had 86 full-time employees. In the third quarter of 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.

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 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 recalls and certain device field removals and corrections to the FDA;
- and obtaining premarket notification 510(k) clearance for devices prior to marketing.

As previously disclosed, the Audit Committee found, among other things, that we, out of a concern for the DABRA catheters' performance, engaged in efforts to replace product held by customers, which constituted product recalls, but were not documented as such. As disclosed above, we have entered to a Settlement Agreement, and the agreements with the participating states, resolving a DOJ civil investigation concerning certain Covered Conduct, and the OIG has agreed, conditioned upon our full payment of amounts owed in the Settlement Agreement, and in consideration of our obligations under a Corporate Integrity Agreement, to release our permissive exclusion rights and refrain from instituting any administrative action seeking to exclude us from participating in Medicare, Medicaid, or other federal health care programs as a result of the Covered Conduct. The Corporate Integrity Agreement has a five-year term and imposes monitoring, reporting, certification, documentation, oversight, screening, and training obligations on us, including the hiring of a compliance officer and independent review organization.

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. We do not believe any 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. For example, as discussed above, on December 28, 2020, we entered into a Settlement Agreement with the DOJ to resolve a civil False Claims Act investigation and related civil action, and in connection with the Settlement Agreement, we also have reached agreements that resolve previously disclosed related investigations conducted by certain state attorneys general. Under the Settlement Agreement, and the agreements with the participating states, we are required to make an initial payment of $2.5 million, of which we paid $2.4 million in December 2020 and $0.1 million in April 2021. We also may be required to make additional payments in the future upon the achievement of revenue targets or consummating a change-in-control transaction. We also entered into a 5-year Corporate Integrity Agreement with the OIG. The Settlement Agreement does not include a release for any conduct other than the Covered Conduct or any criminal liability related to the Covered Conduct. The Settlement Agreement does not release any claims that were under investigation by the U.S. Securities and Exchange Commission. The DOJ criminal investigation is ongoing, and we are cooperating with that investigation. These investigations may result in 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; fines and penalties for violation of our Corporate Integrity Agreement, 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. As previously disclosed, the Audit Committee found that we lacked documentation of sufficient detail and specificity regarding 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 that could be perceived as an improper attempt to obtain business or to gain special advantage, and we subsequently entered into the Settlement Agreement with the DOJ relating to claims under the civil False Claims Act investigation concerning, among other things, 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. 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 for years after any resolution of these investigations and any resulting claims are resolved.

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. Our ability to enroll patients in clinical trials, including our atherectomy indication trial, could be impacted by the COVID-19 outbreak, as many patients are electing or being asked to delay procedures at this time.

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 device 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 premarket 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. For example, the COVID-19 outbreak could affect the FDA's ability to review applications or supplements. 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 voluntary recalls 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. For example, 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.

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. Prior to making 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 premarket application and obtain clearance or approval.

If a regulatory agency discovers previously unknown problems with our products, 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 our products, such regulatory agency or enforcement authority may impose restrictions on that product or us, including requiring withdrawal of the product from the market. In addition to this type of penalty for failing 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. As disclosed previously, we settled a DOJ civil False Claims Act investigation concerning, among other things, whether we marketed and promoted DABRA devices for unapproved uses that were not covered by federal healthcare programs.

Any government adverse finding, regulatory sanction or 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, we have conducted four recent recalls related to our DABRA and Pharos products. In August 2018, we initiated a voluntary recall of our Pharos laser due to the potential for the laser to calibrate with the iris closed. This recall was classified as a Class II recall by FDA (a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote). The four affected lasers were corrected, and the recall has been terminated by the FDA. In August 2019, we initiated a voluntary recall of a limited number of Pharos lasers due to a software error that caused the device to fail at low doses. This recall was classified as a Class II recall by the FDA. The software was revised, and the affected lasers were corrected. The FDA classified this recall as complete. In September 2019, we initiated a voluntary recall of our DABRA catheters to replace 12-month shelf life labeled catheters with two-month shelf life labeled catheters, which we believe will significantly reduce the number of catheters that fail to calibrate. We submitted a request for termination to the FDA in February 2020, and as of July 2020, 98% of the affected product has been returned to us. Finally, a voluntary recall of DABRA lasers was initiated in January 2020 to correct a software issue that could result in user or patient injury or may adversely impact laser performance. This recall was classified as a Class II recall by the FDA. The Company considers this recall complete and submitted to the FDA a final status report in July 2020 requesting termination of this field correction. In addition, in July 2020 we initiated a voluntary recall of our DABRA lasers to replace the wheels with lower profile wheels that were cleared by the FDA in the DABRA 510(k). We formally notified the FDA of this recall in accordance with applicable law and expect it will be classified by the FDA in due course. This field correction was completed in March 2021. 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. These voluntary recalls and any future recalls of our products could divert managerial and financial resources, harm our reputation and adversely affect our business.

