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 September 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 the close of business on November 10, 2021, the registrant had7,029,765 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
(in thousands, except par value data)
(Unaudited)

	September 30, 2021	December 31, 2020
ASSETS		
Current Assets		
Cash and cash equivalents	$ 20,616	$ 23,906
Accounts receivable, net	17	24
Inventories	997	877
Prepaid expenses and other current assets	1,169	1,100
Current assets of discontinued operations	—	1,713
Total current assets	22,799	27,620
Property and equipment, net	2,030	2,527
Operating lease right-of-use assets	2,205	2,484
Other long-term assets	45	45
Long-term assets of discontinued operations	—	762
TOTAL ASSETS	$ 27,079	$ 33,438
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 543	$ 471
Accrued expenses	2,632	4,147
Current portion of operating lease liabilities	301	356
Current portion of equipment financing	—	265
Current portion of PPP promissory note	—	421
Current liabilities of discontinued operations	—	2,102
Total current liabilities	3,476	7,762
Operating lease liabilities	2,054	2,264
PPP promissory note	—	1,579
Long-term liabilities of discontinued operations	—	686
Total liabilities	5,530	12,291
Commitments and contingencies (Note 14)		
Stockholders' Equity		
Preferred stock, $0.0001 par value; 10,000 shares authorized; no shares issued	—	—
Common stock, $0.0001 par value; 300,000 shares authorized; 7,042 and 3,189 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	7	7
Additional paid-in capital	191,527	174,342
Accumulated deficit	(169,985)	(153,202)
Total stockholders' equity	21,549	21,147
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 27,079	$ 33,438

See accompanying notes to unaudited condensed financial statements.

RA MEDICAL SYSTEMS, INC.
Condensed Statements of Operations
(in thousands, except per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Net revenues				
Product sales	$ 5	$ 66	$ 17	$ 254
Service and other	—	2	—	5
Total net revenues	5	68	17	259
Cost of revenues				
Product sales	68	323	676	1,131
Service and other	178	245	537	615
Total cost of revenues	246	568	1,213	1,746
Gross loss	(241)	(500)	(1,196)	(1,487)
Operating expenses				
Selling, general and administrative	4,211	4,695	11,285	18,154
Research and development	2,942	2,312	8,521	5,534
Total operating expenses	7,153	7,007	19,806	23,688
Operating loss	(7,394)	(7,507)	(21,002)	(25,175)
Other income (expense), net				
Other income (expense), net	16	(8)	5	97
Gain on extinguishment of PPP promissory note	—	—	2,023	—
Total other income (expense), net	16	(8)	2,028	97
Loss from continuing operations before income taxes	(7,378)	(7,515)	(18,974)	(25,078)
Income taxes	—	—	—	—
Loss from continuing operations	(7,378)	(7,515)	(18,974)	(25,078)
Discontinued operations (Note 3)				
Income (loss) from discontinued operations (including gain on sale of $3,500 in 2021) before income taxes	3,080	(264)	2,191	(523)
Income taxes	—	—	—	—
Income (loss) from discontinued operations	3,080	(264)	2,191	(523)
Net loss	$ (4,298)	$ (7,779)	$ (16,783)	$ (25,601)
Net (loss) income per share, basic and diluted				
Continuing operations	$ (1.15)	$ (3.15)	$ (4.23)	$ (19.32)
Discontinued operations	0.48	(0.11)	0.49	(0.40)
Total net loss per share, basic and diluted	$ (0.67)	$ (3.26)	$ (3.74)	$ (19.72)
Weighted average number of shares used in computing net income (loss) per share, basic and diluted	6,415	2,386	4,487	1,298

See accompanying notes to unaudited condensed financial statements.

RA MEDICAL SYSTEMS, INC.
Condensed Statements of Comprehensive Loss
(in thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss	$ (4,298)	$ (7,779)	$ (16,783)	$ (25,601)
Other comprehensive loss:				
Unrealized losses related to short-term investments	—	—	—	(26)
Comprehensive loss	$ (4,298)	$ (7,779)	$ (16,783)	$ (25,627)

See accompanying notes to unaudited condensed financial statements.

RA MEDICAL SYSTEMS, INC.
Condensed Statements of Cash Flows
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (16,783)	$ (25,601)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on sale of discontinued operations	(3,473)	—
Gain on extinguishment of PPP promissory note	(2,023)	—
Stock-based compensation	1,967	3,044
Depreciation and amortization	1,250	1,845
(Gain) loss on sales and disposals of property and equipment	(489)	64
Provision for doubtful accounts	—	25
Changes in operating assets and liabilities:		
Accounts receivable	93	286
Inventories	(262)	78
Prepaid expenses and other assets	9	1,437
Accounts payable	171	(633)
Accrued expenses	(1,875)	1,678
Deferred revenue	(234)	(876)
Other liabilities	(265)	(237)
Net cash used in operating activities	(21,914)	(18,890)
CASH FLOWS FROM INVESTING ACTIVITIES		
Proceeds from sale of discontinued operations	3,700	—
Payment of fees related to sale of discontinued operations	(227)	—
Proceeds from sales of property and equipment	554	—
Purchases of property and equipment	(224)	(72)
Proceeds from maturities of available-for-sale securities	—	16,000
Net cash provided by investing activities	3,803	15,928
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock and warrants, net	15,430	19,887
Payments of offering costs related to the issuance of common stock and warrants	(370)	(499)
Payments on equipment financing	(265)	(218)
Proceeds from purchases under employee stock purchase plan	26	27
Proceeds from PPP promissory note	—	2,000
Proceeds from issuance of common stock in connection with the exercise of warrants	—	827
Net cash provided by financing activities	14,821	22,024
NET CHANGE IN CASH AND CASH EQUIVALENTS	(3,290)	19,062
CASH AND CASH EQUIVALENTS, beginning of period	23,906	14,584
CASH AND CASH EQUIVALENTS, end of period	$ 20,616	$ 33,646
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Unpaid property and equipment	$ 26	$ —
Unpaid offering costs	$ —	$ 281
Transfer of lasers from inventories to property and equipment	$ —	$ 107
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash payments for interest	$ 2	$ 23
Cash payments for taxes	$ 2	$ —

See accompanying notes to unaudited condensed financial statements.

RA MEDICAL SYSTEMS, INC.
Condensed Statements of Stockholders' Equity
(in thousands)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
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 employee stock purchase plan	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 issued, net	1,139	—	4,350	—	—	4,350
Warrant issued	—	—	132	—	—	132
Stock-based compensation	—	—	102	—	—	102
Net loss	—	—	—	—	(4,298)	(4,298)
Balances at September 30, 2021	7,042	$ 7	$ 191,527	$ —	$ (169,985)	$ 21,549

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
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 employee stock purchase plan	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
Common stock issued, net	1,371	3	6,338	—	—	6,341
Warrants issued, net	—		4,028	—	—	4,028
Stock-based compensation	—		964	—	—	964
Net loss	—		—	—	(7,779)	(7,779)
Balances at September 30, 2020	2,898	$ 7	$ 173,289	$ —	$ (142,758)	$ 30,538

See accompanying notes to unaudited condensed financial statements.

Note 1. Organization and Nature of Operations

The Company

Ra Medical Systems, Inc. (the "Company") is a medical device company that develops, manufactures and markets an advanced excimer laser and single-use catheter system, together referred to as "DABRA", used by physicians as a tool in the treatment of peripheral artery disease ("PAD"). The Company was formed on September 4, 2002 in the state of California and reincorporated in Delaware on July 14, 2018.

On August 16, 2021, the Company completed the sale of its Pharos dermatology business (the "Dermatology Business"). As a result, the Company has reported the operating results of the Dermatology Business as discontinued operations in the condensed statements of operations for all periods presented. In addition, the related assets and liabilities associated with the Dermatology Business were reported as assets of discontinued operations and liabilities of discontinued operations in the condensed balance sheets. Unless otherwise noted, discussion within these notes to the unaudited condensed financial statements relates to continuing operations. See *Note 3. Discontinued Operations* for additional information.

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 affect 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 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 and Market Conditions

The global spread of the novel coronavirus ("COVID-19") has created significant volatility, uncertainty and economic disruption. The ultimate effects of COVID-19 on the Company's business, operations and financial condition are unknown at this time. In the near term, the Company expects that enrollment in its atherectomy clinical trial will continue to be slowed, as patients elect to postpone voluntary treatments and many physicians' offices have been either closed or operating at a reduced capacity. The Company's manufacturing facility located in Carlsbad, California is currently operational. The Company has experienced delays in receiving shipments of parts which has had an impact on the timing of its key engineering efforts but has not affected its ability to support its atherectomy clinical study. 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. The Company is also experiencing increased difficulty in attracting and retaining key personnel due to a tight labor market.

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 $170.0 million at September 30, 2021. For the nine months ended September 30, 2021, the Company used cash of $21.9 million in operating activities from continuing and discontinued operations. As of September 30, 2021, the Company had cash and cash equivalents of $20.6 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 the DABRA catheter 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 U.S. Food and Drug Administration in July 2021. Although eligible, the Company has not resumed commercial sales and is evaluating its commercial catheter strategy. The Company also expects the COVID-19 pandemic to have a continued negative impact on 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 2021 and 2020, has an effective shelf registration statement and an "at the market"("ATM") 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 has 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 its 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 accompanying 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

Basis of Presentation

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 nine months ended September 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 after reclassifications related to discontinued operations. 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 Securities and Exchange Commission ("SEC") on March 17, 2021.

Reclassifications

Certain prior period amounts have been reclassified to conform to the current period presentation.

Use of estimates

The unaudited condensed financial statements have been prepared by management in accordance with accounting principles generally accepted in the United States ("GAAP"). 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 or obsolete 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. 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 sales of products and services. Product sales consist of the sales of catheters for use with the DABRA laser system. The Company has paused selling commercial product and is only selling catheters for use in the 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 billable services, including fees related to DABRA laser commercial usage agreements.

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", which provides for specific terms of continued use of the 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 periodic fees are nominal, the usage agreement provides the Company the exclusive rights to supply related single-use catheters to the customer which aggregate the majority of the product sales revenue. There are no specified minimum purchase commitments for the catheters.

The Company recognizes revenue associated with the usage agreements and catheter supply arrangements in accordance with Financial Accounting Standards Board ("FASB") "*Revenue from Contracts with Customers (Topic 606),"* since (i) the contracts primarily include variable payments, (ii) the catheters are priced at their standalone selling price and (iii) 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 catheters.

Distributor Transactions

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

The following accounting policies are specifically related to the Company's discontinued operations:

Laser Sales

The Company recognized revenue on laser sales at the point in time that control transferred to the customer. Control of the product typically transferred upon shipment.

Warranty Service Revenue

The Company typically provided a 12-month warranty with the purchase of its laser systems. Customers could extend the warranty period through the purchase of extended warranty service contracts. Extended warranty service contracts were sold with contract terms ranging from 12 to 60 months and covered periods after the end of the initial 12-month warranty period. The warranty provided the customer with maintenance services in addition to the assurance that the laser product complied with agreed-upon specifications. Therefore, the warranty service was treated as a separate performance obligation from the laser system. Warranty services were a stand-ready obligation, and the Company recognized revenue on a straight-line basis over the service contract term. Warranty service revenue was included in service and other revenue.

Contract Costs

The Company capitalized costs to obtain contracts that were considered incremental and recoverable, such as sales commissions. The capitalized costs were amortized to selling, general and administrative expense over the estimated period of benefit of the asset, which was the contract term. The Company elected to use the practical expedient to expense the costs to obtain a contract when the amortization period was less than one year.

These lease arrangements contained one lease component (the laser) and one non-lease component (warranty service) for which the Company elected the practical expedient to not separate the non-lease component from the lease component. The Company accounted for the combined lease component as an operating lease and recognized lease income on a straight-line basis over the lease term.

Rental Income

The Company also derived income pursuant to its product operating lease agreements for its Pharos laser systems, prior to the sale of the Dermatology Business. Consequently, the Company retained title to the equipment. Depreciation expense on the leased lasers was recorded to cost of revenues on a straight-line basis. The costs to maintain the leased lasers were charged to cost of revenues as incurred.

These lease arrangements contained one lease component (the laser) and one non-lease component (warranty service) for which the Company elected the practical expedient to not separate the non-lease component from the lease component. The Company accounted for the combined lease component as an operating lease and recognized lease income on a straight-line basis over the lease term.

Segment Information

After the sale of the Dermatology Business, the Company began operating its business inone segment, which includes all activities related to the research, development and manufacture of the DABRA system. The chief operating decision-maker reviews the operating results on an aggregate basis and manages the operations as a single operating segment.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date. The Company has evaluated recently issued accounting pronouncements and, based on its preliminary assessment, does not believe any will have a material impact on the condensed financial statements or related footnote disclosures.

Note 3. Discontinued Operations

Consistent with the Company's continued focus on the PAD market, the Company completed the sale of its Dermatology Business to Strata Skin Sciences, Inc. ("Strata") on August 16, 2021 for cash proceeds of $3.7 million. The Company paid broker and legal fees of approximately $0.2 million related to the sale of the Dermatology Business. In addition, the Company issued a warrant to the broker to purchase 74,247 shares of common stock at an exercise price of $2.99 per share. The warrant is immediately exercisable and expires five years following the date of issuance. The warrant was valued at approximately $0.1 million on the grant date using the Black-Scholes option pricing model based on the following assumptions: expected volatility of 104.55%, risk-free interest rate of 0.32%, expected dividend yield of 0% and an expected term of 2.5 years.

The Dermatology Business was previously disclosed as a separate reportable segment of the Company. The sale of the Dermatology Business resulted in a gain of $3.5 million which is included as a component of income (loss) from discontinued operations in the condensed statements of operations for the three and nine months ended September 30, 2021.

Beginning in the third quarter of 2021, the Company has reported the results of the Dermatology Business in income (loss) from discontinued operations in the condensed statements of operations and excluded them from continuing operations for all periods presented. The assets and liabilities of the Dermatology Business are recorded as assets of discontinued operations and liabilities of discontinued operations, respectively, in the condensed balance sheets.

Certain overhead costs previously allocated to the Dermatology Business for segment reporting purposes did not qualify for classification within discontinued operations and have been reallocated to continuing operations for all periods presented.

The following table summarizes the carrying amounts of the assets and liabilities included as discontinued operations in the condensed balance sheet at December 31, 2020 (in thousands):

	December 31, 2020
Assets of discontinued operations	
Accounts receivable, net	$ 214
Inventories	1,341
Prepaid expenses and other current assets	158
Property and equipment, net	684
Other long-term assets	78
Total assets of discontinued operations	$ 2,475
Liabilities of discontinued operations	
Accounts payable	$ 100
Accrued expenses	201
Deferred revenue	2,487
Total liabilities of discontinued operations	$ 2,788

The assets and liabilities of discontinued operations have been classified as current and long-term, as applicable, in the condensed balance sheet at December 31, 2020.

The following table summarizes the major classes of items constituting income (loss) from discontinued operations in the condensed statements of operations for each of the periods presented (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net revenues				
Product sales	$ 140	$ 118	$ 852	$ 670
Service and other	349	729	1,748	2,259
Total net revenues	489	847	2,600	2,929
Cost of revenues				
Product sales	158	347	1,201	1,127
Service and other	238	504	1,089	1,296
Total cost of revenues	396	851	2,290	2,423
Gross income (loss)	93	(4)	310	506
Operating expenses				
Selling, general and administrative	330	236	1,110	958
Research and development	134	21	388	47
Total operating expenses	464	257	1,498	1,005
Operating loss	(371)	(261)	(1,188)	(499)
Interest expense, net	(22)	(3)	(94)	(24)
Loss from discontinued operations	(393)	(264)	(1,282)	(523)
Gain on sale of the Dermatology Business	3,473	—	3,473	—
Income (loss) from discontinued operations	$ 3,080	$ (264)	$ 2,191	$ (523)

Depreciation expense for the Dermatology Business was $0.1 million for each of the three months ended September 30, 2021 and 2020 and $0.3 million for each of the nine months ended September 30, 2021 and 2020. There were no capital expenditures for the Dermatology Business during the nine months ended September 30, 2021 and 2020.

Stock-based compensation expense for the Dermatology Business was de minimis and approximately $14,000 for the three months ended September 30, 2021 and 2020, respectively. Stock-based compensation expense was approximately $18,000 and $0.1 million for the nine months ended September 30, 2021 and 2020, respectively. Stock-based compensation expense of approximately $4,000 and $30,000 was capitalized to inventory and property and equipment during the three months ended September 30, 2021 and 2020, respectively. Stock-based compensation expense of approximately $0.1 million was capitalized to inventory and property and equipment during each of the nine months ended September 30, 2021 and 2020.

Note 4. Fair Value Measurements

Cash equivalents of approximately $9.4 million and $18.4 million at September 30, 2021 and December 31, 2020, respectively, were comprised of money market funds which were measured at fair value on a recurring basis based on Level 1 of the fair value hierarchy.

Note 5. Inventories

Inventories consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Raw materials	$ 884	$ 547
Work in process	60	270
Finished goods	53	60
Total inventories	$ 997	$ 877

Note 6. Property and Equipment

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

	September 30, 2021	December 31, 2020
Lasers	$ 3,151	$ 3,194
Machinery and equipment	812	834
Computer hardware and software	353	353
Construction in progress	209	51
Leasehold improvements	119	119
Automobiles	62	1,054
Furniture and fixtures	48	48
Property and equipment, gross	4,754	5,653
Accumulated depreciation	(2,724)	(3,126)
Total property and equipment, net	$ 2,030	$ 2,527

Depreciation expense was $0.2 million and $0.4 million for the three months ended September 30, 2021 and 2020, respectively, and $0.7 million and $1.3 million for the nine months ended September 30, 2021 and 2020, respectively. During the nine months ended September 30, 2021, automobiles were sold for a gain of $0.5 million which is included in selling, general and administrative expenses in the accompanying condensed statements of operations.

Note 7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Accrued legal expenses	$ 1,393	$ 957
Compensation and related benefits	496	2,479
Accrued warranty (Note 8)	195	204
Other accrued expenses	548	507
Total accrued expenses	$ 2,632	$ 4,147

Note 8. Accrued Warranty

Activity in the warranty accrual is included in accrued expenses in the condensed balance sheets and consisted of the following (in thousands):

	Nine Months Ended September 30, 2021	Year Ended December 31, 2020
Balance at beginning of period	$ 204	$ 234
Increase in warranty accrual	—	19
Change in liability for pre-existing warranties	—	4
Claims satisfied	(9)	(53)
Total accrued warranty	$ 195	$ 204

The accrued warranty balances at September 30, 2021 and December 31, 2020 each included $0.1 million related 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 9. 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 ("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 have been due in May 2022. On June 5, 2020, the Paycheck Protection Program Flexibility Act of 2020 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 have been due in May 2022. The principal and interest could be forgiven if the proceeds were 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 of $2.0 million was included in other income (expense), net in the condensed statement of operations for the nine months ended September 30, 2021. Interest expense on the PPP Promissory Note for the three months ended September 30, 2021 and 2020 was nil and approximately $5,000, respectively. Interest expense on the PPP Promissory Note for the nine months ended September 30, 2021 and 2020 was approximately $10,000 and $8,000, respectively.

Note 10. Leases

The Company has two operating leases for office and manufacturing space which require 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 December 2021.

At September 30, 2021, the weighted average remaining lease term was 6.3 years. The operating leases are included in the condensed balance sheets at the present value of the lease payments at a 7% discount rate which approximates 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 September 30, 2021 and 2020, operating lease expense and cash paid for leases was $0.1 million. For each of the nine months ended September 30, 2021 and 2020, operating lease expense and cash paid for leases was $0.4 million. Amortization for operating lease right-of-use assets was $0.1 million for each of the three months ended September 30, 2021 and 2020 and $0.3 million for each of the nine months ended September 30, 2021 and 2020. Variable costs were de minimis.

Maturities of operating lease liabilities as of September 30, 2021 were as follows (in thousands):

Years Ending December 31,		
2021 (remaining three months)	$	132
2022		432
2023		445
2024		459
2025		472
2026		486
Thereafter		501
Total operating lease payments		2,927
Less: imputed interest		(572)
Total operating lease liabilities	$	2,355

Note 11. Net Loss per Share

The Company calculates basic net 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 include warrants, stock options and non-vested restricted stock awards and restricted stock 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 share equivalents excluded from the computation of diluted net loss per share at September 30, 2021 consisted of warrants of 2,419,280, stock options of 126,998, restricted stock awards of 312,380, restricted stock units of 45,832 and Employee Stock Purchase Plan shares of 10,462.

Anti-dilutive share equivalents excluded from the computation of diluted net loss per share at September 30, 2020 consisted of warrants of 2,345,033, stock options of 144,851, restricted stock awards of 5,000, restricted stock units of 20,678 and Employee Stock Purchase Plan shares of 3,772.

Note 12. Equity Offerings

In February 2021, the Company completed an ATM offering of 35,768 shares of common stock at a price of $8.39 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 fees and other expenses in association with filing the related Registration Statement on Form S-3 with the SEC.

On various dates in May 2021 and June 2021, the Company completed ATM offerings of 2,582,019 shares of common stock at a weighted average price of $4.29 per share. The Company received approximately $10.6 million in net proceeds, after deducting placement agent's fees.

On various dates in July 2021 and August 2021, the Company completed ATM offerings of 1,139,306 shares of common stock, at a weighted average price of $4.00 per share. The Company received approximately $4.4 million in net proceeds, after deducting offering fees.

Note 13. Stock-Based Compensation

A summary of the stock option activity under the 2018 Equity Incentive Plan (the "2018 Plan") and the 2018 Stock 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	(15,173)	$ 87.28		
Outstanding at September 30, 2021	108,998	$ 401.74	4.82	$ —
Exercisable at September 30, 2021	95,096	$ 455.95	4.32	$ —
Vested and expected to vest at September 30, 2021	108,998	$ 401.74	4.80	$ —

A summary of the stock option activity under the 2020 Inducement Equity Incentive Plan (the "2020 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	18,000	$ 25.50	9.24	
Outstanding at September 30, 2021	18,000	$ 25.50	8.50	$ —
Exercisable at September 30, 2021	6,750	$ 25.50	8.50	$ —
Vested and expected to vest at September 30, 2021	18,000	$ 25.50	8.50	$ —

A summary of the restricted stock unit activity 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	(1,845)	$ 64.80
Forfeited	(15,485)	$ 14.67
Outstanding at September 30, 2021	45,832	$ 11.06

A summary of the restricted stock award activity under the 2018 Plan is presented below:

	Restricted Stock Awards	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2020	286,161	$ 4.77
Granted	103,939	$ 4.82
Vested	(31,388)	$ 6.96
Forfeited	(50,082)	$ 5.10
Outstanding at September 30, 2021	308,630	$ 4.51

A summary of the restricted stock award activity under the 2020 Plan is presented below:

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Selling, general and administrative	$ 78	$ 757	$ 1,551	$ 2,424
Research and development	27	115	251	317
Stock-based compensation in operating expenses	$ 105	$ 872	$ 1,802	$ 2,741

Stock-based compensation expense of approximately $5,000 and $48,000 was capitalized to inventory and property and equipment during the three months ended September 30, 2021 and 2020, respectively. Stock-based compensation of approximately $0.1 million was capitalized to inventory and property and equipment during each of the nine months ended September 30, 2021 and 2020.

Unrecognized compensation expense for stock options issued as of September 30, 2021 was $0.4 million and is expected to be recognized over a weighted average period of 1.9 years. Unrecognized compensation expense for the restricted stock units as of September 30, 2021 was $0.3 million and is expected to be recognized over a weighted average period of 2.0 years. Unrecognized compensation expense for the restricted stock awards as of September 30, 2021 was $0.8 million and is expected to be recognized over a weighted average period of 2.4 years.

Note 14. 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 ("U.S.") 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 initial public offering. 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. The court has not yet ruled on defendants' motion to dismiss. On November 12, 2021, following a private settlement mediation with the lead plaintiffs, the parties executed a stipulation of settlement that resolved the claims asserted in the securities class action. The settlement provides for a payment to the plaintiff class of $10.0 million. The Company expects to pay approximately $1.0 million towards the settlement, the amount remaining on its self-insured retention/deductible, and the Company's insurers will pay the remaining balance. The proposed settlement requires both preliminary and final approval by the court. Should the court not approve the proposed settlement or if the proposed settlement otherwise does not become final, the parties will be returned to their litigation postures prior to the execution of the stipulation of settlement. 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.

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 U.S. 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.

Settlement Agreements with the Department of Justice and Participating States

As previously announced on December 28, 2020, the Company entered into a Settlement Agreement with the U.S., acting through the Department of Justice ("DOJ") and on behalf of the Office of Inspector General ("OIG"), and other settlement agreements with certain state attorneys general to resolve investigations and a related civil action concerning its marketing of the DABRA laser system and DABRA-related remuneration to certain physicians.

Pursuant to the terms of the Settlement Agreement and the agreements with the participating states, (a) if the Company's revenue exceeds $10 million in any of fiscal years 2021-2024, the Company also is required to pay for the corresponding year: $500,000 for 2021, $750,000 for 2022, $1 million for 2023, and $1.25 million for 2024; (b) if the Company is acquired or is otherwise involved in a change in control transaction before the end of 2024, the Company 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 the Company's obligations under the Settlement Agreement are avoided by bankruptcy, the U.S. 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.

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, or Quarterly Report, 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 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 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. 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 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 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.

References to "we", "us" and "our" refer to Ra Medical Systems, Inc.

Overview and Recent Developments

Ra Medical Systems, Inc. is a medical device company leveraging its advanced excimer laser-based platform for use in the treatment of vascular immune-mediated inflammatory diseases. We believe our products enhance patients' quality of life by restoring blood-flow in arteries.

Consistent with our business strategy to continue focusing on the peripheral artery disease, or PAD, market, we completed the sale of our Pharos laser business, or Dermatology Business, to Strata Sciences, Inc., or Strata, on August 16, 2021. Accordingly, we removed the related assets and liabilities from the condensed balance sheets as of that date and included the results of the Dermatology Business in discontinued operations for all periods presented. See *Note 3. Discontinued Operations* to our unaudited condensed financial statements for additional information on discontinued operations. Unless otherwise noted, amounts for all periods discussed below reflect the results of operations and financial condition from our continuing operations.

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 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 business strategy is focused on multiple engineering efforts to improve our catheter offering and explore new markets, as well as conducting a clinical study to obtain an atherectomy "indication for use" in the United States, or U.S. 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 we 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 in the first quarter of 2022 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 pre-specified 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 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 2021 and 2020, the novel coronavirus, or 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 November 10, 2021, we have enrolled 85 subjects and seven sites have been cleared to enroll subjects. 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 their 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 sales as we continue evaluating our commercial catheter strategy.

Finally, we are conducting research to prove the feasibility of using a DABRA-derived catheter technology to fracture calcium in arteries in a procedure known as lithotripsy. Preliminary research work has demonstrated that the DABRA laser system can be utilized to create shockwaves of sufficient magnitude to fracture calcium in arteries. Fracturing calcium in coronary or peripheral arteries can help make the arteries less rigid, thus making subsequent procedures easier and/or safer to perform. We have fabricated a prototype system and intend to conduct a preclinical study in the next few months to confirm our initial benchtop results.

COVID-19 and Market Conditions

The global spread of COVID-19 has created significant volatility, uncertainty and economic disruption. The ultimate effects of COVID-19 on our business, operations and financial condition are unknown at this time. In the near term, we expect that enrollment in our atherectomy clinical trial will continue to be slowed, as patients elect to postpone voluntary treatments and physicians' offices are either closed or operating at a reduced capacity. Our manufacturing facility located in Carlsbad, California is currently operational. We have experienced delays in receiving shipments of parts which has had an impact on the timing of our key engineering efforts but has not affected our ability to support our atherectomy clinical study. 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. We are also experiencing increased difficulty in attracting and retaining key personnel due to a tight labor market.

Components of our Results of Operations

Net Revenue

Product sales consist of the sales of catheters for use with the DABRA laser. We are currently not selling commercial product and are only selling catheters for use in our atherectomy clinical trial.

Service and other revenue consists primarily of billable services, including fees related to DABRA laser commercial usage agreements which are recognized when the services are provided.

We have historically used distributors outside the U.S. in markets where we have received regulatory approval. We expect to continue to seek regulatory approvals for our product in additional strategic markets.

Cost of Revenue

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

Cost of revenue for service and other consists primarily of depreciation on the lasers we own.

Gross Profit (Loss)

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, 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 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 R&D 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 primarily consist of employee-related expenses, including salaries, benefits, travel expense, sales commissions and stock-based compensation expense. Other SG&A expenses 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.

Results of Operations

The following table sets forth our results of continuing operations for the periods presented (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
Net revenue	$ 5	$ 68	$ (63)	$ 17	$ 259	$ (242)
Cost of revenue	246	568	(322)	1,213	1,746	(533)
Research and development expenses	2,942	2,312	630	8,521	5,534	2,987
Selling, general and administrative expenses	4,211	4,695	(484)	11,285	18,154	(6,869)
Other income (expense), net	16	(8)	24	2,028	97	1,931

Comparison of the Three and Nine Months Ended September 30, 2021 and 2020

Net Revenue

The decreases in net revenue of $0.1 million and $0.2 million for the three and nine months ended September 30, 2021, respectively, as compared to the corresponding periods in the prior year were due to decreased catheter unit sales as a result of pausing commercial sales in late 2020 while we conducted further studies on the stability of the catheter's shelf life. However, we have continued to supply catheters to clinical trial sites.

We expect our net revenue to be negatively impacted in the short term as we sell catheters only to support our atherectomy clinical study while we continue efforts to remedy the inconsistencies in our DABRA catheter performance and obtain an atherectomy indication.

Cost of Revenue

The decreases in cost of revenue of $0.3 million and $0.5 million for the three and nine months ended September 30, 2021, respectively, as compared to the corresponding periods in the prior year were due to decreases in catheter unit sales, partially offset by increases in costs of repairs and maintenance on catheter manufacturing equipment.

Research and Development Expenses

The increase in R&D expenses of $0.6 million for the three months ended September 30, 2021 as compared to the corresponding period in the prior year was primarily due to increases of $0.7 million in personnel and consulting expenses, $0.2 million in clinical study expenses and $0.1 million in other expenses, partially offset by decreases of $0.2 million in R&D supplies expense and $0.1 million in stock-based compensation expense. These increases were due to engineering efforts on our next-generation catheters, including increased shelf life and improved deliverability, and also progress on the atherectomy clinical study.

The increase in R&D expenses of $3.0 million for the nine months ended September 30, 2021 as compared to the corresponding period in the prior year was due to increases of $1.9 million in personnel and consulting expenses, $0.6 million in R&D supplies expense, $0.2 million in clinical study expenses, $0.3 million in other expenses, partially offset by a decrease of $0.1 million in stock-based compensation expense. These increases were due to engineering efforts on our next-generation catheters, including increased shelf life and improved deliverability, and progress on the atherectomy clinical study.

Selling, General and Administrative Expenses

The decrease in SG&A expenses of $0.5 million for the three months ended September 30, 2021 as compared to the corresponding period in the prior year was due to decreases of $0.7 million in stock-compensation expense, $0.3 million in insurance expense due to a reduction in premiums, $0.2 million in depreciation expense and $0.2 million in other costs, including sales related costs, travel and trade shows and public company expenses, partially offset by a $0.9 million increase in legal expenses, primarily due to amounts accrued relating to the securities class action lawsuit.

The decrease in SG&A expenses of $6.9 million for the nine months ended September 30, 2021 as compared to the corresponding period in the prior year was due to decreases of $2.7 million in legal expenses due to a decrease in legal expenses, $1.4 million in salary, benefits, recruiting expenses and other personnel-related costs primarily due to reduced headcount as a result of continued cost reduction efforts, $0.9 million in stock-based compensation expense, $0.9 million in insurance expense due to a reduction in premiums, $0.6 million in depreciation expense, $0.5 million in public company expenses, $0.2 million in sales and marketing related costs and $0.1 million in other costs, partially offset by an increase of $0.9 million in consulting and professional expenses. In addition, we had a $0.5 million gain on sale of vehicles during the nine months ended September 30, 2021. We had no such gain during the nine months ended September 30, 2020.

Other Income (Expense), Net

The increase in other income (expense), net was de minimis for the three months ended September 30, 2021 as compared to the corresponding period of the prior year.

The increase in other income (expense), net of $1.9 million for the nine months ended September 30, 2021 as compared to the corresponding period in the prior year was primarily due to the $2.0 million gain from the forgiveness of the loan received in the form of a Paycheck Protection Program Promissory Note and Agreement, or PPP Promissory Note, under the Coronavirus Aid, Relief and Economic Security Act.

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

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

A reconciliation for each non-GAAP financial measure to the most directly comparable financial measure stated in accordance with GAAP is included below. Investors are encouraged to review the related GAAP financial measures and the reconciliation of these non-GAAP financial measures to their most directly comparable GAAP financial measures, and not to rely on any single financial measure to evaluate our business. We define Adjusted EBITDA as our GAAP loss from continuing operations as adjusted to exclude depreciation and amortization, interest income, interest expense, income tax expense, stock-based compensation, gain on extinguishment of the PPP promissory note and loss (gain) on sales and disposals of property and equipment.

The following is a reconciliation of loss from continuing operations to Adjusted EBITDA (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Loss from continuing operations	$ (7,378)	$ (7,515)	$ (18,974)	$ (25,078)
Depreciation and amortization	319	528	974	1,530
Interest income	—	(4)	(2)	(128)
Interest expense	—	12	12	31
Income tax expense	—	—	—	—
EBITDA	(7,059)	(6,979)	(17,990)	(23,645)
Stock-based compensation	110	919	1,887	2,867
Gain on extinguishment of PPP promissory note	—	—	(2,023)	—
Loss (gain) on sales and disposals of property and equipment	4	—	(489)	—
Adjusted EBITDA	$ (6,945)	$ (6,060)	$ (18,615)	$ (20,778)

The increase in negative Adjusted EBITDA of $0.9 million for the three months ended September 30, 2021 as compared to the corresponding period in the prior year is primarily due to the increase in R&D expenses related to efforts to improve our catheter design and costs related to our clinical study and the increase in SG&A expenses primarily due to higher legal expenses from amounts accrued related to the securities class action lawsuit.

The decrease in negative Adjusted EBITDA of $2.2 million for the nine months ended September 30, 2021 as compared to the corresponding period in the prior year is primarily due to the decrease in SG&A expenses consisting of a decrease in legal expenses related to the government investigations and a decrease in personnel and other expenses due to continued cost saving initiatives, partially offset by an increase in R&D expenses related to efforts to improve our catheter design and costs related to our clinical study.

Liquidity and Capital Resources

As of September 30, 2021, we had cash and cash equivalents of $20.6 million and an accumulated deficit of $170.0 million. Our primary sources of capital have been the net proceeds of $67.3 million from our initial public offering, the net proceeds of $19.1 million from our 2020 public offerings, the net proceeds of $15.1 million from our "at the market", or ATM, offerings, the net proceeds of $3.5 million from the sale of our Dermatology Business, the proceeds of $2.0 million received in the form of a PPP Promissory Note 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 withour reduced commercial footprint, and as we continue to incur costs related to our atherectomy clinicaltrial, 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 the timing of enrollment inour 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 14. Commitments and Contingencies* in the notes to the unaudited 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 amount and timing of revenue generated by sales of our DABRA products 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 DABRA;
- 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 DABRA 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 2021 and 2020, have an effective shelf registration statement, 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 has 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.

Further, SEC regulations limit the amount of funds we can raise during any 12-month period pursuant to our shelf registration statement on Form S-3. We are currently subject to General Instruction I.B.6 to Form S-3, or the Baby Shelf Rule, and the amount of funds we can raise through primary public offerings of securities in any 12-month period using our registration statement on Form S-3 is limited to one-third of the aggregate market value of the voting and non-voting common equity held by non-affiliates. We are currently limited by the Baby Shelf Rule as of the filing of this Quarterly Report, until such time as our public float exceeds $75 million.

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

The following information reflects cash flows for continuing operations and discontinued operations for the periods presented (in thousands):

	Nine Months Ended September 30,	
	2021	2020
Net cash used in operating activities	$ (21,914)	$ (18,890)
Net cash provided by investing activities	3,803	15,928
Net cash provided by financing activities	14,821	22,024

Net Cash Used in Operating Activities

Net cash used in operating activities of $21.9 million for the nine months ended September 30, 2021 consisted of a net loss of $16.8 million and non-cash adjustments to net loss of $6.0 million, consisting of the gain on sale of the Dermatology Business of $3.5 million, gain on extinguishment of the PPP Promissory Note of $2.0 million and gain on sale of property and equipment of $0.5 million. In addition, we experienced a decrease in net operating assets and liabilities of $2.3 million and non-cash charges of $3.2 million, consisting of stock-based compensation and depreciation and amortization.

Net cash used in operating activities of $18.9 million for the nine months ended September 30, 2020 consisted of a net loss of $25.6 million and a decrease in net operating assets and liabilities of $1.7 million and non-cash charges of $5.0 million, consisting primarily of stock-based compensation and depreciation and amortization.

Net Cash Provided by Investing Activities

Net cash provided by investing activities of $3.8 million for the nine months ended September 30, 2021 consisted primarily of the net proceeds from the sale of the Dermatology Business of $3.5 million and proceeds from sales of property and equipment of $0.5 million, partially offset by purchases of property and equipment of $0.2 million.

Net cash provided by investing activities of $15.9 million for the nine months ended September 30, 2020 consisted primarily of $16.0 million in proceeds from maturities of available-for-sale securities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities of $14.8 million for the nine months ended September 30, 2021 consisted primarily of net proceeds of $15.1 million from our ATM offerings, partially offset by payments of $0.3 million on our equipment financing.