In addition, the FDA conducted an unannounced facility inspection in December 2019. The FDA issued to us a Form 483 that included observations that schedules for the adjustment, cleaning, and other maintenance of equipment have not been adequately established, a device master record index was not current, and document control procedures have not been fully established. We responded to the FDA with the corrective measures we are taking and to address the issued identified in the Form 483 and based on this information, the FDA issued to us an Establishment Inspection Report, or EIR, closing out the inspection. All actions are complete, and the final Form 483 report was sent to the FDA on September 25, 2020.

Also, we have been engaged in additional shelf life testing at the FDA's request as part of a special 510(k). Due to recent variations noted in the shelf life of the catheter during our testing procedures, we have paused commercial sales of DABRA catheters not being used for the atherectomy clinical trial. We submitted additional test data in March 2021 related to the DABRA catheter shelf life in a traditional 510(k), which was cleared by the FDA in July 2021.

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 findings, 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 clearances or 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. At that time, 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. We have not requested, and the FDA has not issued, an EIR related to this inspection. 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 May 2018 observations to FDA's satisfaction. Although we have since identified and made the appropriate reports to the FDA, these prior 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. If required, we may not be able to obtain additional 510(k) clearances or premarket approvals for new devices or for modifications to, or 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.

If we or our suppliers 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 and our suppliers 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 or manufacturing processes or our suppliers' facilities or 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 new 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 clinical 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 have revised and continue to monitor our internal

operating procedures for complaint handling and adverse event classifications. We reviewed all adverse medical events thatwere reported to us prior to and during the Audit Committee investigation 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 PPACA was passed. The PPACA was intended to make significant changes to the way healthcare is financed by both federal and state governments and private insurers, with direct impacts to the medical device industry. Among other provisions, the PPACA imposed, with limited exceptions, a deductible excise tax of 2.3% on sales of medical devices by entities, including us, that manufacture or import certain medical devices offered for sale in the U.S., including many of our products. The Consolidated Appropriations Act, 2016 (Pub. L. 114-113), signed into law in December 2015, included a two-year moratorium on the medical device excise tax. A second two-year moratorium on the medical device excise tax was signed into law in January 2018 as part of the Extension of Continuing Appropriations Act, 2018 (Pub. L. 115-120), extending the moratorium through December 31, 2019. On December 20, 2019, President Trump signed into law a permanent repeal of the medical device tax under the PPACA, but there is no guarantee that Congress or the President will not reverse course in the future. If such an excise tax on sales of certain of our products in the United States is enacted, it could have a material adverse effect on our business, financial condition, and results of operations.

In addition, the PPACA and the Medicare Access and CHIP Reauthorization Act of 2015 substantially changed the way healthcare is delivered and financed by both governmental and private insurers. These changes included the creation of demonstration programs and other value-based purchasing initiatives that provide financial incentives for physicians and hospitals to reduce costs, including incentives for furnishing low-cost therapies for chronic wounds even if those therapies are less effective than our products. Under the Trump Administration, there were ongoing efforts to modify or repeal all or part of PPACA or take executive action that affects its implementation. Tax reform legislation was passed that includes provisions that impact healthcare insurance coverage and payment such as the elimination of the tax penalty for individuals who do not maintain health insurance coverage (the so-called “individual mandate”). Such actions or similar actions could have a negative effect on the utilization of our products. We are uncertain as to the extent such efforts will continue under the Biden administration and to what extent there will be additional reform proposals at federal and state levels. On December 18, 2019, the United States Court of Appeals for the Fifth Circuit upheld a lower court’s determination in *Texas v. Azar*, 4:18-cv-00167, that the individual mandate was unconstitutional and remanded the case to the lower court for further analysis as to whether PPACA as a whole is unconstitutional because the individual mandate is not severable from other provisions of the law. In November 2020, the United States Supreme Court held oral arguments on the Fifth Circuit United States Court of Appeals decision that held that the individual mandate is unconstitutional. It is uncertain how the United States Supreme Court will rule on this case or how healthcare measures of the Biden administration will impact the PPACA and our business. Litigation and legislation over the PPACA are likely to continue, with unpredictable and uncertain results. We cannot predict the ultimate results of the *Texas* case or whether additional legislative reform proposals will be adopted, when they will be adopted, or what impact they may have on us, but any such proposals could have a negative impact on our business and provide incentives for hospitals and physicians to not use our products.