Net cash provided by financing activities of $22.0 million for the nine months ended September 30, 2020 consisted primarily of net proceeds of $19.4 million from our 2020 public offerings, $0.8 million in proceeds from the exercise of warrants associated with the May 2020 public offering and $2.0 million in proceeds from the PPP Promissory Note, partially offset by payments of $0.2 million on our equipment financing.

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, which have been prepared in accordance with accounting principles generally accepted in the U.S., 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 nine months ended September 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 $20.6 million as of September 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.

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 September 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 September 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 September 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 U.S. District Court for the Southern District of California against us, certain current and former officers and directors, and certain underwriters of our initial public offering, or 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. The court has not yet ruled on defendants' motion to dismiss. On November 12, 2021, following a private settlement mediation with the lead plaintiffs, the parties executed a stipulation of settlement that resolved the claims asserted in the securities class action. The settlement provides for a payment to the plaintiff class of $10.0 million. We expect to pay approximately $1.0 million towards the settlement, the amount remaining on our self-insured retention/deductible, and our insurers will pay the remaining balance. The proposed settlement requires both preliminary and final approval by the court. Should the court not approve the proposed settlement or if the proposed settlement otherwise does not become final, the parties will be returned to their litigation postures prior to the execution of the stipulation of settlement. 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 U.S. 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.

Settlement Agreements with the Department of Justice and Participating States

As previously announced 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, and other settlement agreements with certain state attorneys general to resolve investigations and a related civil action concerning our marketing of the DABRA laser system and DABRA-related remuneration to certain physicians.

Pursuant to the terms of the Settlement Agreement and the agreement with the participating states, (a) if our revenue exceeds $10 million in 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 before the end of 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 U.S. 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.

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, 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. 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 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. 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 September 30, 2021, we had cash and cash equivalents of $20.6 million and an accumulated deficit of $170.0 million. For the nine months ended September 30, 2021 and the year ended December 31, 2020, we used cash of $21.9 million and $28.3 million, respectively, in operating activities from continuing and discontinued operations. 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 the securities class action and derivative lawsuits, as well as compliance with, and payments under, the terms of our Settlement Agreement and Corporate Integrity Agreement associated with our settlements with the DOJ and the participating states . 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;
- 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 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 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 relative to alternative treatment methods;
- matters arising out of our completed Audit Committee investigation, securities class action and derivative lawsuit, 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 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.

If we do not adequately educate physicians about 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 sales. 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 losses from continuing operations of $19.0 million and $35.5 million for the nine months ended September 30, 2021 and the year ended December 31, 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $170.0 million. We expect to continue to incur significant manufacturing, product development, regulatory and other expenses as we continue to remedy the inconsistencies in our DABRA catheter performance, to obtain regulatory clearances or approvals for our products in additional jurisdictions and for additional indications, 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 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.

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 delays in receiving shipments of parts which has had an impact on the timing of our key engineering efforts but has not affected 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 14. Commitments and Contingencies* in the notes to the unaudited condensed financial statements included elsewhere in this Quarterly Report.

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 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.

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 is 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. 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. Submitting the required applications for additional indications may require substantial additional funding beyond our cash and cash equivalents as of September 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, 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. Without admitting any liability or wrongdoing, on December 28, 2020, we entered into a Settlement Agreement with the DOJ, other settlement agreements with certain state attorneys general and a related Corporate Integrity Agreement that resolved civil investigations and a related civil lawsuit. 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 nine 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 with certain state attorneys general.

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 and the concluded SEC 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 U.S., 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 our sales and operations outside the U.S., 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 may result in a materially significant diversion of managements attention and resources and significant defense costs and other professional fees. Any violation of the FCPA, other applicable anti-bribery, anti-corruption laws, healthcare laws, and anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could have a material and adverse effect on our reputation, business, financial condition, and results of operations 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 have sold DABRA outside of the U.S. in the past. 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 U.S., 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.

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.

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, 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 September 30, 2021, we had 67 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. This settlement and our ongoing obligations under the Corporate Integrity Agreement 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.

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 product. 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. 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 FDA terminated this recall on November 1, 2021. 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. This field correction was completed in March 2021. The Company considers this recall complete and submitted to the FDA a final status report in March 2021 requesting termination of this field correction. In October 2020 we initiated a voluntary recall of our DABRA lasers to replace the footswitch with a footswitch that meets specification for protection from ingress of solids or liquids. We formally notified the FDA of this recall in accordance with applicable law. This recall was classified as a Class II recall by the FDA. This field correction was completed in October 2021. The Company considers this recall complete and submitted to the FDA a final status report in October 2021 requesting termination of this field correction. 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 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 beinterrupted, 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, 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 that were 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 U.S. 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 U.S. 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 U.S. Supreme Court held oral arguments on the Fifth Circuit U.S. Court of Appeals decision that held that the individual mandate is unconstitutional. It is uncertain how the U.S. 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 centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed, and enacted federal legislation

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

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

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

Our products are purchased principally by 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 have historically sold into foreign markets and plan to continue to do so when we re-commercialize DABRA. Conducting international operations subjects us to risks that could be different than those faced by us in the U.S. 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. 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.

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 U.S. 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, 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 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 U.S. 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 U.S. 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 U.S., 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 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 U.S. 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. 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, or the '327 patent, U.S. Pat. No. 7,261,729, or the '729 patent, and U.S. Pat. No. 8,387,621, or the '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 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 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, 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 September 30, 2021, we had outstanding 7,029,438 shares of our common stock.

In connection with our 2020 equity offerings, we issued warrants to investors and our placement agent. In connection with the sale of the Dermatology Business in 2021, we issued a warrant to the broker. We had an aggregate of 2,419,280 warrants outstanding as of September 30, 2021. We have an effective shelf registration statement and an ATM offering. During the nine months end September 30, 2021, we completed ATM offerings of 3,757,093 shares of common stock. In addition, pursuant to

our 2018 Equity Incentive Plan, or 2018 Plan, equity incentive awards representing up to anaggregate of 122,801 shares of our common stock were available for issuance to our employees, directors and consultants as of September 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 September 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 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 September 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, SEC regulations limit the amount of funds we can raise during any 12-month period pursuant to our shelf registration statement on Form S-3. We are currently subject to the Baby Shelf Rule, and the amount of funds we can raise through primary public offerings of securities in any 12-month period using our registration statement on Form S-3 is limited to one-third of the aggregate market value of the voting and non-voting common equity held by non-affiliates. We are currently limited by the Baby Shelf Rule as of the filing of this Quarterly Report on Form 10-Q, until such time as our public float exceeds $75 million. If we are required to file a new registration statement on another form, we may incur additional costs and be subject to delays due to review by SEC staff.

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 U.S. 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 U.S. 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.

The continued listing of our common stock on the 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 the 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
10.1	Asset Purchase Agreement, dated August 16, 2021, by and between Strata Skin Sciences, Inc. and Ra Medical Systems, Inc.
10.2	Services Agreement, dated August 16, 2021, by and between Ra Medical Systems, Inc. and Strata Skin Sciences, Inc.
10.3	Trademark Assignment Agreement, dated August 16, 2021, by and between Ra Medical Systems, Inc. and Strata Skin Sciences, Inc.
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: November 15, 2021

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

Exhibit 10.1

ASSET PURCHASE AGREEMENT

BY AND BETWEEN

STRATA SKIN SCIENCES, INC.

AND

RA MEDICAL SYSTEMS, INC.

DATED AS OF AUGUST 16, 2021

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ASSET PURCHASE AGREEMENT

THIS ASSET PURCHASE AGREEMENT (as may be amended from time to time in accordance with its terms, this "***Agreement***") is made and entered into as of August 16, 2021 (the "***Effective Date***"), by and among **STRATA SKIN SCIENCES, INC.** ("***Purchaser***"), a Delaware corporation, and **RA MEDICAL SYSTEMS, INC.**, a Delaware corporation (the "***Company***" or the "***Seller***"). Certain capitalized terms used in this Agreement are defined in Exhibit A.

RECITALS

A. The Company is engaged in the domestic and international business of developing, manufacturing, selling, distributing and servicing the excimer laser device that emits highly concentrated ultraviolet light (the "***Laser***") with dermatological applications, which is marketed under the trademark "PHAROS" (the "***Business***"). For purposes of clarity, the "***Business***" shall include solely those assets of Company that are used in the Company's PHAROS business applicable to the dermatological application of the Laser, and shall not include any other business of Company or any applications of the Laser outside of the dermatology field.

B. The Company desires to sell and assign to Purchaser, and Purchaser desires to purchase and assume from the Company, certain specified assets and certain specified liabilities of the Business, upon the terms and subject to the conditions set forth in this Agreement.

C. The Company has obtained the approval of the transactions contemplated by this Agreement by the affirmative vote of the Company's board of directors.

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

AGREEMENT

SECTION 1. PURCHASE AND SALE

1.1 Assets to be Purchased and Sold. Subject to the terms and conditions of this Agreement, at the Closing, the Company shall sell, transfer, convey, assign and deliver ("***Transfer***") to Purchaser, and Purchaser shall purchase, free and clear of any Liens, all of the Company's rights, title and interest in and to all of the assets, properties and rights of every kind and nature, whether real, personal or mixed, tangible or intangible (including goodwill), wherever located and whether now existing or hereafter acquired (other than the Excluded Assets), which relate to, or are used or held for use in connection with, the Business set forth in Exhibit X (the "***Transferred Assets***").

1.2 Excluded Assets. The Company will not Transfer to Purchaser, and the Transferred Assets will not include any of the assets, properties or rights or interest therein set forth in Exhibit X (the "***Excluded Assets***").

1.3 Assumed Liabilities. Purchaser shall only assume obligations and Liabilities first arising after the Closing Date in respect of the Assumed Contracts (only to the extent such

Assumed Contracts are assigned to Purchaser or Purchaser otherwise assumes such obligations and Liabilities pursuant to Section 1.7) but only to the extent that such obligations and Liabilities do not relate to any failure to perform, breach, default or violation by the Company on or prior to the Closing Date (collectively, the "***Assumed Liabilities***").

1.4 Excluded Liabilities. Notwithstanding the provisions of Section 1.3 or any other provision in this Agreement to the contrary, Purchaser shall not assume and shall not be responsible to pay, perform or discharge any obligations or Liabilities of the Business, the Company or any of its Affiliates of any kind or nature whatsoever other than the Assumed Liabilities (the "***Excluded Liabilities***"). Without limiting the generality of the foregoing, the Excluded Liabilities shall include, but not be limited to, the following:

(a) any Liabilities of Seller arising or incurred in connection with the negotiation, preparation, investigation and performance of this Agreement, the Ancillary Documents and the transactions contemplated hereby and thereby, including, without limitation, fees and expenses of counsel, accountants, consultants, advisers and others;

(b) any Liability for (i) Taxes of Seller (or any stockholder or Affiliate of Seller) or relating to the Business, the Transferred Assets or the Assumed Liabilities for any period prior to Closing Date; (ii) Taxes that arise out of the consummation of the transactions contemplated hereby or that are the responsibility of Seller pursuant to Sections 4.6, 4.7 and 4.9; or (iii) other Taxes of Seller (or any stockholder or Affiliate of Seller) of any kind or description (including any Liability for Taxes of Seller (or any stockholder or Affiliate of Seller) that becomes a Liability of Purchaser under any common law doctrine of de facto merger or transferee or successor liability or otherwise by operation of contract or Law);

(c) any Liabilities relating to or arising out of the Excluded Assets (including under any Contracts, commitments or understandings related thereto);

(d) any Liabilities in respect of any pending or threatened Proceeding arising out of, relating to or otherwise in respect of the operation of the Business or the Transferred Assets to the extent such Proceeding relates to such operation on or prior to the Closing Date;

(e) any product Liability or similar claim for injury to a Person or property which arises out of or is based upon any express or implied representation, warranty, agreement or guaranty made by Seller, or by reason of the improper performance or malfunctioning of a product, improper design or manufacture, failure to adequately package, label or warn of hazards or other related product defects of any products at any time manufactured or sold or any service performed by Seller;

(f) any recall, design defect or similar claims of any products manufactured or sold or any service performed by Seller prior to Closing;

(g) any Liabilities of Seller arising under or in connection with any Employee Plan providing benefits to any present or former employee of Seller;

(h) any Liabilities of Seller for any present or former employees, officers, directors, retirees, independent contractors or consultants of Seller, including, without limitation, any Liabilities associated with any claims for wages or other benefits, bonuses, accrued vacation, workers' compensation, severance, retention, termination or other payments;

(i) any Environmental Claims, or Liabilities under Environmental Laws, to the extent arising out of or relating to facts, circumstances or conditions existing on or prior to the Closing or otherwise to the extent arising out of any actions or omissions of Seller;

(j) any trade accounts payable of Seller (i) arising out of or relating to the operation of the Business and the Transferred Assets on or prior to the Closing Date; (ii) which constitute intercompany payables owing to Affiliates of Seller; (iii) which constitute debt, loans or credit facilities to financial institutions; or (iv) which did not arise in the ordinary course of business;

(k) any Liabilities of the Business relating or arising from unfulfilled commitments, quotations, purchase orders, customer orders or work orders that (i) do not constitute part of the Transferred Assets issued by the Business' customers to Seller on or before the Closing; (ii) did not arise in the ordinary course of business; or (iii) are not validly and effectively assigned to Purchaser pursuant to this Agreement;

(l) any Liabilities to indemnify, reimburse or advance amounts to any present or former officer, director, employee or agent of Seller (including with respect to any breach of fiduciary obligations by same), except for indemnification of same pursuant to Section 5.3 as Seller Indemnitees;

(m) any Liabilities under the Excluded Contracts or any other Contracts, including Intellectual Property Agreements, (i) which are not validly and effectively assigned to Purchaser pursuant to this Agreement; (ii) which do not conform to the representations and warranties with respect thereto contained in this Agreement; or (iii) to the extent such Liabilities arise out of or relate to a breach by Seller of such Contracts prior to Closing;

(n) any Liabilities associated with debt, loans or credit facilities of Seller and/or the Business owing to financial institutions; and

(o) any Liabilities arising out of, in respect of or in connection with the failure by Seller or any of its Affiliates to comply with any Law or Governmental Order.

1.5 Purchase Price.

(a) The aggregate purchase price for the Transferred Assets shall be an amount equal to (i) Five Million Dollars ($5,000,000), *less* (ii) the difference between (A) $1,500,000, which represents an amount equal to the estimated cost (including parts and labor) of the remaining term of any existing customer warranty obligations and existing service agreement obligations to existing customers (the "***Obligations***") related to the Business, and (B) $250,000, which represents an amount equal to the value of the Business Inventory acquired as of the Closing Date, *less* (iii) $50,000 (which shall be applied towards any indemnification obligations of Seller that may arise pursuant to Section 5.2(c)) (such aggregate amount, the "***Purchase Price***"), plus the

assumption of the Assumed Liabilities. The Purchase Price shall be paid as provided in Sections 1.8(c), subject to Section 1.5(b). For purposes of clarity, the parties agree that as of Closing, Seller shall have no further obligations or responsibilities as to the Obligations, which shall become Purchaser's sole responsibility, to the extent not otherwise an Excluded Liability (including, but not limited to, Section 1.4(f)).

(b) Purchaser shall be entitled to deduct and withhold from the Purchase Price all Taxes that Purchaser may be required to deduct and withhold under any provision of Tax Law. All such withheld amounts shall be treated as delivered to Seller hereunder. Seller shall provide to Buyer a Form W-9 at the Closing, and accordingly, it is anticipated that no Tax withholding shall be required.

1.6 Allocation of Purchase Price. Not later than sixty (60) days after the Closing Date, Purchaser shall prepare and deliver to the Company a schedule (the "***Purchase Price Allocation Schedule***") allocating the Purchase Price among the Acquired Assets (it being understood that such schedule will be prepared in compliance with Section 1060 of the Code and the regulations promulgated thereunder), and such allocation will be conclusive and binding upon the parties hereto for all purposes. Purchaser and the Company shall each file all Tax Returns (including amended returns and claims for refund) in a manner consistent with such allocation (including the filing of IRS Form 8594), unless otherwise required by applicable Law. Neither Purchaser nor the Company shall take any position with respect to Taxes that is inconsistent with the agreed upon allocation, including in any audit or examination by any Tax Authority, unless otherwise required by applicable Law. Purchaser and the Company shall prepare and timely file such reports and information returns as may be required under applicable Laws to report the allocation of the Purchase Price among the Transferred Assets in accordance with the Purchase Price Allocation Schedule. Each party agrees to notify the other party in the event that any Tax Authority takes or proposes to take a position for Tax purposes that is inconsistent with the allocation set forth in the Purchase Price Allocation Schedule.

1.7 Absence of Consents. To the extent that Seller's rights under any Contract or Governmental Authorization constituting a Transferred Asset, or any other Transferred Asset, may not be Transferred to Purchaser without the Consent of another Person which has not been obtained, this Agreement shall not constitute an agreement to Transfer the same if an attempted Transfer would constitute a breach thereof or be unlawful, and Seller, at its expense, shall use its reasonable best efforts to obtain any such required Consent(s) as promptly as possible. If any such Consent shall not be obtained or if any attempted Transfer would be ineffective or would impair Purchaser's rights under the Transferred Asset in question so that Purchaser would not in effect acquire the benefit of all such rights, Seller, to the maximum extent permitted by law and the Transferred Asset, shall act after the Closing as Purchaser's agent in order to obtain for it the benefits thereunder and shall cooperate, to the maximum extent permitted by Law and the Transferred Asset, with Purchaser in any other reasonable arrangement designed to provide such benefits to Purchaser.

1.8 Closing; Closing Conditions and Deliverables.

(a) Closing. The consummation of the transactions contemplated by this Agreement (the "***Closing***") shall take place by electronic communication on the Closing Date, and shall be effective as of 11:59 p.m. Eastern Time on such date.

(b) Closing Conditions. The obligation of Purchaser to consummate the Closing is subject to the satisfaction of the following conditions in this Section 1.8(b) and the delivery of the agreements and other deliverables set forth in this Section 1.8(b):

(i) Representations and Warranties. Each of the representations and warranties of Company made in Section 2 shall be true and correct in all material respects as of the Closing Date as though made at such time (except those representations and warranties that address matters only as of a specified date, which shall be true and correct in all respects as of that specified date).

(ii) Covenants. Company shall have performed and complied in all material respects with all covenants and agreements set forth in this Agreement required to be performed or complied with by it at or prior to the Closing Date.

(iii) No Injunction, Etc. No provision of any applicable Law and no Governmental Order or proceeding shall be in effect that shall prohibit the consummation of the Closing. No proceeding challenging this Agreement, the Ancillary Documents, or the transactions contemplated by this Agreement or the Ancillary Documents; seeking to prohibit or materially delay the Closing; or seeking material damages incident to this Agreement, the Ancillary Documents, or the transactions contemplated by this Agreement or the Ancillary Documents shall have been instituted by any Person before any Governmental Body and be pending.

(iv) Company Closing Deliverables. At the Closing, the Company shall execute (as applicable) and deliver each of the following to Purchaser:

(1) a bill of sale in the form of Exhibit B attached hereto (the "***Bill of Sale***") and duly executed by Seller, transferring Seller's right, title and interest in and to the tangible personal property included in the Transferred Assets to Purchaser;

(2) an assignment and assumption agreement in the form of Exhibit C attached hereto (the "***Assignment and Assumption Agreement***") and duly executed by Seller, effecting the assignment to and assumption by Purchaser of the Transferred Assets and the Assumed Liabilities;

(3) a trademark assignment agreement in the form of Exhibit D attached hereto (the "***Trademark Assignment Agreement***") and duly executed by Seller, transferring all of Seller's right, title and interest in and to the Intellectual Property Assets to Purchaser;

(4) the Services Agreement in the form of Exhibit E attached hereto (the "***Services Agreement***") and duly executed by Seller;

(5) a power of attorney in the form of Exhibit F attached hereto and duly executed by Seller;

(6) a certificate, dated the Closing Date and signed by a duly authorized officer of Seller, that each of the conditions set forth in Sections 1.8(b)(i), (ii) and (iii) have been satisfied;

(7) a certificate duly executed by the Company pursuant to Treasury Regulations Section 1.1445-2(b) that the Company is not a foreign person within the meaning of Section 1445 of the Code;

(8) releases (in recordable form), pay-off letters and UCC-3 termination statements (in recordable form) from any Person having a Lien on any Transferred Asset, or such other evidence of termination of such Lien as is acceptable to Purchaser;

(9) all Document Deliverables, and other materials related to the Business and its administration and recordkeeping (which the Company may deliver to Purchaser's principal place of business promptly following the Closing);

(10) a certificate of the Secretary or Assistant Secretary of the Company certifying: (A) the certificate of incorporation of the Company as certified by the secretary of state of the state of incorporation of the Company; (B) the bylaws of the Company; (C) a good standing certificate of the Company, dated as of a recent date prior to the Closing Date, as issued by the secretary of state of the state of incorporation of the Company; (D) that attached thereto are true and complete copies of all resolutions adopted by the board of directors of Seller authorizing the execution, delivery and performance of this Agreement and the Ancillary Documents and the consummation of the transactions contemplated hereby and thereby, and that all such resolutions are in full force and effect and are all the resolutions adopted in connection with the transactions contemplated hereby and thereby; and (E) the names and signatures of the officers of Seller authorized to sign this Agreement, the Ancillary Documents and the other documents to be delivered hereunder and thereunder; and

(11) such other customary instruments of transfer, assumption, filings or documents, in form and substance reasonably satisfactory to Purchaser, as may be required to give effect to this Agreement.

Any condition specified in this Section 1.8 may be waived if consented to by Purchaser in writing.

(c) Purchaser Closing Deliverables. The obligation of the Company to consummate the Closing is subject to the satisfaction of the following conditions in this Section 1.8(c) and the delivery of the agreements and other deliverables set forth in this Section 1.8(c):

(i) Representations and Warranties. Each of the representations and warranties of Purchaser made in Section 3 shall be true and correct in all material respects as of the Closing Date as though made at such time (except those representations and warranties that address matters only as of a specified date, which shall be true and correct in all respects as of that specified date).

(ii) Covenants. Purchaser shall have performed and complied in all material respects with all covenants and agreements set forth in this Agreement required to be performed or complied with by it at or prior to the Closing Date.

(iii) No Injunction, Etc. No provision of any applicable Law and no Governmental Order or proceeding shall be in effect that shall prohibit the consummation of the Closing. No proceeding challenging this Agreement, the Ancillary Documents, or the transactions contemplated by this Agreement or the Ancillary Documents; seeking to prohibit or materially delay the Closing; or seeking material damages incident to this Agreement, the Ancillary Documents, or the transactions contemplated by this Agreement or the Ancillary Documents shall have been instituted by any Person before any Governmental Body and be pending.

(iv) At the Closing, Purchaser shall deliver to Seller the following:

(1) the Purchase Price by wire transfer of immediately available funds to an account designated in writing by Seller to Purchaser;

(2) the Assignment and Assumption Agreement duly executed by Purchaser;

(3) the Services Agreement duly executed by Purchaser;

(4) a sales tax resale certificate or other comparable document, as appropriate, reasonably satisfactory to Seller, with respect to the Purchased Assets being purchased for resale; and

(5) a certificate, dated the Closing Date and signed by a duly authorized officer of Purchaser, that each of the conditions set forth in Sections 1.8(c)(i), (ii) and (iii) have been satisfied.

SECTION 2. REPRESENTATIONS AND WARRANTIES OF THE COMPANY

The Company represents and warrants to Purchaser as of the Closing as follows:

2.1 Organization and Qualification. The Company is duly organized, validly existing and in good standing under the laws of the State of Delaware and has all necessary corporate power and authority to own, lease and operate the Transferred Assets and to operate the Business as it is now being conducted. The Company is qualified to do business as a foreign corporation, and in good standing, under the laws of every jurisdiction where the nature of its business requires such qualification.

2.2 Title to Assets. Except as set forth on Schedule 2.2, the Company has good, valid and marketable title to all of the Transferred Assets, and the Company has the full right to sell, transfer and assign all of the Transferred Assets to Purchaser, free and clear of all Liens. Following the Closing, Purchaser will be the lawful owner of, and have good, valid and marketable title to, all the Transferred Assets free and clear of all Liens.

2.3 Authority; Binding Nature of Agreement. The Company has all necessary corporate power and authority to enter into and to perform its obligations under this Agreement and each of the Ancillary Documents to which is a party. The execution, delivery and performance of this Agreement and each Ancillary Document to which the Company is a party by the Company and the consummation of the transactions hereunder and thereunder have been duly authorized and approved by all necessary corporate and stockholder action. This Agreement and each Ancillary

Document to which the Company is a party constitute legal, valid and binding obligations of the Company, enforceable against the Company in accordance with their terms, subject to (a) laws of general application relating to bankruptcy, insolvency and the relief of debtors, and (b) rules of law governing specific performance, injunctive relief and other equitable remedies.

2.4 Non-Contravention; Consents. Except as set forth on Schedule 2.4, the execution and delivery by the Company of this Agreement and each of the Ancillary Documents to which it is a party and the consummation by the Company of the transactions contemplated by this Agreement and each of the Ancillary Documents to which it is a party do not and will not (a) conflict with or result in a violation or breach of, or default under, any provision of the certificate of incorporation, bylaws or other organizational documents of Seller; (b) conflict with or result in a violation or breach of any provision of any Law or Governmental Order applicable to Seller, the Business or the Transferred Assets; (c) require the Consent, notice or other action by any Person under, conflict with, result in a violation or breach of, constitute a default or an event that, with or without notice or lapse of time or both, would constitute a default under, result in the acceleration of or create in any party the right to accelerate, terminate, modify or cancel any Contract or Governmental Authorization to which Seller is a party or by which Seller or the Business is bound or to which any of the Transferred Assets are subject (including any Assigned Contract); or (d) result in the creation or imposition of any Encumbrance on the Transferred Assets. No Consent, approval, Governmental Authorization, Governmental Order, declaration or filing with, or notice to, any Governmental Body is required by or with respect to Seller in connection with the execution and delivery of this Agreement or any of the Ancillary Documents and the consummation of the transactions contemplated hereby and thereby.

2.5 Compliance with Laws.

(a) The Company has been, with respect to the Business, in compliance with all applicable Laws, including all applicable Health Care Laws.

(b) Neither the Company nor any Person engaged by Company to provide any service with respect to the Business, has received (i) any unresolved FDA Form 483 observations, untitled letters or warning letters directly relating to the Product since December 31, 2019, or (ii) any written notice or, to the Knowledge of the Company, other communication from any Governmental Body (A) requiring the termination or suspension of any manufacturing, marketing, sale, importation, export or other exploitation of the Product or (B) alleging any material violation of any Law, providing notice of any fine, sanction, or penalty, or commencing or indicating an intention to conduct any investigation with respect to the Product. There is no order, judgment, agreement, consent decree, or other obligation to which the Company is bound which would in any way impede the Transfer of the Transferred Assets to Purchaser and Purchaser's assumption of the Business pursuant to the terms of this Agreement without adverse impact of any nature.

2.6 Litigation. There are no and there have not been any Proceedings pending or, to the Knowledge of the Company, threatened against the Company affecting the Business or the Transferred Assets at law or in equity, including any such Proceeding before or by any Governmental Body. Neither the Company nor any Transferred Asset is subject to or bound by any outstanding orders, judgments, injunctions, awards or decrees of any Governmental Body or

agreements with any Governmental Body, including corporate integrity agreements, corporate compliance agreements, or deferred or non-prosecution agreements.

2.7 Business Inventory. All Business Inventory consists of a quality and quantity usable and salable in the ordinary course of business consistent with past practice, except for obsolete, damaged, defective or slow-moving items that have been written off or written down to fair market value or for which adequate reserves have been established. All Business Inventory is owned by Seller free and clear of all Encumbrances, and no Business Inventory is held on a consignment basis. The quantities of each item of Business Inventory (whether raw materials, work-in-process or finished goods) are not excessive, but are reasonable in the present circumstances of Seller.

2.8 Absence of Certain Changes, Events and Conditions. Since January 1, 2021, other than (i) in the ordinary course of business consistent with past practice, (ii) the consummation of this Agreement and the Ancillary Documents and (iii) as may have been publicly disclosed by Seller under Legal Proceedings in Form 10-K and Form 10-Q SEC filings prior to Closing, there has not been any, there has not been any:

(a) event, occurrence or development that has had, or could reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect;

(b) material change in any method of accounting or accounting practice for the Business, except as required by GAAP or as disclosed in the notes to the Financial Statements;

(c) material change in cash management practices and policies, practices and procedures with respect to accounts receivable, inventory control, prepayment of expenses, payment of trade accounts payable, accrual of other expenses, deferral of revenue and acceptance of customer deposits;

(d) entry into any Contract that would constitute a Material Contract;

(e) incurrence, assumption or guarantee of any indebtedness for borrowed money in connection with the Business except unsecured current obligations and Liabilities;

(f) transfer, assignment, sale or other disposition of any of the Transferred Assets;

(g) cancellation or forgiveness of any debts or claims or amendment, termination or waiver of any rights relating to Transferred Assets;

(h) transfer or assignment of or grant of any license or sublicense under or with respect to any material Intellectual Property Assets or Intellectual Property Agreements;

(i) abandonment or lapse of or failure to maintain in full force and effect any Intellectual Property Registration, or failure to take or maintain reasonable measures to protect the confidentiality or value of any Trade Secrets included in the Intellectual Property Assets;

(j) material damage, destruction or loss, or any material interruption in use, of any Transferred Assets, whether or not covered by insurance;

(k) acceleration, termination, material modification to or cancellation of any Assigned Contract or Governmental Authorization;

(l) material capital expenditures which would constitute an Assumed Liability;

(m) imposition of any Encumbrance upon any of the Transferred Assets;

(n) adoption of any plan of merger, consolidation, reorganization, liquidation or dissolution or filing of a petition in bankruptcy under any provisions of federal or state bankruptcy Law or consent to the filing of any bankruptcy petition against it under any similar Law;

(o) purchase, lease or other acquisition of the right to own, use or lease any property or assets in connection with the Business for an amount in excess of $25,000, individually (in the case of a lease, per annum) or $50,000 in the aggregate (in the case of a lease, for the entire term of the lease, not including any option term);

(p) any Contract to do any of the foregoing, or any action or omission that would result in any of the foregoing.

2.9 Condition and Sufficiency of Assets. The items of tangible personal property included in the Transferred Assets are structurally sound, are in good operating condition and repair, and are adequate for the uses to which they are being put, and none of such items of tangible personal property is in need of maintenance or repairs except for ordinary, routine maintenance and repairs that are not material in nature or cost. The Transferred Assets are sufficient for the continued conduct of the Business after the Closing in the same manner as conducted prior to the Closing and constitute all of the rights, property and assets necessary to conduct the Business as currently conducted. None of the Excluded Assets are necessary for the operation of the Business.

2.10 Intellectual Property.

(a) Schedule 1.1(b) contains a correct, current and complete list of: (i) all Intellectual Property Registrations, specifying as to each, as applicable: the title, mark, or design; the jurisdiction by or in which it has been issued, registered or filed; the patent, registration or application serial number; the issue, registration or filing date; and the current status; (ii) all unregistered Copyrights and Trademarks included in the Intellectual Property Assets; (iii) all proprietary Software included in the Intellectual Property Assets; and (iv) all other Intellectual Property Assets (whether or not they are registrable or patentable) that are used or held for use in the conduct of the Business as currently conducted.

(b) Schedule 2.10(b) contains a correct, current and complete list of all Intellectual Property Agreements, specifying for each the date, title, and parties thereto, and separately identifying the Intellectual Property Agreements: (i) under which Seller is a licensor or otherwise grants to any Person any right or interest relating to any Intellectual Property Asset; (ii) under which Seller is a licensee or otherwise granted any right or interest relating to the Intellectual Property of any Person; and (iii) which otherwise relate to the Seller's ownership or use of any Intellectual Property in the conduct of the Business as currently conducted, in each case identifying the Intellectual Property covered by such Intellectual Property Agreement. Seller has provided

Purchaser with true and complete copies (or in the case of any oral agreements, a complete and correct written description) of all such Intellectual Property Agreements, including all modifications, amendments and supplements thereto and waivers thereunder. Each Intellectual Property Agreement is valid and binding on Seller in accordance with its terms and is in full force and effect. Neither Seller nor any other party thereto is, or is alleged to be, in breach of or default under, or has provided or received any notice of breach of, default under, or intention to terminate (including by non-renewal), any Intellectual Property Agreement.

(c) Except as set forth in Schedule 2.10(c), Seller is the sole and exclusive legal and beneficial, and with respect to the Intellectual Property Registrations, record, owner of all right, title and interest in and to the Intellectual Property Assets, and has the valid and enforceable right to use all other Intellectual Property used or held for use in or necessary for the conduct of the Business as currently conducted, in each case, free and clear of Encumbrances. The Intellectual Property Assets are all of the Intellectual Property necessary to operate the Business as presently conducted. Seller has entered into binding, valid and enforceable written Contracts with each current and former employee and independent contractor whereby such employee or independent contractor (i) acknowledges Seller's exclusive ownership of all Intellectual Property Assets invented, created or developed by such employee or independent contractor within the scope of his or her employment or engagement with Seller; (ii) grants to Seller a present, irrevocable assignment of any ownership interest such employee or independent contractor may have in or to such Intellectual Property; and (iii) irrevocably waives any right or interest, including any moral rights, regarding such Intellectual Property, to the extent permitted by applicable Law. All assignments and other instruments necessary to establish, record, and perfect Seller's ownership interest in the Intellectual Property Registrations have been validly executed, delivered, and filed with the relevant Governmental Bodies and authorized registrars.

(d) Neither the execution, delivery, or performance of this Agreement, nor the consummation of the transactions contemplated hereunder, will result in the loss or impairment of or payment of any additional amounts with respect to, or require the consent of any other Person in respect of, the Purchaser's right to own or use any Intellectual Property Assets in the conduct of the Business as currently conducted. Immediately following the Closing, all Intellectual Property Assets will be owned or available for use by Purchaser on identical terms as they were owned or available for use by Seller immediately prior to the Closing.

(e) All of the Intellectual Property Assets is valid and enforceable, all Intellectual Property Registrations are subsisting and in full force and effect and all Intellectual Property Agreements are in full force and effect and have not been breached by any party thereto. Seller has taken all reasonable and necessary steps to maintain and enforce the Intellectual Property Assets and to preserve the confidentiality of all Trade Secrets included in the Intellectual Property Assets, including by requiring all Persons having access thereto to execute binding, written non-disclosure agreements. All required filings and fees related to the Intellectual Property Registrations have been timely submitted with and paid to the relevant Governmental Bodies and authorized registrars.

(f) The conduct of the Business as currently and formerly conducted, including the use of the Intellectual Property Assets in connection therewith, and the products, processes, and services of the Business have not infringed, misappropriated, or otherwise violated and will not

infringe, misappropriate, or otherwise violate the Intellectual Property or other rights of any Person. No Person has infringed, misappropriated, or otherwise violated any Intellectual Property Assets.

(g) There are no Proceedings (including any opposition, cancellation, revocation, review, or other proceeding), whether settled, pending or threatened (including in the form of offers to obtain a license): (i) alleging any infringement, misappropriation, or other violation of the Intellectual Property of any Person by Seller in the conduct of the Business; (ii) challenging the validity, enforceability, registrability, patentability, or ownership of any Intellectual Property Assets; or (iii) by Seller or any other Person alleging any infringement, misappropriation, or other violation by any Person of any Intellectual Property Assets. To the Knowledge of the Company, there are no facts or circumstances that could reasonably be expected to give rise to any such Proceeding. Seller is not subject to any outstanding or prospective Governmental Order (including any motion or petition therefor) that does or could reasonably be expected to restrict or impair the use of any Intellectual Property Assets.

(h) Schedule 2.10(h) contains a correct, current, and complete list of all social media accounts used by Seller in the conduct of the Business, including username and password. Seller has complied with all terms of use, terms of service, and other Contracts and all associated policies and guidelines relating to its use of any social media platforms, sites, or services in the conduct of the Business (collectively, "***Platform Agreements***"). There are no Proceedings settled, pending, or threatened alleging (A) any breach or other violation of any Platform Agreement by Seller; or (B) defamation, any violation of publicity rights of any Person, or any other violation by Seller in connection with its use of social media in the conduct of the Business.

(i) Seller has complied with all applicable Laws and all internal or publicly posted policies, notices, and statements concerning the collection, use, processing, storage, transfer, and security of personal information in the conduct of the Business. In the past two years, Seller has not (i) experienced any actual, alleged, or suspected data breach or other security incident involving personal information in its possession or control or (ii) been subject to or received any notice of any audit, investigation, complaint, or other Proceeding by any Governmental Body or other Person concerning the Company's collection, use, processing, storage, transfer, or protection of personal information or actual, alleged, or suspected violation of any applicable Law concerning privacy, data security, or data breach notification, in each case in connection with the conduct of the Business, and there are no facts or circumstances that could reasonably be expected to give rise to any such Proceeding.

2.11 Contracts.

(a) Schedule 2.11(a) sets forth an accurate list of all of the Company's Contracts to which the Seller is a party and in any way related to the Business:

(i) each Contract (other than purchase orders for Business Inventory) that involves performance of services or delivery of goods or materials;

(ii) each Contract (other than purchase orders for Business Inventory) that involves performance of services or delivery of goods or materials to any Company of an amount or value in excess of $50,000;

(iii) each lease, rental or occupancy agreement, license, installment and conditional sale agreement, and other Contract affecting the ownership of, leasing of, title to, use of, or any leasehold or other interest in, any tangible personal property (but specifically excluding any of the forgoing relating to real estate);

(iv) each Contract in respect of Intellectual Property Assets;

(v) each Contract containing covenants that restrict the business activity of the Business;

(vi) each Contract providing for indemnification by the Company to customers or vendors;

(vii) any employment or consulting Contract with any Company employee, or any consultant or contractor of the Company, other than at-will arrangements that do not include severance or "change of control" or equivalent provisions; and

(viii) each amendment, supplement, and modification (whether oral or written) in respect of any of the foregoing.