Other healthcare reform legislative changes have also been proposed and adopted in the U.S. since the PPACA 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, which, due to subsequent legislative amendments, will stay in effect through 2030, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2021, unless additional congressional action is taken. 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 centersand 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 physician office-based labs, 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 PPACA, some of which could significantly affect our business. It is uncertain what impact the current U.S. presidential administration will have on healthcare spending. 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 sales into foreign markets expose us to risks associated with international sales and operations.

We are currently selling into foreign markets and plan to expand such sales. Conducting international operations subjects us to risks that could be different than those faced by us in the United States. The sale and shipment of our products across international borders, as well as the purchase of components and products from international sources, subject us to extensive U.S. and foreign governmental trade, import and export and customs regulations and laws, including but not limited to, the Export Administration Regulations and trade sanctions against embargoed countries, which are administered by the Office of Foreign Assets Control within the Department of the Treasury, as well as the laws and regulations administered by the Department of Commerce. These regulations limit our ability to market, sell, distribute or otherwise transfer our products or technology to prohibited countries or persons.

Compliance with these regulations and laws is costly, and failure to comply with applicable legal and regulatory obligations could adversely affect us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments and restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities.

These risks may limit or disrupt our expansion, restrict the movement of funds or result in the deprivation of contractual rights or the taking of property by nationalization or expropriation without fair compensation. Operating in international markets also requires significant management attention and financial resources.

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.For example, the Audit Committee investigation identified certain behavior inconsistent with the Company's Code of Ethics and Conduct and related policies. In addition, as discussed above, we entered into to a Settlement Agreement with the DOJ to resolve a civil investigation and related civil action, and in connection with the Settlement Agreement, entered into a 5-year Corporate Integrity Agreement with the OIG. We have, and will continue to incur, costs related to compliance under, and payments made pursuant to, the Settlement Agreement and Corporate Integrity Agreement. These expenses 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. In addition, as disclosed above, there is an ongoing DOJ criminal investigation. If such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in government investigations, civil and criminal proceedings,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. In the future, whether or not we are successful in defending against such further 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 or marketing 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, including a failure to timely make at least two MDRs to the FDA, replacement of product held by customers, which constituted product recalls, but were not documented as such, a lack of sufficient documentation to support certain payments to physicians, and as to three physicians did not accurately reflect the purpose and nature of the payments, instructions to salespeople to characterize DABRA as performing atherectomy and encouragement to doctors to seek reimbursement using atherectomy codes, and direction of potentially valuable benefits and opportunities to doctors that were informed in part by sales prospects. As disclosed above, we entered into a Settlement Agreement with the DOJ to resolve a civil investigation and related civil complaint concerning Covered Conduct. Also as disclosed above, the DOJ is conducting a criminal investigation. We are cooperating with that investigation.

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.

If a breach of our measures protecting personal data covered by HIPAA, the HITECH Act, or the CCPA occurs, we may incur significant liabilities.

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the HITECH Act, and the regulations that have been issued under it, impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of protected health information. The requirements and restrictions apply to "covered entities" (which include health care providers and insurers) as well as to their business associates that receive protected health information from them in order to provide services to or perform certain activities on their behalf. The statute and regulations also impose notification obligations on covered entities and their business associates in the event of a breach of the privacy or security of protected health information. We occasionally receive protected health information from our customers in the course of our business. As such, we believe that we are business associates and therefore subject to HIPAA's requirements and restrictions with respect to handling such protected health information and have executed business associate agreements with certain customers.

In addition, California has enacted the California Consumer Privacy Act, or CCPA, which came into effect on January 1, 2020. Pursuant to the CCPA, certain businesses are required, among other things, to make certain enhanced disclosures related to California residents regarding the use or disclosure of their personal information, allow California residents to opt-out of certain uses and disclosures of their personal information without penalty, provide Californians with other choices related to personal data in our possession, and obtain opt-in consent before engaging in certain uses of personal information relating to Californians under the age of 16. The California Attorney General may seek substantial monetary penalties and injunctive relief in the event of our non-compliance with the CCPA. The CCPA also allows for private lawsuits from Californians in the event of certain data breaches. Aspects of the CCPA remain uncertain, and we may be required to make modifications to our policies or practices in order to comply.