(b) Except as set forth in Schedule 2.11(b), as of the date hereof, all of the Contracts are in full force and effect and are enforceable in accordance with their terms except to the extent that such enforceability (i) may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws relating to creditors' rights generally, and (ii) is subject to general principles of equity.

(c) Except as set forth in Schedule 2.11(c), as of the date hereof, the Company is not in breach in any material respect of or default under (and to Knowledge of the Company, no event has occurred which with notice or the passage of time or both would constitute a breach in any material respect of or default under) any Contract nor, to the Knowledge of the Company, is any other party to any such Contract in breach in any material respect of or default under such Contract.

(d) Schedule Z sets forth an accurate and complete list of the customers of the Business (the "***Customers***"), together, if available and practical, with (i) the name of such Customer, including contact information and email address(es), (ii) the type of Product(s) used by each Customer, (iii) location of the Product, (iv) the expiration date of such Customer's warranty, if applicable, and (v) if purchased by the Customer, the expiration date of such Customer's service contract.

(e) Seller has provided to Purchaser a complete and accurate copy of Seller's standard form of: (i) warranty provided to Customers; and (ii) service Contract with a Customer, each of which are currently used by Seller or currently in effect and attached to Schedule 2.11(e) (collectively, the "***Seller Standard Form Contracts***"). Except as set forth in Schedule 2.11(e), no

Contract between Seller and a Customer (each, a "***Customer Warranty/Service Contract***") that relates to (x) any warranty provided to such Customer, or (y) service Contract with such Customer deviates from the Seller Standard Form Contract. Schedule 2.11(e) sets forth, for each Customer with respect to their respective Customer Warranty/Service Contract, (A) the date of such agreement, (B) the service period, (C) the annual service fee rate or other amount to be charged to such Customer, (D) the payment date(s) for any service fee or amount to be paid by such Customer following the Closing Date, and (E) whether such rate or amount includes service and technician time.

(f) Seller represents and warrants that (i) except for those as set forth in Schedule 2.11(f), Seller has no Obligations or any other warranty or similar types of obligations to any Customer under any Assigned Contract, including, but not limited to, any warranty, service or rental Contract, and (ii) no Contract or Customer identified in Schedule 2.11(f) relates to a Customer located outside of the United States.

2.12 Environmental Matters.

(a) The operations of Seller with respect to the Business and the Transferred Assets are currently and have been in compliance with all Environmental Laws. Seller has not received from any Governmental Body, with respect to the Business or the Transferred Assets, any: (i) Environmental Notice or Environmental Claim; or (ii) written request for information pursuant to Environmental Law, which, in each case, either remains pending or unresolved, or is the source of ongoing obligations or requirements as of the Closing Date.

(b) Seller has obtained and is in material compliance with all Environmental Permits (each of which is disclosed in Schedule 2.12(b)) necessary for the conduct of the Business as currently conducted or the ownership, lease, operation or use of the Transferred Assets and all such Environmental Permits are in full force and effect and shall be maintained in full force and effect by Seller through the Closing Date in accordance with Environmental Law, and Seller is not aware of any condition, event or circumstance that might prevent or impede, after the Closing Date, the conduct of the Business as currently conducted or the ownership, lease, operation or use of the Transferred Assets. With respect to any such Environmental Permits, Seller has undertaken, or will undertake prior to the Closing Date, all measures necessary to facilitate transferability of the same, and Seller is not aware of any condition, event or circumstance that might prevent or impede the transferability of the same, and has not received any Environmental Notice or written communication regarding any material adverse change in the status or terms and conditions of the same.

(c) There has been no Release of hazardous materials in contravention of Environmental Law with respect to the Business or the Transferred Assets, and Seller has not received an Environmental Notice that any of the Business or the Transferred Assets (including soils, groundwater, surface water, buildings and other structure located thereon) has been contaminated with any hazardous material which could reasonably be expected to result in an Environmental Claim against, or a violation of Environmental Law or Environmental Permit by, Seller.

(d) Seller has not retained or assumed, by Contract or operation of Law, any Liabilities or obligations of third parties under Environmental Law.

(e) Seller is not aware of or reasonably anticipates, as of the Closing Date, any condition, event or circumstance concerning the Release or regulation of Hazardous Materials that might, after the Closing Date, prevent, impede or materially increase the costs associated with the ownership, lease, operation, performance or use of the Business or the Transferred Assets as currently carried out.

2.13 Undisclosed Liabilities. The Company has no Liabilities with respect to the Business, except (a) those set forth on the Company's financial statements for fiscal year ending December 31, 2020, and (b) those which have been incurred in the ordinary course of business consistent with past practice since January 1, 2021 and which are not, individually or in the aggregate, material in amount and which have not been set forth in an exhibit to this Agreement.

2.14 Stockholder Approval. The Company represents and warrants that no shareholder approval is required to effectuate the transactions herein described.

2.15 Third Party Approval. No approval by any third party is required to effectuate the transactions herein described.

2.16 Financial Advisor. Other than with respect to obligations owed to M.M. Dillon & Co. Group LLC, none of the Company or any Person acting on behalf of the Company has agreed or has any obligation or Liability to pay to any broker, finder, investment banker or any other Person, a brokerage, finder's or other brokerage fee or commission in connection with this Agreement, any matter related hereto or the consummation of the transactions contemplated hereby, nor has any broker, finder, investment banker or any other Person taken any action on which a claim for any such payment could be based. The Company shall be solely responsible for paying any and all fees, commissions or other compensation to which any such broker, finder, investment banker or any other Person is entitled or claims on account of the execution of this Agreement or the consummation of the transactions contemplated hereby.

2.17 Taxes.

(a) All Tax Returns with respect to the Business required to be filed by Seller for any period prior to the Closing Date have been, or will be, timely filed after giving effect to extensions. Such Tax Returns are, or will be, true, complete and correct in all respects. All Taxes due and owing by Seller (whether or not shown on any Tax Return) have been, or will be, timely paid.

(b) Seller has withheld and paid each Tax required to have been withheld and paid in connection with amounts paid or owing to any employee, independent contractor, creditor, customer, shareholder or other party, and complied with all information reporting and backup withholding provisions of applicable Law.

(c) No extensions or waivers of statutes of limitations have been given or requested with respect to any due and outstanding Taxes of Seller.

(d) All deficiencies asserted, or assessments made, against Seller as a result of any examinations by any taxing authority have been fully paid.

(e) Except as set forth in Schedule 2.17(e), Seller is not a party to any Proceeding by any Tax Authority. There are no pending or, to the Knowledge of the Company, threatened Proceedings by any Tax Authority.

(f) There are no Encumbrances for Taxes upon any of the Transferred Assets nor, to the Knowledge of the Company, is any taxing authority in the process of imposing any Encumbrances for Taxes on any of the Transferred Assets (other than for current Taxes not yet due and payable).

(g) Seller is not a "foreign person" as that term is used in Treasury Regulations Section 1.1445-2.

(h) Seller is not, and has not been, a party to, or a promoter of, a "reportable transaction" within the meaning of Section 6707A(c)(1) of the Code and Treasury Regulations Section 1.6011-4(b).

(i) None of the Transferred Assets is (i) required to be treated as being owned by another person pursuant to the so-called "safe harbor lease" provisions of former Section 168(f)(8) of the Internal Revenue Code of 1954, as amended, (ii) subject to Section 168(g)(1)(A) of the Code, or (iii) subject to a disqualified leaseback or long-term agreement as defined in Section 467 of the Code.

(j) None of the Transferred Assets is tax-exempt use property within the meaning of Section 168(h) of the Code.

(k) Purchaser to execute and deliver a sales tax resale certificate or other comparable document, as appropriate, reasonably satisfactory to Seller, with respect to the Purchased Assets being purchased for resale.

2.18 Full Disclosure. No representation or warranty by Seller in this Agreement and no statement contained in the Disclosure Schedules to this Agreement or any certificate or other document furnished or to be furnished to Purchaser pursuant to this Agreement contains any untrue statement of a material fact, or omits to state a material fact necessary to make the statements contained therein, in light of the circumstances in which they are made, not misleading.

SECTION 3. REPRESENTATIONS AND WARRANTIES OF PURCHASER

Purchaser represents and warrants to the Company as follows:

3.1 Organization and Qualification. Purchaser is a corporation duly incorporated, validly existing and in good standing under the laws of Delaware and has all necessary corporate power and authority to own, lease and operate its properties and to carry on its business as it is now being conducted.

3.2 Authority; Binding Nature of Agreement. Purchaser has all necessary corporate power and authority to enter into and to perform its obligations under this Agreement and each of the Ancillary Documents to which Purchaser is a party, and the execution, delivery and performance by Purchaser of this Agreement has been duly authorized by all necessary action on the part of Purchaser. This Agreement and the Ancillary Documents to which Purchaser is a party have been duly authorized, executed and delivered by Purchaser and this Agreement and each Ancillary Document to which Purchaser is a party constitute legal, valid and binding obligations of Purchaser, enforceable against Purchaser in accordance with their terms, subject to (a) laws of general application relating to bankruptcy, insolvency and the relief of debtors, and (b) rules of law governing specific performance, injunctive relief and other equitable remedies.

3.3 Non-Contravention; Consents. The execution and delivery by Purchaser of this Agreement and each of the Ancillary Documents to which it is a party and the consummation by the Company of the transactions contemplated by this Agreement and each of the Ancillary Documents to which it is a party do not and will not (a) conflict with or result in any breach of any of the provisions of, (b) constitute a default under, (c) result in a violation of, (d) give any third party the right to payment or to terminate or modify or to accelerate any obligation under, (e) result in the creation of any Lien upon, or (f) require any authorization, Consent, exemption or other action by or notice to or filing with any court or other Governmental Body or other Person, under (i) any of the provisions of the certificate of incorporation or bylaws of Purchaser, or (ii) any material Contract or Governmental Authorization of Purchaser, or (iii) any Law to which the Purchaser is subject.

3.4 Litigation. As of the date of this Agreement, there is no Proceeding pending before any court of competent jurisdiction (or, to the knowledge of Purchaser, being overtly threatened) against Purchaser challenging the transactions contemplated by this Agreement.

3.5 Financing. Purchaser has, or will have, sufficient cash available to pay the Purchase Price at Closing.

SECTION 4. COVENANTS OF THE PARTIES

4.1 Public Announcements. Neither Purchaser nor Seller shall issue any press releases or otherwise make any public statements with respect to the transactions contemplated by this Agreement without the prior written consent of the other; *provided, however*, that Purchaser or Seller may, without such approval, make such press releases or other public announcements as required by (a) any listing agreement with any national securities exchange or stock market or (b) applicable Law (including securities Laws) (in which case the disclosing party will provide the other party hereto with the opportunity to review in advance such disclosure).

4.2 Tax Matters.

(a) Seller and Purchaser shall provide each other with such cooperation and information, including but not limited to obtaining any document from any Governmental Body or any other Person, as either reasonably may request of the other in connection with (i) the filing of any Tax Return, amended Tax Return or claim for refund with respect to the Business or the Transferred Assets, (ii) the execution and filing of any Tax election, if required, (iii) determining

liability for Taxes or a right to refund of Taxes or (iv) in conducting any Proceeding in respect of Taxes with respect to the Business or the Transferred Assets. The Company shall file all Tax Returns (including amended returns and claims for refund) in a manner consistent with IRS Form 8594 provided by Purchaser.

(b) For purposes of this Agreement, a portion of each property Tax or similar Tax with respect to the Transferred Assets that is attributable to any taxable period that includes but does not end on the Closing Date will be treated as an Excluded Liability and will be the responsibility of the Company, and that portion shall be equal to the total amount of such Tax for the entire taxable period multiplied by a fraction, the numerator of which is the number of days in such taxable period falling before and including the Closing Date, and the denominator of which is the total number of days in such taxable period. The remainder of any such Tax shall be the responsibility of Purchaser. In the event that either the Company or Purchaser makes a payment of Tax for which the other party is responsible pursuant to this Section 4.2, the other party shall reimburse such Tax promptly but in no event later than thirty days after the presentation of a statement setting forth the amount of reimbursement to which the presenting party is entitled along with such supporting evidence as is reasonably necessary to calculate the amount of reimbursement.

(c) All transfer, documentary, sales, use, stamp, registration, value added and other such Taxes and fees (including any penalties and interest) incurred in connection with this Agreement shall be borne and paid by Seller when due. Seller shall, at their own expense, timely file any Tax Return or other document with respect to such Taxes or fees (and Purchaser shall cooperate with respect thereto as necessary).

4.3 Removal of Transferred Assets. The Company shall cause the tangible and intangible Transferred Assets being transferred hereunder to be ready and available for delivery to Purchaser as and when requested by Purchaser following Closing.

4.4 Post-Closing Services. Seller shall, for the periods set forth in the Service Agreement, provide manufacturing and supply services to Purchaser in connection with the support and sales of the Products. Seller will sell chambers and any other spare parts necessary to Purchaser at cost, in sufficient quantity to fulfill all outstanding warranty and service obligations extant as of the Closing. Cost shall include labor to the extent any assembly is required.

4.5 Restrictive Covenant.

(a) Seller agrees that, during the Restricted Period, Seller shall not, and Seller shall ensure that its Affiliates do not (except in the authorized course of any employment, consulting or independent contractor services provided to Purchaser or any of its Affiliates): (i) engage directly or indirectly in Competition in any part of the Restricted Territory; or (ii) directly or indirectly be or become an officer, director, stockholder, owner, co-owner, Affiliate, partner, promoter, employee, agent, Representative, designer, consultant, advisor or manager of, for or to, or acquire or hold any direct or indirect interest in, any Person that engages directly or indirectly in Competition in any part of the Restricted Territory.

(b) Seller agrees that, during the Restricted Period, Seller shall not, and Seller shall ensure that its Affiliates do not, directly or indirectly, solicit, induce or encourage, or attempt to solicit, induce or encourage, or cause others to solicit, induce or encourage (on its behalf or on behalf of others), any Customer or supplier or vendor of the Business to terminate their service or business arrangement with Purchaser or any of its Affiliates for any reason.

(c) Seller agrees that, during the Restricted Period, except as required by applicable Law, or compelled by process of Law, Seller shall not, and Seller shall not intentionally publicly libel, slander or disparage Purchaser in such capacity in any manner that would reasonably be expected to be harmful to such Person or to the business or business reputation of such Person in such capacity; provided, however, that the foregoing shall not prohibit, or otherwise apply to (i) any truthful statements in connection with this Agreement or the transactions contemplated hereby, including, but not limited to, the enforcement of or any disputes in relation to thereto, (ii) any truthful statements or testimony made under oath, (iii) any information or statements pursuant to a valid subpoena or order by a court or other governmental body, or as otherwise required by Law or Proceeding, or any other legally-required truthful statements or disclosure, or (iv) disclosing any information or any statements in private and in confidence, including any statements to Seller's legal, financial, tax or other advisors.

(d) Seller acknowledges and agrees that all Confidential Information and all physical embodiments thereof are confidential and proprietary to, and are and will remain the sole and exclusive property of, of Purchaser effective as of Closing. At all times after the date of this Agreement, the Company will hold such Confidential Information in trust and strictest confidence, and will not, directly or indirectly, use, reproduce, distribute, divulge, disclose or otherwise disseminate the Confidential Information or any physical embodiments thereof other than to Purchaser and its Representatives, and neither Company nor any officer or director shall take any action causing, or fail to take any action necessary in order to prevent, any Confidential Information to lose its character or cease to qualify as Confidential Information. At the Closing, the Seller shall deliver to Purchaser all Confidential Information (and all embodiments thereof) then in such Seller’s possession, custody or control.

(e) Seller hereby agrees and acknowledges that: (i) the restrictions imposed upon Seller under this Section 4.5 are reasonable and necessary to protect Purchaser's legitimate business interests and the goodwill or customer relationships in the Business; (ii) the geographic scope of the Restricted Territory is reasonable and necessary to protect Purchaser's legitimate business interests; (iii) Seller's experience and capabilities are such that it can continue to operate without breaching the terms and conditions of this Agreement; (iv) the restrictions contained in this Section 4.5 are fair and reasonable under the circumstances and do not limit fair competition; (v) the duration, area and scope of the covenants contained in this Section 4.5 have been considered by Seller and that Seller has received independent legal counsel with respect thereto, and (vi) Seller, either alone or through its Affiliates, has received sufficiently high consideration and other benefits as a result of this Agreement and the transactions contemplated hereby, and such consideration and other benefits justify the covenants contained in this Section 4.5.

(f) Notwithstanding anything in this Agreement to the contrary, any term or provision of Section 4.5 that is illegal, invalid or unenforceable in any situation in any jurisdiction shall not affect the legality, validity or enforceability of the remaining terms and provisions of this Section

4.5 or the legality, validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. If the final judgment of a court of competent jurisdiction declares that any term or provision of this Section 4.5 is illegal, invalid or unenforceable, then the parties agree that the court making such determination shall have the power to limit the term or provision, to delete specific words or phrases, or to replace any illegal, invalid or unenforceable term or provision with a term or provision that is legal, valid and enforceable and that comes closest to expressing the intention of the illegal, invalid or unenforceable term or provision, and this Section 4.5 shall be enforceable as so modified. In the event such court does not exercise the power granted to it in the prior sentence, the parties agree to amend this Section 4.5 to replace such illegal, invalid or unenforceable term or provision with a legal, valid and enforceable term or provision that will achieve, to the extent possible, the economic, business and other purposes of such illegal, invalid or unenforceable term or provision and that comes closest to expressing the intention of the illegal, invalid or unenforceable term or provision.

(g) "***Confidential Information***" includes all Intellectual Property, Regulatory Documentation, and all other confidential and/or proprietary data and/or information primarily relating to the Transferred Assets or the Business and its operations which is owned or used by the Company and which has value to the Business and the Company and is not known to the Company's competitors. Such Confidential Information shall include proprietary technology, operating procedures, financial statements or other financial information, know-how, market studies and forecasts, competitive analysis, pricing policies and procedures, the substance of arrangements with customers, suppliers and others, servicing and training programs and arrangements, marketing or similar arrangements, customer or supplier lists and any other documents embodying such Confidential Information. Confidential Information shall not include any data or information that (A) has been voluntarily disclosed to the public by the Company prior to the date hereof, (B) has been independently developed and disclosed to the public by others, (C) otherwise enters the public domain through lawful means, or (D) is required by Law to be disclosed by the Company; *provided*, that prior to such disclosure, the Company provides written notice to Purchaser of its intent to disclose such matter, and further provides Purchaser a reasonable opportunity to contest such disclosure with the appropriate Governmental Body.

(h) Seller agrees that Purchaser or its successors or assigns will suffer irreparable harm from a breach by Seller of any of the covenants or agreements contained in this Section 4.5 that cannot adequately be compensated for with monetary damages. Notwithstanding anything in this Agreement to the contrary, Seller agrees that, in the event of a breach or an alleged or threatened breach by Seller of any of the provisions of this Section 4.5, Purchaser and each of its successors and assigns shall be entitled to (and in addition to any other remedy that may be available to it, including monetary damages) apply to any court of competent jurisdiction for specific performance and/or injunctive or other relief in order to enforce or prevent any violations of the provisions hereof, in each case without the requirement of posting a bond or proving actual damages.

4.6 INTENTIONALLY OMITTED.

4.7 Bulk Sales Laws. The parties hereby waive compliance with the provisions of any bulk sales, bulk transfer or similar Laws of any jurisdiction that may otherwise be applicable with respect to the sale of any or all of the Transferred Assets to Purchaser; it being understood that any

Liabilities arising out of the failure of Seller to comply with the requirements and provisions of any bulk sales, bulk transfer or similar Laws of any jurisdiction shall be treated as Excluded Liabilities.

4.8 Receivables. From and after the Closing, if Seller or any of its Affiliates receives or collects any funds relating to any Transferred Asset, Seller or its Affiliate shall remit such funds to Purchaser within five business days after its receipt thereof. From and after the Closing, if Purchaser or its Affiliate receives or collects any funds relating to any Excluded Asset, Purchaser or its Affiliate shall remit any such funds to Seller within five business days after its receipt thereof.

4.9 Recalls after Closing. From and after Closing, in the event that there is any recall, design defect or similar claims of any products manufactured or sold, including, but not limited to, the Product, or any service performed by Seller prior to Closing that may give rise to any potential Liability of Seller, Company agree to (i) provide prompt written notice thereof to Seller, (ii) provide Seller with reasonable periodic updates if requested by Seller, and (iii) provide Seller a reasonable opportunity to confer with Company to mitigate any potential Liability to Seller. The failure by Company to give Seller such prompt written notice shall not, however, relieve Seller of its Liabilities related thereto.

4.10 Further Assurance. Following the Closing, each of the parties hereto shall, and shall cause their respective Affiliates to, execute and deliver such additional documents, instruments, conveyances and assurances and take such further actions as may be reasonably required to carry out the provisions hereof and give effect to the transactions contemplated by this Agreement. Seller agrees that, after the Closing, it will hold and will promptly transfer and deliver to Purchaser, from time to time as and when received by either such party, any cash, checks with appropriate endorsements (which they shall not convert to cash), or other property that it may receive on or after the Closing which properly belongs to Purchaser in accordance with the terms of this Agreement, including without limitation any insurance proceeds and payment of accounts receivable, and will account to the other for all such receipts.

SECTION 5. INDEMNIFICATION

5.1 Survival. Subject to the limitations and other provisions of this Agreement, the representations and warranties contained herein shall survive the Closing and shall remain in full force and effect until the third anniversary of the Closing Date and shall in no way be affected by any investigation or knowledge of the subject matter thereof made by or on behalf of the Purchaser or the Company; provided, that the representations and warranties in (i) Section 2.1, Section 2.2, Section 2.3, Section 2.9, Section 2.11(d), Section 2.11(e), Section 2.11(f), Section 2.16, Section 3.1, and Section 3.2 shall survive indefinitely, and (ii) Section 2.17 shall survive for the full period of all applicable statutes of limitations (giving effect to any waiver, mitigation or extension thereof) plus 60 calendar days. All covenants and agreements of the parties contained herein shall survive the Closing indefinitely or for the period explicitly specified therein. Notwithstanding the foregoing, any claims asserted in good faith with reasonable specificity (to the extent known at such time) and in writing by notice from the non-breaching party to the breaching party prior to the expiration date of the applicable survival period shall not thereafter be barred by the expiration of the relevant representation or warranty and such claims shall survive until finally resolved.

5.2 Indemnification By Seller. Subject to the other terms and conditions of this Section 5, Seller shall indemnify and defend each of Purchaser and its Affiliates and their respective Representatives (collectively, the "***Purchaser Indemnitees***") against, and shall hold each of them harmless from and against, and shall pay and reimburse each of them for, any and all Losses incurred or sustained by, or imposed upon, the Purchaser Indemnitees based upon, arising out of, with respect to or by reason of:

(a) any inaccuracy in or breach of any of the representations or warranties of Seller contained in this Agreement, the Ancillary Documents or in any certificate or instrument delivered by or on behalf of Seller pursuant to this Agreement, as of the date such representation or warranty was made or as if such representation or warranty was made on and as of the Closing Date (except for representations and warranties that expressly relate to a specified date, the inaccuracy in or breach of which will be determined with reference to such specified date);

(b) any breach or non-fulfillment of any covenant, agreement or obligation to be performed by Seller pursuant to this Agreement, the Ancillary Documents or any certificate or instrument delivered by or on behalf of Seller pursuant to this Agreement;

(c) any Obligations or any other warranty or similar types of obligations to any Person not identified in Schedule 2.11(f);

(d) any sales or use tax or similar Tax payable with respect to the Products to any Tax Authority prior to the Closing Date;

(e) any Excluded Asset or any Excluded Liability; or

(f) any Third Party Claim based upon, resulting from or arising out of the Business, operations, properties, assets or obligations of Seller or any of its Affiliates as conducted, existing or arising on or prior to the Closing Date.

5.3 Indemnification By Purchaser. Subject to the other terms and conditions of this Section 5, Purchaser shall indemnify and defend each of Seller and its Affiliates and their respective Representatives (collectively, the "***Seller Indemnitees***") against, and shall hold each of them harmless from and against, and shall pay and reimburse each of them for, any and all Losses incurred or sustained by, or imposed upon, the Seller Indemnitees based upon, arising out of, with respect to or by reason of:

(a) any inaccuracy in or breach of any of the representations or warranties of Purchaser contained in this Agreement or in any certificate or instrument delivered by or on behalf of Purchaser pursuant to this Agreement, as of the date such representation or warranty was made or as if such representation or warranty was made on and as of the Closing Date (except for representations and warranties that expressly relate to a specified date, the inaccuracy in or breach of which will be determined with reference to such specified date);

(b) any breach or non-fulfillment of any covenant, agreement or obligation to be performed by Purchaser pursuant to this Agreement; or

(c) any Assumed Liability.

5.4 Certain Limitations. The indemnification provided for in Section 5.2 and Section 5.3 shall be subject to the following limitations:

(a) Seller shall not be liable to the Purchaser Indemnitees for indemnification under Section 5.2(a) until the aggregate amount of all Losses in respect of indemnification under Section 5.2(a) exceeds $25,000 (the "***Basket***"), in which event Seller shall be required to pay or be liable for all such Losses from the first dollar.

(b) Purchaser shall not be liable to the Seller Indemnitees for indemnification under Section 5.3(a) until the aggregate amount of all Losses in respect of indemnification under Section 5.3(a) exceeds the Basket, in which event Purchaser shall be required to pay or be liable for all such Losses from the first dollar.

(c) Notwithstanding the foregoing, the limitations set forth in Section 5.4(a) and Section 5.4(b) shall not apply to Losses based upon, arising out of, with respect to or by reason of any inaccuracy in or breach of any representation or warranty in Section 2.1, Section 2.2, Section 2.3, Section 2.9, Section 2.11(d), Section 2.11(e), Section 2.11(f), Section 2.14, Section 2.16, Section 2.17, Section 2.18, Section 3.1, and Section 3.2.

(d) Seller shall not be liable to the Seller Indemnitees for indemnification under Section 5.2(c) until the amount of all such Losses exceeds, in the aggregate, $50,000 (the "***Deductible***"), in which event Seller shall only pay or be liable for Losses in excess of the Deductible.

(e) For purposes of this Section 5, any inaccuracy in or breach of any representation or warranty shall be determined without regard to any materiality, Material Adverse Effect or other similar qualification contained in or otherwise applicable to such representation or warranty.

5.5 Indemnification Procedures. The party making a claim under this Section 5 is referred to as the "***Indemnified Party***", and the party against whom such claims are asserted under this Section 5 is referred to as the "***Indemnifying Party***".

(a) Third Party Claims. If any Indemnified Party receives notice of the assertion or commencement of any Proceeding made or brought by any Person who is not a party to this Agreement or an Affiliate of a party to this Agreement or a Representative of the foregoing (a "***Third Party Claim***") against such Indemnified Party with respect to which the Indemnifying Party is obligated to provide indemnification under this Agreement, the Indemnified Party shall give the Indemnifying Party reasonably prompt written notice thereof, but in any event not later than 30 calendar days after receipt of such notice of such Third Party Claim. The failure to give such prompt written notice shall not, however, relieve the Indemnifying Party of its indemnification obligations, except and only to the extent that the Indemnifying Party forfeits rights or defenses by reason of such failure. Such notice by the Indemnified Party shall describe the Third Party Claim in reasonable detail, shall include copies of all material written evidence thereof and shall indicate the estimated amount, if reasonably practicable, of the Loss that has been or may be sustained by the Indemnified Party. The Indemnifying Party shall have the right to participate in, or by giving written notice to the Indemnified Party, to assume the defense of any Third Party Claim at the

Indemnifying Party's expense and by the Indemnifying Party's own counsel, and the Indemnified Party shall cooperate in good faith in such defense; *provided, that* if the Indemnifying Party is Seller, such Indemnifying Party shall not have the right to defend or direct the defense of any such Third Party Claim that (x) is asserted directly by or on behalf of a Person that is a supplier or customer of the Business, or (y) seeks an injunction or other equitable relief against the Indemnified Party. In the event that the Indemnifying Party assumes the defense of any Third Party Claim, subject to Section 5.5(b), it shall have the right to take such action as it deems necessary to avoid, dispute, defend, appeal or make counterclaims pertaining to any such Third Party Claim in the name and on behalf of the Indemnified Party. The Indemnified Party shall have the right to participate in the defense of any Third Party Claim with counsel selected by it subject to the Indemnifying Party's right to control the defense thereof. The fees and disbursements of such counsel shall be at the expense of the Indemnified Party, *provided, that* if in the reasonable opinion of counsel to the Indemnified Party, (A) there are legal defenses available to an Indemnified Party that are different from or additional to those available to the Indemnifying Party; or (B) there exists a conflict of interest between the Indemnifying Party and the Indemnified Party that cannot be waived, the Indemnifying Party shall be liable for the reasonable fees and expenses of counsel to the Indemnified Party in each jurisdiction for which the Indemnified Party determines counsel is required. If the Indemnifying Party elects not to compromise or defend such Third Party Claim, fails to promptly notify the Indemnified Party in writing of its election to defend as provided in this Agreement, or fails to diligently prosecute the defense of such Third Party Claim, the Indemnified Party may, subject to Section 5.5(b), pay, compromise or defend such Third Party Claim and seek indemnification for any and all Losses based upon, arising from or relating to such Third Party Claim. Seller and Purchaser shall cooperate with each other in all reasonable respects in connection with the defense of any Third Party Claim, including making available (subject to the provisions of Section 4.5) records relating to such Third Party Claim and furnishing, without expense (other than reimbursement of actual out-of-pocket expenses) to the defending party, management employees of the non-defending party as may be reasonably necessary for the preparation of the defense of such Third Party Claim.

(b) Settlement of Third Party Claims. Notwithstanding any other provision of this Agreement, the Indemnifying Party shall not enter into settlement of any Third Party Claim without the prior written consent of the Indemnified Party, except as provided in this Section 5.5(b). If a firm offer is made to settle a Third Party Claim without leading to liability or the creation of a financial or other obligation on the part of the Indemnified Party and provides, in customary form, for the unconditional release of each Indemnified Party from all liabilities and obligations in connection with such Third Party Claim and the Indemnifying Party desires to accept and agree to such offer, the Indemnifying Party shall give written notice to that effect to the Indemnified Party. If the Indemnified Party fails to consent to such firm offer within ten days after its receipt of such notice, the Indemnified Party may continue to contest or defend such Third Party Claim and in such event, the maximum liability of the Indemnifying Party as to such Third Party Claim shall not exceed the amount of such settlement offer. If the Indemnified Party fails to consent to such firm offer and also fails to assume defense of such Third Party Claim, the Indemnifying Party may settle the Third Party Claim upon the terms set forth in such firm offer to settle such Third Party Claim. If the Indemnified Party has assumed the defense pursuant to Section 5.5(a), it shall not agree to any settlement without the written consent of the Indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed).

(c) Direct Claims. Any Proceeding by an Indemnified Party on account of a Loss which does not result from a Third Party Claim (a "***Direct Claim***") shall be asserted by the Indemnified Party giving the Indemnifying Party reasonably prompt written notice thereof, but in any event not later than 30 days after the Indemnified Party becomes aware of such Direct Claim. The failure to give such prompt written notice shall not, however, relieve the Indemnifying Party of its indemnification obligations, except and only to the extent that the Indemnifying Party forfeits rights or defenses by reason of such failure. Such notice by the Indemnified Party shall describe the Direct Claim in reasonable detail, shall include copies of all material written evidence thereof and shall indicate the estimated amount, if reasonably practicable, of the Loss that has been or may be sustained by the Indemnified Party. The Indemnifying Party shall have 30 days after its receipt of such notice to respond in writing to such Direct Claim. The Indemnified Party shall allow the Indemnifying Party and its professional advisors to investigate the matter or circumstance alleged to give rise to the Direct Claim, and whether and to what extent any amount is payable in respect of the Direct Claim and the Indemnified Party shall assist the Indemnifying Party's investigation by giving such information and assistance (including access to the Indemnified Party's premises and personnel and the right to examine and copy any accounts, documents or records) as the Indemnifying Party or any of its professional advisors may reasonably request. If the Indemnifying Party does not so respond within such 30 day period, the Indemnifying Party shall be deemed to have rejected such claim, in which case the Indemnified Party shall be free to pursue such remedies as may be available to the Indemnified Party on the terms and subject to the provisions of this Agreement.

5.6 Payments.

(a) Once a Loss is agreed to by the Indemnifying Party or finally adjudicated to be payable pursuant to this Section 5, the Indemnifying Party shall satisfy its obligations within 15 business days of such final, non-appealable adjudication by wire transfer of immediately available funds. The parties hereto agree that should an Indemnifying Party not make full payment of any such obligations within such 15 business day period, any amount payable shall accrue interest from and including the date of agreement of the Indemnifying Party or final, non-appealable adjudication to and including the date such payment has been made at a rate per annum equal to five percent (5%) per annum. Such interest shall be calculated daily on the basis of a 365 day year and the actual number of days elapsed.

(b) Any Losses payable to a Purchaser Indemnitee pursuant to this Section 5 shall be satisfied from Seller.

5.7 Tax Treatment of Indemnification Payments. All indemnification payments made under this Agreement shall be treated by the parties herein as an adjustment to the Purchase Price for Tax purposes, unless otherwise required by Law.

5 . 8 Effect of Investigation. The representations, warranties and covenants of the Indemnifying Party, and the Indemnified Party's right to indemnification with respect thereto, shall not be affected or deemed waived by reason of any investigation made by or on behalf of the Indemnified Party (including by any of its Representatives) or by reason of the fact that the Indemnified Party or any of its Representatives knew or should have known that any such

representation or warranty is, was or might be inaccurate or by reason of the Indemnified Party's waiver of any condition set forth in Section 1.8, as the case may be.

5.9 Exclusive Remedies. Subject to Section 6.10, the parties acknowledge and agree that their sole and exclusive remedy with respect to any and all claims (other than claims arising from fraud, criminal activity or willful misconduct on the part of a party hereto in connection with the transactions contemplated by this Agreement) for any breach of any representation, warranty, covenant, agreement or obligation set forth herein or otherwise relating to the subject matter of this Agreement, shall be pursuant to the indemnification provisions set forth in this Section 5. In furtherance of the foregoing, each party hereby waives, to the fullest extent permitted under Law, any and all rights, claims and causes of action for any breach of any representation, warranty, covenant, agreement or obligation set forth herein or otherwise relating to the subject matter of this Agreement it may have against the other parties hereto and their Affiliates and each of their respective Representatives arising under or based upon any Law, except pursuant to the indemnification provisions set forth in this Section 5. Nothing in this Section 5.9 shall limit any Person's right to seek and obtain any equitable relief to which any Person shall be entitled or to seek any remedy on account of any party's fraudulent, criminal or intentional misconduct.

SECTION 6. MISCELLANEOUS PROVISIONS

6.1 Amendment. This Agreement may not be amended except by an instrument in writing signed by each of the parties.

6.2 Expenses. All fees and expenses incurred in connection with this Agreement, the Ancillary Documents and the transactions contemplated by this Agreement shall be paid by the party incurring such expenses.

6.3 Waiver.

(a) No failure on the part of any party to exercise any power, right, privilege or remedy under this Agreement, and no delay on the part of any party in exercising any power, right, privilege or remedy under this Agreement, shall operate as a waiver of such power, right, privilege or remedy; and no single or partial exercise of any such power, right, privilege or remedy shall preclude any other or further exercise thereof or of any other power, right, privilege or remedy.

(b) No party shall be deemed to have waived any claim arising out of this Agreement, or any power, right, privilege or remedy under this Agreement, unless the waiver of such claim, power, right, privilege or remedy is expressly set forth in a written instrument duly executed and delivered on behalf of such party; and any such waiver shall not be applicable or have any effect except in the specific instance in which it is given.

6.4 Entire Agreement; Counterparts. This Agreement and the Ancillary Documents and other documents and instruments referred to herein that are to be delivered by the parties at the Closing constitute the entire agreement and supersede all prior agreements and understandings, both written and oral, between the parties with respect to the subject matter hereof and thereof. This Agreement may be executed in several counterparts, each of which shall be deemed an

original and all of which shall constitute one and the same instrument. This Agreement may be executed by facsimile or electronic transmission, each of which shall be deemed an original.

6.5 Applicable Law; Jurisdiction; Waiver of Jury Trial.

(a) This Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware, regardless of the laws that might otherwise govern under applicable principles of conflicts of laws thereof.

(b) Each of the parties irrevocably and unconditionally (i) consents to submit itself to the sole and exclusive personal jurisdiction of the state courts of the State of Delaware or any court of the United States located in the State of Delaware in connection with any dispute, claim, or controversy arising out of or relating to this Agreement or the transactions contemplated hereby, (ii) agrees that it shall not attempt to deny or defeat such personal jurisdiction by motion or other request for leave from any such court, and (iii) agrees that it shall not bring any action, suit, or proceeding in connection with any dispute, claim, or controversy arising out of or relating to this Agreement or the transactions contemplated hereby in any court or tribunal other than the state courts of the State of Delaware or any court of the United States located in the State of Delaware. Each of the parties hereto irrevocably and unconditionally consents to service being made through the notice procedures set forth in Section 6.6. Each of the parties hereto hereby agrees that service of any process, summons, notice or document by prepaid certified or registered mail to the respective addresses set forth in Section 6.6 shall be effective service of process for any action, suit, or proceeding in connection with any dispute, claim, or controversy arising out of or relating to this Agreement and any of the transactions contemplated hereby. Nothing herein shall be deemed to limit or prohibit service of process by any other manner as may be permitted by applicable law.