It is possible the data protection laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country and state to state and may vary based on whether testing is performed in the United States or in the local country. Complying with these various laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Further, compliance with data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. We can provide no assurance that we are or will remain in compliance with diverse privacy and security requirements in all of the jurisdictions in which we do business. If we fail to comply or are deemed to have failed to comply with applicable privacy protection laws and regulations such failure could result in government enforcement actions and create liability for us, which could include substantial civil and/or criminal penalties, as well as private litigation and/or adverse publicity that could negatively affect our operating results and business.

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. The legal 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 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 other intellectual 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. 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, including shelf life and non-calibrations. 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.

Our future operating results depend upon our ability to obtain components in sufficient quantities on commercially reasonable terms or according to schedules, prices, quality and volumes that are acceptable to us, and suppliers may fail to deliver components or we may be unable to manage these components effectively or obtain these components on such terms.

Because we currently obtain certain components globally, some of which are uniquely customized, from limited sources, we are subject to significant supply and pricing risks and exposed to multiple potential sources of component shortages. Many components, including those that are available from multiple sources, are at times subject to industry-wide shortages and significant commodity pricing fluctuations that could materially adversely affect our financial condition and operating results. We are sourcing alternative parts to mitigate the challenges caused by these shortages, but there is no guarantee we may be able to continually do so as we scale production to meet our growth targets. The unavailability of any component or supplier could result in production delays, idle manufacturing facilities, product design changes and loss of access to important technology and tools for producing and supporting our products, as well as impact our capacity production. Our suppliers may not be willing or able to sustainably meet our timelines or our cost, quality and volume needs, or to do so may cost us more, which may require us to replace them with other sources. If our supply of components for a new or existing product continues to be delayed or constrained for any reason, including if an outsourcing partner delayed shipments of completed products to us or additional time is required to obtain sufficient quantities from the original source, or if we have to identify and obtain sufficient quantities from an alternative source, then our financial condition and operating results could be materially adversely affected. In addition, the continued availability of these components at acceptable prices, or at all, can be affected for any number of reasons,

including if suppliers decide to concentrate on the production of common components or components for other customers instead of components customized to meet our requirements. While we have entered into agreements for the supply of many components, there can be no assurance that we will be able to extend or renew these agreements on similar terms, or at all. Component suppliers may suffer from poor financial conditions, which can lead to business failure for the supplier or consolidation within a particular industry, further limiting our ability to obtain sufficient quantities of components on commercially reasonable terms. While we believe that we will be able to secure additional or alternate sources or develop our own replacements for most of our components, there is no assurance that we will be able to do so quickly or at all. Additionally, we may be unsuccessful in our continuous efforts to negotiate with existing suppliers to obtain cost reductions and avoid unfavorable changes to terms, source less expensive suppliers for certain parts and redesign certain parts to make them less expensive to produce. Any of these occurrences may harm our business, prospects, financial condition and operating results.

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

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 American, 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 report, these factors include:

- increased expenses from remedying the performance issues 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;
- 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, 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.

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

As of December 31, 2020, we had net operating loss carryforwards, or NOLs, of approximately $14.3 million for federal income tax purposes, and $13.4 million for state income tax purposes. The federal net operating loss can be carried forward indefinitely and the state net operating losses begin expiring in 2032. 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 completed an IRC Section 382 analysis regarding the limitation of net operating losses through December 31, 2020 and determined that an ownership change occurred in May 2020. The effect of the ownership change is reflected in the NOL balances as of December 31, 2020. The Company calculated the limitation on net operating losses and other tax attributes and reduced the value of the deferred tax assets resulting in a tax expense impact of $20.8M. The tax expense was offset by tax benefit recorded on the reduction in valuation allowance recorded for the deferred tax assets for the year ended December 31, 2020. 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. Ownership changes that materially limit our use of our historical NOLs could harm our future operating results by effectively increasing our future tax obligations. In addition, as a result of the Tax Cuts and Jobs Act of 2017, as modified by the recently enacted Coronavirus Aid, Relief, and Economic Security Act of 2020, or CARES Act, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely and deductibility of federal NOLs generally may be limited in future years.

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 their own legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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 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 NYSE American 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, 2021, we had outstanding 5,902,612 shares of our common stock.