(c) EACH OF THE PARTIES TO THIS AGREEMENT HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY RIGHT TO TRIAL BY JURY OF ANY CLAIM, DEMAND, ACTION, OR CAUSE OF ACTION (i) ARISING UNDER THIS AGREEMENT OR (ii) IN ANY WAY CONNECTED WITH OR RELATED OR INCIDENTAL TO THE DEALINGS OF THE PARTIES HERETO IN RESPECT OF THIS AGREEMENT OR ANY OF THE TRANSACTIONS RELATED HERETO, IN EACH CASE WHETHER NOW EXISTING OR HEREAFTER ARISING, AND WHETHER IN CONTRACT, TORT, EQUITY, OR OTHERWISE. EACH OF THE PARTIES TO THIS AGREEMENT HEREBY AGREES AND CONSENTS THAT, ANY SUCH CLAIM, DEMAND, ACTION, OR CAUSE OF ACTION SHALL BE DECIDED BY COURT TRIAL WITHOUT A JURY AND THAT THE PARTIES TO THIS AGREEMENT MAY FILE AN ORIGINAL COUNTERPART OF A COPY OF THIS AGREEMENT WITH ANY COURT AS WRITTEN EVIDENCE OF THE CONSENT OF THE PARTIES HERETO TO THE WAIVER OF THEIR RIGHT TO TRIAL BY JURY.

6.6 Assignability. This Agreement shall be binding upon, and shall be enforceable by and inure solely to the benefit of, the parties hereto and their respective successors and assigns; *provided, however*, that neither this Agreement nor any of the rights or obligations hereunder may be assigned or delegated by the Company or Purchaser without the prior written consent of the other party, and any attempted assignment or delegation of this Agreement or any of such rights or obligations without such consent shall be void and of no effect; provided *further, however*, that

Purchaser may (a) assign and delegate in whole or in part its rights and obligations hereunder without such consent in connection with the acquisition (whether by merger, consolidation, sale or otherwise) of Purchaser or of that part of Purchaser's business to which this Agreement relates, as long as Purchaser provides written notice to the Company of such assignment, and (b) assign its rights hereunder without such consent as collateral security to any Person providing financing to Purchaser or any of its Affiliates.

6.7 Third Party Beneficiaries. Except as provided in Section 5, nothing in this Agreement, express or implied, is intended to or shall confer upon any Person (other than the parties hereto) any right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

6.8 Notices. Any notice or other communication required or permitted to be delivered to either party under this Agreement shall be in writing and shall be deemed properly delivered, given and received (a) upon receipt when delivered by hand, (b) upon transmission, if sent by facsimile or electronic transmission during normal business hours (in each case with receipt verified by electronic confirmation), or (c) one (1) business day after being sent by courier or express delivery service or being sent by facsimile or electronic transmission outside of normal business hours; *provided*, that in each case the notice or other communication is sent to the address, facsimile telephone number or email address set forth beneath the name of such party below (or to such other address, facsimile telephone number or email address as such party shall have specified in a written notice given to the other party hereto):

if to Purchaser:

Strata Skin Sciences, Inc.
5 Walnut Grove Drive, Suite 140
Horsham, PA 19044
Attention: Bob Moccia, Chief Executive Officer
Email: bmoccia@strataskin.com

in the case of notices to Purchaser, with a copy to (which shall not constitute notice):

Stevens & Lee, P.C.
620 Freedom Business Center Drive, Suite 200
King of Prussia, PA 19406
Attention: Sunjeet Gill
Email: ssg@stevenslee.com

if to the Company:

Ra Medical Systems, Inc.
2070 Las Palmas Drive
Carlsbad, CA 92011
Attention: Will McGuire, Chief Executive Officer
Email: wmcguire@ramed.com

in the case of notices to the Company, with a copy to (which shall not constitute notice):

Diamond Law, Professional Corporation
5755 Oberlin Drive, Suite 301
San Diego, CA 92121
Attention: Daniel Diamond
Email: dan@diamondlawcorp.com

6.9 Severability. Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining terms and provisions hereof or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction. If the final judgment of a court of competent jurisdiction declares that any term or provision hereof is invalid or unenforceable, the parties hereto agree that the court making such determination shall have the power to limit the term or provision, to delete specific words or phrases, or to replace any invalid or unenforceable term or provision with a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision, and this Agreement shall be enforceable as so modified. In the event such court does not exercise the power granted to it in the prior sentence, the parties hereto agree to replace such invalid or unenforceable term or provision with a valid and enforceable term or provision that will achieve, to the extent possible, the economic, business and other purpose(s) of such invalid or unenforceable term.

6.10 Specific Performance. Each of the parties hereto agrees that this Agreement is intended to be legally binding and specifically enforceable pursuant to its terms and that Purchaser and the Company would be irreparably harmed if any of the provisions of this Agreement are not performed in accordance with their specific terms and that monetary damages would not provide adequate remedy in such event. Accordingly, in addition to any other remedy to which a non-breaching party may be entitled at law, a non-breaching party shall be entitled to seek injunctive relief to prevent breaches of this Agreement and to specifically enforce the terms and provisions hereof.

6.11 Construction

(a) For purposes of this Agreement, whenever the context requires: the singular number shall include the plural, and vice versa; the masculine gender shall include the feminine and neuter genders; the feminine gender shall include the masculine and neuter genders; and the neuter gender shall include masculine and feminine genders.

(b) The parties hereto agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting party shall not be applied in the construction or interpretation of this Agreement.

(c) As used in this Agreement, the words “include” and “including,” and variations thereof, shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words “without limitation.”

(d) Except as otherwise indicated, all references in this Agreement to "Sections," "Exhibits" and "Schedules" are intended to refer to Sections of this Agreement and Exhibits or Schedules to this Agreement.

(e) The headings contained in this Agreement are for convenience of reference only, shall not be deemed to be a part of this Agreement and shall not be referred to in connection with the construction or interpretation of this Agreement.

(f) All references to "dollars" or "$" or "US$" in this Agreement or any Ancillary Document refer to United States dollars, which is the currency used for all purposes in this Agreement and any Ancillary Document.

6.12 Further Actions. The parties hereto shall cooperate reasonably with each other and with their respective Representatives in connection with any steps required to be taken as part of their respective obligations under this Agreement, including the timely assignment, conveyance or other Transfer of the Transferred Assets to Purchaser, assumption of the Assumed Liabilities by Purchaser, and the consolidation, vesting and recordation of the full ownership thereof. The parties hereto shall (a) furnish upon reasonable request to each other such further information, (b) execute and deliver to each other such other documents and (c) do such other acts and things, all as any other party hereto may reasonably request for the purpose of carrying out the intent of this Agreement.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed as of the date first above written.

PURCHASER:

STRATA SKIN SCIENCES, INC.

By: /s/ Robert J. Moccia
Name: Robert J. Moccia
Title: Chief Executive Officer

COMPANY:

RA MEDICAL SYSTEMS, INC.

By: /s/ Will McGuire
Name: Will McGuire
Title: Chief Executive Officer

EXHIBIT A

CERTAIN DEFINITIONS

For purposes of the Agreement (including this Exhibit A), the following defined terms shall have the following meanings:

"***Affiliate***" means, with respect to any Person, any other Person that directly, or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, such first Person.

"***Ancillary Documents***" means the Bill of Sale, the Assignment and Assumption Agreement, Trademark Assignment Agreement, the Services Agreement, and the other agreements, instruments and documents required to be delivered at the Closing.

"***Business IT Systems***" means all Software, computer hardware, servers, networks, platforms, peripherals, and similar or related items of automated, computerized, or other information technology (IT) networks and systems (including telecommunications networks and systems for voice, data, and video) owned, leased, licensed, or used (including through cloud-based or other third-party service providers) in the conduct of the Business.

"***Closing Date***" means the Effective Date.

"***Code***" means the Internal Revenue Code of 1986, as amended.

"***Competition***" means engaging, directly or indirectly, in the design, development, production, manufacturing, distribution, provision, licensing, promotion, marketing or sale of any products or services that compete with any products or services (including, but not limited to, the Products) in the field of dermatology, including, but not limited to, both the treatment and diagnosis of skin disorders.

"***Consent***" means any notification, authorization, consent, approval or waiver.

"***Contract***" means any note, bond, mortgage, indenture, loan, contract, factoring arrangement, license, agreement, lease or other instrument or obligation, written or oral, to which the party in question is a party or by which it or any of its assets may be bound.

"***Document Deliverables***" mean, without duplication, (a) all Regulatory Documentation; (b) books, records, manuals, files, invoices, inventory records, product specifications, customer lists (for the 36 months immediately preceding the date of this Agreement, where practical and available), cost and pricing information, physician lists, supplier lists, business plans, catalogs, customer literature, quality control records and credit records of customers; (c) research, design and development files, records and laboratory books; (d) all sales, advertising, marketing, promotional and training materials and all other printed or written materials used or held for use primarily in the operation of the Business; (e) all data relevant to the manufacturing of the Product; (f) copies of current and former employee and contractor agreements relating to the nonuse and nondisclosure (or the like) of Intellectual Property Assets; (g) copies of current and former employee and contractor agreements relating to the nonuse and nondisclosure (or the like) of

Intellectual Property with such Person's former employer; and (h) all other documentation related to the Transferred Assets.

"***Effective Date***" has the meaning set forth in the preamble to this Agreement.

"***Employee Plans***" means all "employee benefit plans" within the meaning of Section 3(3) of Employee Retirement Income Security Act of 1974, as amended, all formal written and informal plans and all other compensation and benefit plans, Contracts, policies, programs and arrangements maintained, sponsored, or contributed or required to be contributed to by the Company on behalf of any Business Employee (other than routine administrative procedures), including all pension, profit sharing, savings and thrift, bonus, stock bonus, stock option or other cash or equity-based incentive or deferred compensation, severance pay and medical and life insurance plans in which any present or former employees, officers, directors, retirees, independent contractors or consultants of Seller or their dependents participate.

"***Encumbrance***" means any charge, claim, community property interest, pledge, condition, equitable interest, Lien, option, security interest, mortgage, easement, encroachment, right of way, right of first refusal, or restriction of any kind, including any restriction on use, voting, transfer, receipt of income or exercise of any other attribute of ownership.

"***Environmental Claim***" means any Proceeding, Governmental Order, Lien, fine, penalty, or, as to each, any settlement or judgment arising therefrom, by or from any Person alleging liability of whatever kind or nature (including liability or responsibility for the costs of enforcement proceedings, investigations, cleanup, governmental response, removal or remediation, natural resources damages, property damages, personal injuries, medical monitoring, penalties, contribution, indemnification and injunctive relief) arising out of, based on or resulting from: (a) the presence, Release of, or exposure to, any Hazardous Materials; or (b) any actual or alleged non-compliance with any Environmental Law or term or condition of any Environmental Permit.

"***Environmental Law***" means any applicable Law, and any Governmental Order or binding agreement with any Governmental Body: (a) relating to pollution (or the cleanup thereof) or the protection of natural resources, endangered or threatened species, human health or safety, or the environment (including ambient air, soil, surface water or groundwater, or subsurface strata); or (b) concerning the presence of, exposure to, or the management, manufacture, use, containment, storage, recycling, reclamation, reuse, treatment, generation, discharge, transportation, processing, production, disposal or remediation of any Hazardous Materials. The term "***Environmental Law***" includes, without limitation, the following (including their implementing regulations and any state analogs): the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended by the Superfund Amendments and Reauthorization Act of 1986, 42 U.S.C. §§ 9601 et seq.; the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended by the Hazardous and Solid Waste Amendments of 1984, 42 U.S.C. §§ 6901 et seq.; the Federal Water Pollution Control Act of 1972, as amended by the Clean Water Act of 1977, 33 U.S.C. §§ 1251 et seq.; the Toxic Substances Control Act of 1976, as amended, 15 U.S.C. §§ 2601 et seq.; the Emergency Planning and Community Right-to-Know Act of 1986, 42 U.S.C. §§ 11001 et seq.; the Clean Air Act of 1966, as amended by the Clean Air Act

Amendments of 1990, 42 U.S.C. §§ 7401 et seq.; and the Occupational Safety and Health Act of 1970, as amended, 29 U.S.C. §§ 651 et seq.

"***Environmental Notice***" means any written directive, notice of violation or infraction, or notice respecting any Environmental Claim relating to actual or alleged non-compliance with any Environmental Law or any term or condition of any Environmental Permit.

"***Environmental Permit***" means any Governmental Authorization, letter, clearance, consent, waiver, closure, exemption, decision or other action required under or issued, granted, given, authorized by or made pursuant to Environmental Law.

"***FDA***" means the United States Food and Drug Administration and any comparable agencies in foreign countries, together in each case, with any successor agencies.

"***FDCA***" means the Federal Food, Drug and Cosmetics Act, as amended, and all related rules, regulations and guidelines promulgated thereunder by the FDA.

"***Federal Health Care Program***" means any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States government and any state health care program, as defined in 42 U.S.C. § 1320a-7(h).

"***Financial Statements***" means the segment information relating to the "Dermatology" segment of Seller included in the consolidated financial statements (including all related notes and schedules) of Seller included or incorporated by reference in the Seller SEC Documents.

"***GAAP***" means generally accepted accounting principles as in effect from time to time in the United States of America.

"***Governmental Authorization***" means any permit, license, registration, authorization, certificate, franchise, concession, approval, consent, ratification, permission, or clearance for the Product issued, granted, given or otherwise made available by or under the authority of any Governmental Body or pursuant to any Law, including (a) pricing or reimbursement approvals, (b) 510(k)s and supplements and amendments thereto, and (c) labeling approvals.

"***Governmental Body***" means any national, federal, regional, state, provincial, local, or foreign or other governmental authority or instrumentality, legislative body, court, administrative agency, regulatory body, commission or instrumentality, including any multinational authority having governmental or quasi-governmental powers, or any other industry self-regulatory authority.

"***Governmental Order***" means any order, writ, judgment, injunction, decree, stipulation, determination or award entered by or with any Governmental Body.

"***Health Care Laws***" means, to the extent applicable, all: (a) Laws administered by the FDA, including the FDCA, and any other federal, state and foreign Laws governing the manufacturer, distribution, and sale of medical devices; (b) federal fraud and abuse Laws, including the federal physician self-referral law, 42 U.S.C. § 1395nn, the federal anti-kickback statute, 42 U.S.C. § 1320a-7b, the federal civil monetary penalty statute, 42 U.S.C. § 1320a-7a, federal laws and regulations governing exclusion including 42 U.S.C. § 1320a-7, the civil false claims act (31 U.S.C. § 3729 et seq.) and the regulations promulgated pursuant to such statutes, as well as similar state laws and regulations; (c) federal and state Laws regarding the submission of false claims, false billing and false coding, fee splitting, and health care professional self-referrals; (d) the Health Insurance Portability and Accountability Act of 1996 and all Laws promulgated pursuant thereto or in connection therewith, the Health Information Technology for Economic and Clinical Health Act, found in the American Recovery and Reinvestment Act of 2009 at Division A, Title XIII and Division B, Title IV, and any other Law governing; (e) any Law or applicable regulation with respect to expulsion, suspension or debarment from any Federal Health Care Program; (f) any other Law applicable to any other aspect of the Business; and (g) with regard to clauses (a) through (f) above, any Law succeeding thereto and all amendments and supplements to such Laws.

"***Intellectual Property***" means all of the following in any jurisdiction throughout the world, together with all income, royalties, damages and payments due or payable as of the Closing or thereafter (including damages and payments for past, present or future infringements or misappropriations thereof, the right to sue and recover for past infringements or misappropriations thereof and any and all corresponding rights that, now or hereafter, may be secured throughout the world): (a) patents and industrial designs (including utility model rights, design rights and industrial property rights), patent and industrial design applications, patent disclosures and inventions (whether or not patentable and whether or not reduced to practice), design specifications and drawings, and any reissue, continuation, continuation-in-part, revision, extension or reexamination thereof (collectively, "***Patents***"); (b) trademarks, service marks, trade dress, logos, slogans, trade names, Internet domain names, corporate names and other designations and indicia of origin (and all translations, adaptations, derivations and combinations of the foregoing and all logos related to any of the foregoing), together with all goodwill associated therewith (collectively, "***Trademarks***"); (c) copyrights, works of authorship, copyrightable works and mask works; (d) and all registrations, applications and renewals for any of the foregoing referenced in any of (a) through (c), together with all moral rights therein; (e) trade secrets and confidential and proprietary information (including ideas, discoveries, formulae, compositions, know-how, related processes and techniques, research and development information, models, drawings, specifications, designs, plans, proposals and technical data and manuals, nonclinical and clinical research data and results, regulatory, quality manufacturing and vendor/supplier data, files filings and information, instructions, materials, expertise and other technology applicable to formulations, compositions or products or to their manufacture, development, registration, use or marketing or to methods of assaying or testing them or processes for their manufacture, formulations containing them or compositions incorporating or comprising them, and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, instructions, processes, formulae, expertise and information, relevant to the research, development, manufacture, use, importation, offering for sale or sale of, and/or which may be useful in studying, testing, developing, producing or formulating, products, or intermediates for the synthesis thereof ("***Trade Secrets***"); (f) software, computer programs, operating systems, applications, firmware and other code, including all source code, object code, application programming interfaces, data files, databases, protocols, specifications, and other documentation thereof, and related flow-charts, programmer notes, updates and data, whether in

object or source code form and all other documentation associated therewith ("***Software***"); (g) all other properties recognized as intellectual property anywhere in the world and any similar, corresponding or equivalent rights; and (h) all copies and tangible embodiments of any of the foregoing referenced in any of (a) through (g).

"***Intellectual Property Agreements***" means all licenses, sublicenses, consent to use agreements, settlements, coexistence agreements, covenants not to sue, waivers, releases, permissions and other Contracts, whether written or oral, relating to any Intellectual Property that is used or held for use in the conduct of the Business as currently conducted to which the Company is a party, beneficiary or otherwise bound.

"***Intellectual Property Assets***" means all Intellectual Property that is owned by the Company and used or held for use in the conduct of the Business as currently conducted (and not, for example, solely in any other vertical or business of the Company), together with all (i) royalties, fees, income, payments, and other proceeds now or hereafter due or payable to the Company with respect to such Intellectual Property; and (ii) claims and causes of action with respect to such Intellectual Property, whether accruing before, on, or after the date hereof/accruing on or after the date hereof, including all rights to and claims for damages, restitution, and injunctive and other legal or equitable relief for past, present, or future infringement, misappropriation, or other violation thereof. For the avoidance of doubt, there are no Patents applicable to the Business.