In connection with our May 2020 and August 2020 equity offerings, we issued warrants to investors and our placement agent, and an aggregate of 2,345,033 warrants are outstanding as of June 30, 2021. We have an effective shelf registration statement and an "at the market" offering ("ATM"). In the first six months of 2021, we completed ATM offerings of 2,617,787 shares of common stock. In addition, pursuant to our 2018 Equity Incentive Plan, or 2018 Plan, equity incentive awards representing up to an aggregate of 71,679 shares of our common stock were available for issuance to our employees, directors and consultants as of June 30, 2021. 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 26,510 shares were available for sale under our ESPP as of June 30, 2021. 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. In addition to the increase in shares available to grant in 2020 due to the "evergreen" provisions contained in the 2018 Plan and the ESPP, in the first quarter of 2020 we adopted the 2020 Inducement Equity Incentive Plan (or, the 2020 Plan) for the purpose of attracting, retaining and incentivizing employees in furtherance of our success. On adoption, 32,000 shares of common stock were reserved solely for the granting of inducement stock options, restricted stock, restricted stock units and other awards and 9,000 shares were available for issuance as of June 30, 2021. 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 certificate of incorporation and 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 certificate of incorporation relating to the issuance of preferred stock and management of our business or our 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 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 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 certificate of incorporation and 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 certificate of incorporation provides that the Court of Chancery of the State of 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 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 certificate of incorporation or our bylaws; any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; and any action asserting a claim against us that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Our 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. The enforceability of similar exclusive federal forum provisions in other companies' organizational documents has been challenged in legal proceedings, and while the Delaware Supreme Court has ruled that this type of exclusive federal forum provision is facially valid under Delaware law, there is uncertainty as to whether other courts would enforce such provisions and that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

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 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.

If we fail to comply with the continued listing standards of the NYSE American, our common stock could be delisted. If it is delisted, the market value and the liquidity of our common stock would be impacted.

We recently transferred the listing of our common stock from the NYSE to the NYSE American. The continued listing of our common stock on NYSE American is contingent on our continued compliance with a number of listing standards. In order to maintain this listing, we must maintain certain share prices, financial and share distribution targets, including maintaining a minimum amount of shareholders' equity and a minimum number of public shareholders. In addition to these objective standards, the NYSE American may delist the securities of any issuer: (i) if, in its opinion, the issuer's financial condition and/or operating results appear unsatisfactory; (ii) if it appears that the extent of public distribution or the aggregate market value of the security has become so reduced as to make continued listing on the NYSE American inadvisable; (iii) if the issuer sells or disposes of principal operating assets or ceases to be an operating company; (iv) if an issuer fails to comply with the NYSE American's listing requirements; (v) if an issuer's common stock sells at what the NYSE American considers a "low selling price" and the issuer fails to correct this via a reverse split of shares after notification by the NYSE American; or (vi) if any other event occurs or any condition exists which makes continued listing on the NYSE American, in its opinion, inadvisable. There is no assurance that we will remain in compliance with these standards.

Delisting from NYSE American would adversely affect our ability to raise additional financing through the public or private sale of equity securities, significantly affect the ability of investors to trade our securities and negatively affect the value and liquidity of our common stock. Delisting also could limit our strategic alternatives and attractiveness to potential counterparties and have other negative results, including the potential loss of employee confidence, decreased analyst coverage of our securities, the loss of institutional investors or interest in business development opportunities. Moreover, we committed in connection with the sale of securities to use commercially reasonable efforts to maintain the listing of our common stock during such time that certain warrants are outstanding.

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

Not applicable.

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 3.1 to the Registrant's Current Report on Form 8-K filed on November 17, 2020 (File No. 001-38677)).
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1(*)	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.
32.2(*)	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL 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: August 11, 2021

By: /s/ Andrew Jackson
Andrew Jackson
Chief Financial Officer

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jonathan Will McGuire, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report 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

   (d) 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: August 11, 2021

By: /s/ Jonathan Will McGuire
Jonathan Will McGuire
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report 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

   (d) 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: August 11, 2021

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

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE 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, Jonathan Will McGuire, hereby certify that, to my knowledge:

(i) the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 to which this Certification isattached as Exhibit 32.1 (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: August 11, 2021

By: /s/ Jonathan Will McGuire
Jonathan Will McGuire
Chief Executive Officer (Principal Executive 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.

Exhibit 32.2

CERTIFICATION OF CHIEF 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, 2021 to which this Certification isattached as Exhibit 32.2 (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: August 11, 2021

By: /s/ Andrew Jackson
Andrew Jackson
Chief Financial Officer (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.