"***Intellectual Property Registrations***" means all Intellectual Property Assets that are subject to any issuance, registration, or application by or with any Governmental Body or authorized private registrar in any jurisdiction, including issued Patents, registered Trademarks, domain names and copyrights, and pending applications for any of the foregoing.

"***Knowledge of the Company***" means the actual knowledge of the Company's Board of Directors, Chief Executive Officer, Chief Financial Officer, or General Counsel, after conducting a reasonable inquiry and investigation (consistent with such Person's title).

"***Law***" means any federal, state, local, municipal, foreign or other law, statute, constitution, principle of common law, rule, regulation, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Body.

"***Liabilities***" means liabilities, obligations or commitments of any nature whatsoever, asserted or unasserted, known or unknown, absolute or contingent, accrued or unaccrued, matured or unmatured or otherwise.

"***Lien***" means any mortgage, deed of trust, pledge, security interest, hypothecation, assignment, lien (statutory or other), charge, or other encumbrance of any kind or nature whatsoever (including, without limitation, pursuant to any conditional sale or other title retention agreement, any financing lease having substantially the same economic effect as any of the foregoing, and the filing of any financing statement under the UCC or comparable law of any jurisdiction to evidence any of the foregoing) on personal or real property or fixtures.

"***Losses***" means losses, damages, liabilities, deficiencies, judgments, interest, awards, penalties, fines, costs or expenses of whatever kind, including reasonable attorneys' fees and the cost of enforcing any right to indemnification hereunder and the cost of pursuing any insurance providers; *provided, however*, that "Losses" shall not include punitive damages, except to the extent actually awarded to a Governmental Body or other third party.

"***Material Adverse Effect***" means any event, occurrence, fact, condition or change that is, or could reasonably be expected to become, individually or in the aggregate, materially adverse to (a) the business, results of operations, condition (financial or otherwise) or assets of the Business, (b) the value of the Transferred Assets, or (c) the ability of Seller to consummate the transactions contemplated hereby on a timely basis; *provided, however,* that "***Material Adverse Effect***" shall not include any event, occurrence, fact, condition or change, directly or indirectly, arising out of or attributable to: (i) general economic or political conditions; (ii) conditions generally affecting the industries in which the Business operates; (iii) any changes in financial or securities markets in general; (iv) acts of war (whether or not declared), armed hostilities or terrorism, or the escalation or worsening thereof; (v) any action required or permitted by this Agreement; or (vi) any changes in applicable Laws or accounting rules, including GAAP; *provided further, however,* that any event, occurrence, fact, condition or change referred to in clauses (i) through (iv) immediately above shall be taken into account in determining whether a Material Adverse Effect has occurred or could reasonably be expected to occur to the extent that such event, occurrence, fact, condition or change has a disproportionate effect on the Business compared to other participants in the industries in which the Business operates.

"***Person***" means any individual, entity, trust, other partnership or association, or Governmental Body.

"***Proceeding***" means any action, arbitration, audit, hearing, investigation, litigation or suit (whether civil, criminal, administrative, judicial or investigative, whether formal or informal, whether public or private) commenced, brought, conducted or heard by or before, or otherwise involving, any Governmental Body or arbitrator.

"***Product***" means that PHAROS excimer laser product, including any line extensions, modifications, improvements, additions, and successors thereto.

"***Record***" means data and information that is inscribed on a tangible medium or that is stored in an electronic or other medium and is retrievable in perceivable form, including data and information used in, generated by, obtained for the benefit of, arising out of, related to, or otherwise used in connection with or necessary to the operation of the Business.

"***Release***" means any actual or threatened release, spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, abandonment, disposing or allowing to escape or migrate into or through the environment (including, without limitation, ambient air (indoor or outdoor), surface water, groundwater, land surface or subsurface strata or within any building, structure, facility or fixture).

"***Regulatory Documentation***" means, with respect to the Product, all (a) documentation comprising the Governmental Authorizations, including all submissions, reports and

correspondence relating thereto, (b) correspondence and reports necessary to, or otherwise describing the ability to, commercially distribute, sell or market such Product, submitted to or received from Governmental Body (including minutes and official contact reports relating to any communications with any Governmental Body) and relevant supporting documents with respect thereto, including all advertising and promotion documents, annual and periodic reports, adverse event files and complaint files and (c) data contained in any of the foregoing. "***Regulatory Documentation***" shall include all risk analysis reports, Failure Mode and Effects Analyses, Quality management reviews, and Post market surveillance reports.

"***Representative***" shall mean, with respect to any Person, such Person's directors, officers, employees, advisors, agents, consultants, attorneys, accountants, investment bankers or other representatives.

"***Restricted Period***" means the period commencing on the Closing Date and ending on the seventh anniversary of the Closing Date.

"***Restricted Territory***" means any county in the State of California, each state in the United States and each country in the world.

"***Seller SEC Documents***" means any forms, statements, documents and reports filed or furnished by Seller with the SEC on or after August 15, 2019 and publicly available prior to the date hereof (including exhibits and other information incorporated by reference therein but excluding any predictive, cautionary or forward looking disclosures contained under the captions "risk factors", "forward looking statements" or any similar precautionary sections and any other disclosures contained therein that are predictive, cautionary or of a forward looking nature).

"***Tax***" or "***Taxes***" means (a) any federal, state, local, or foreign income, gross receipts, license, payroll, employment, excise, severance, stamp, occupation, premium, windfall profits, environmental, customs duties, capital stock, franchise, profits, withholding, social security (or similar), unemployment, disability, real property, personal property, sales, use, transfer, registration, value added, alternative or add-on minimum, retailer's occupation taxes and other taxes commonly understood to be sales or use taxes, estimated, or other tax of any kind whatsoever, including any interest, penalty, or addition thereto, whether disputed or not, (b) any obligations or liabilities for any amounts or items of the type described in clause (a) above of any other Person whether by Law, Contract or otherwise.

"***Tax Authority***" means any Governmental Body responsible for the administration or collection of any Tax.

"***Tax Return***" means any return (including any information return), report, statement, declaration, estimate, schedule, notice, notification, form, election, certificate or other document or information that is required to be filed with or submitted to, any Tax Authority in connection with the determination, assessment, collection or payment of any Tax or in connection with the administration, implementation or enforcement of or compliance with any Law relating to any Tax.

Exhibit 10.2

SERVICES AGREEMENT

Between

RA MEDICAL SYSTEMS, INC.

And

STRATA SKIN SCIENCES, INC.

dated as of

August 16, 2021

SERVICES AGREEMENT

This Services Agreement, dated as of August 16, 2021 (this "**Agreement**"), is entered into between RA MEDICAL SYSTEMS, INC., a Delaware corporation ("**Seller**"), and STRATA SKIN SCIENCES, INC., a Delaware corporation ("**Purchaser**").

RECITALS

WHEREAS, Purchaser and Seller have entered into that certain Asset Purchase Agreement, dated as of August 16, 2021 (the "**Purchase Agreement**"), pursuant to which Seller has agreed to sell and assign to Purchaser, and Purchaser has agreed to purchase and assume from Seller, certain of the assets, and certain specified liabilities, of the Business (as such term is defined in the Purchase Agreement), all as more fully described therein;

WHEREAS, in order to ensure an orderly transition of the Business to Purchaser and as a condition to consummating the transactions contemplated by the Purchase Agreement, Purchaser and Seller have agreed to enter into this Agreement, pursuant to which Seller will provide, or cause its Affiliates to provide, Purchaser with certain services, subject to the terms and conditions set forth herein; and

WHEREAS, capitalized terms used herein and not otherwise defined shall have the meaning ascribed to such terms in the Purchase Agreement.

NOW, THEREFORE, in consideration of the mutual agreements and covenants hereinafter set forth, Purchaser and Seller hereby agree as follows:

ARTICLE I
Services

Section 1.01 Provision of Services.

(a) Seller agrees to provide, or to cause its Affiliates to provide, the services (the "**Services**") set forth on the exhibits attached hereto (as such exhibits may be amended or supplemented pursuant to the terms of this Agreement, collectively, the "**Service Exhibits**") to Purchaser for the respective periods and on the other terms and conditions set forth in this Agreement and in the respective Service Exhibits.

(b) Notwithstanding the contents of the Service Exhibits, Seller agrees to respond in good faith to any reasonable request by Purchaser for access to any additional services that are necessary for the operation of the Business and which are not currently contemplated in the Service Exhibits, at a price to be agreed upon after good faith negotiations between the parties. Any such additional services so provided by Seller shall constitute Services under this Agreement and be subject in all respect to the provisions of this Agreement as if fully set forth on a Service Exhibit as of the date hereof.

(c) Subject to Section 2.03, Section 2.04, and Section 3.02, the obligations of Seller under this Agreement to provide Services shall terminate with respect to each Service on the end date specified in the applicable Service Exhibit (the "**End Date**"). Notwithstanding the foregoing, the parties acknowledge and agree that Purchaser may determine from time to time that it does not require all the Services set out on one or more of the Service Exhibits or that it does not require such Services for the entire period up to the applicable End Date. Accordingly, Purchaser may terminate any Service, in whole and not in part, upon notification to Seller in writing of any such determination.

Section 1.02 Standard of Service.

(a) Seller represents, warrants and agrees that the Services shall be provided in good faith, in accordance with Law and, except as specifically provided in the Service Exhibits, in a manner generally consistent with, and subject to warranties ("**Seller Warranties**") provided to customers in accordance with, the historical provision of the Services and the Products, including, but not limited to, chambers (new or refurbished), other spare parts (new or refurbished), and consumables, to customers and with the same standard of care as historically provided. Seller represents and warrants to Purchaser that Schedule 1.02 sets forth a true and accurate list of all of the Seller Warranties, including as to warranty duration, that Seller has historically provided to customers. The Seller Warranties shall have a duration of one year or such longer period as is set forth with respect to such subject matter as set forth on Schedule 1.02. Subject to Section 1.03, Seller agrees to assign sufficient resources and qualified personnel as are reasonably required to perform the Services in accordance with the standards set forth in the preceding sentence. Seller must comply and be approved as an approved supplier to Purchaser in accordance to the purchaser quality management system.

(b) Except as expressly set forth in Section 1.02(a) or in any contract entered into hereunder, Seller makes no representations and warranties of any kind, implied or expressed, with respect to the Services, including, without limitation, no warranties of merchantability or fitness for a particular purpose, which are specifically disclaimed. Purchaser acknowledges and agrees that this Agreement does not create a fiduciary relationship, partnership, joint venture or relationships of trust or agency between the parties and that all Services are provided by Seller as an independent contractor.

Section 1.03 Third-Party Service Providers. Seller shall have the right to hire third-party subcontractors to provide all or part of any Service hereunder; *provided*, *however*, that in the event such subcontracting is inconsistent with past practices, Seller shall obtain the prior written consent of Purchaser to hire such subcontractor, such consent not to be unreasonably withheld. Seller shall in all cases retain responsibility for the provision to Purchaser of Services to be performed by any third-party service provider or subcontractor or by any of Seller's Affiliates. Such Third-Party Service Provider should comply with all regulatory mandated regulations and be approved by the Seller and Purchaser.

Section 1.04 Access to Premises.

(a) Seller agrees that all of its and its Affiliates' employees and any third-party service providers and subcontractors, when on the property of Purchaser or when given access to any equipment, computer, software, network or files owned or controlled by Purchaser, shall conform to the policies and procedures of Purchaser concerning health, safety and security which are made known to Seller in advance in writing.

ARTICLE II
Compensation

Section 2.01 Responsibility for Wages and Fees. For such time as any employees of Seller or any of its Affiliates are providing the Services to Purchaser under this Agreement, (a) such employees will remain employees of Seller or such Affiliate, as applicable, and shall not be deemed to be employees of Purchaser for any purpose, and (b) Seller or such Affiliate, as applicable, shall be solely responsible for the payment and provision of all wages, bonuses and commissions, employee benefits, including severance and worker's compensation, and the withholding and payment of applicable Taxes relating to such employment. Seller represents and warrants to Purchaser that Schedule 2.01(a) sets forth a true and accurate list of each employee of Seller who will be providing the Services, on behalf of the Seller, including their annual base salary or hourly wage and fringe and other benefit costs (collectively, for each employee, an "**Employee Cost**"). Schedule 2.01(b) sets forth the terms of a retention bonus to be offered by Seller to certain of its employees. When calculating the fee for Services provided during the two month period following the date hereof, the Employee Cost included in the monthly fee for each such bundled Service shall not be duplicated when calculating the fee for any other bundled Service provided by Seller.

Section 2.02 Terms of Payment and Related Matters.

(a) As consideration for provision of the Services, Purchaser shall pay Seller the amount specified for each Service on such Service's respective Service Exhibit. In addition to such amount, in the event that Seller or any of its Affiliates incurs, at the direction of Purchaser, reasonable and documented out-of-pocket travel-related expenses in the provision of any Service (such included expenses, collectively, "**Travel Costs**"), Purchaser shall reimburse Seller for all such Travel Costs in accordance with the invoicing procedures set forth in Section 2.02(b). Except for the fees described in the Service Exhibit and the Travel Costs, Purchaser shall not be liable for any other expenses or costs in the provision of any Service, including, but not limited to, payments made to employees of Seller or any of its Affiliates pursuant to Section 2.01, license fees and payments to third-party service providers or subcontractors.

(b) As more fully provided in the Service Exhibits and subject to the terms and conditions therein:

(i) Seller shall provide Purchaser, in accordance with Section 5.01 of this Agreement, with monthly invoices ("**Invoices**"), which shall set forth in reasonable detail, with such supporting documentation as Purchaser may reasonably request with respect to Travel Costs and any other amounts payable under this Agreement; and

(ii) payments pursuant to this Agreement shall be made within thirty (30) days after the date of receipt of an Invoice by Purchaser from Seller.

(c) It is the intent of the parties that the compensation set forth in the respective Service Exhibits reasonably approximate the cost of providing the Services, including the cost of employee wages and compensation, without any intent to cause Seller to receive profit or incur loss, and the fees shall remain fixed for the term of the Services provided.

Section 2.03 Extension of Services. The parties agree that Seller shall not be obligated to perform any Service after the applicable End Date; *provided*, *however*, that if Purchaser desires and Seller agrees to continue to perform any of the Services after the applicable End Date, the parties shall negotiate in good faith to determine an amount that compensates Seller for all of its costs for such performance, including the time of its employees and its Travel Costs. The Services so performed by Seller after the applicable End Date shall continue to constitute Services under this Agreement and be subject in all respects to the provisions of this Agreement for the duration of the agreed-upon extension period.

Section 2.04 Terminated Services. Upon termination or expiration of any or all Services pursuant to this Agreement, or upon the termination of this Agreement in its entirety, Seller shall have no further obligation to provide the applicable terminated Services and Purchaser will have no obligation to pay any future compensation or Travel Costs relating to such Services (other than for or in respect of Services already provided in accordance with the terms of this Agreement and received by Purchaser prior to such termination).

Section 2.05 Invoice Disputes. In the event of an Invoice dispute, Purchaser shall deliver a written statement to Seller no later than five (5) days prior to the date payment is due on the disputed Invoice listing all disputed items and providing a reasonably detailed description of each disputed item. Amounts not so disputed shall be deemed accepted and shall be paid, notwithstanding disputes on other items, within the period set forth in Section 2.02(b). The parties shall seek to resolve all such disputes expeditiously and in good faith. Seller shall continue performing the Services in accordance with this Agreement pending resolution of any dispute.

Section 2.06 No Right of Setoff. Each of the parties hereby acknowledges that it shall have no right under this Agreement to offset any amounts owed (or to become due and owing) to the other party, whether under this Agreement, the Purchase Agreement or otherwise, against any other amount owed (or to become due and owing) to it by the other party.

Section 2.07 **Taxes**. Purchaser shall be responsible for all sales or use Taxes imposed or assessed as a result of the provision of Services by Seller.

Section 2.08 **Product Insurance**. During the term of this Agreement, Purchaser shall purchase and maintain an insurance policy sufficient to cover damages to all inventory held by Seller pursuant to this Agreement, including, but not limited to spare parts, the cost of such policy to be borne by Purchaser. Seller will have no liability for loss of inventory to the extent such inventory is underinsured by Purchaser.

ARTICLE III
Termination

Section 3.01 **Termination of Agreement**. This Agreement shall terminate in its entirety on the date upon which Seller shall have no continuing obligation to perform any Services as a result of each of their expiration or termination in accordance with Section 1.01(c).

Section 3.02 **Effect of Termination**. Upon termination of this Agreement in its entirety pursuant to Section 3.01, all obligations of the parties hereto shall terminate, except for the provisions of Section 2.04, Section 2.06, Section 2.07, Section 2.08, Article IV and Article V, which shall survive any termination or expiration of this Agreement.

ARTICLE IV
Confidentiality and Non-Solicitation

Section 4.01 **Confidentiality**.

(a) During the term of this Agreement and thereafter, the parties hereto shall, and shall instruct their respective Representatives to, maintain in confidence and not disclose the other party's financial, technical, sales, marketing, development, personnel, and other information, records, or data, including, without limitation, customer lists, supplier lists, trade secrets, designs, product formulations, product specifications or any other proprietary or confidential information, however recorded or preserved, whether written or oral (any such information, "**Confidential Information**"). Each party hereto shall use the same degree of care, but no less than reasonable care, to protect the other party's Confidential Information as it uses to protect its own Confidential Information of like nature. Unless otherwise authorized in any other agreement between the parties, any party receiving any Confidential Information of the other party (the "**Receiving Party**") may use Confidential Information only for the purposes of fulfilling its obligations under this Agreement (the "**Permitted Purpose**"). Any Receiving Party may disclose such Confidential Information only to its Representatives who have a need to know such information for the Permitted Purpose and who have been advised of the terms of this Section 4.01 and the Receiving Party shall be liable for any breach of these confidentiality provisions by such Persons; *provided*, *however*, that any Receiving Party may disclose such Confidential Information to the extent such Confidential Information is required to be disclosed by a Governmental Order, in which case the Receiving Party shall promptly notify, to the extent

possible, the disclosing party (the "**Disclosing Party**"), and take reasonable steps to assist in contesting such Governmental Order or in protecting the Disclosing Party's rights prior to disclosure, and in which case the Receiving Party shall only disclose such Confidential Information that it is advised by its counsel in writing that it is legally bound to disclose under such Governmental Order.

(b) Notwithstanding the foregoing, "Confidential Information" shall not include any information that the Receiving Party can demonstrate: (i) was publicly known at the time of disclosure to it, or has become publicly known through no act of the Receiving Party or its Representatives in breach of this Section 4.01; (ii) was rightfully received from a third party without a duty of confidentiality; or (iii) was developed by it independently without any reliance on the Confidential Information.

(c) Upon demand by the Disclosing Party at any time, or upon expiration or termination of this Agreement with respect to any Service, the Receiving Party agrees promptly to return or destroy, at the Disclosing Party's option, all Confidential Information. If such Confidential Information is destroyed, an authorized officer of the Receiving Party shall certify to such destruction in writing.

(d) All schedules and attachments hereto shall be kept confidential, and, if required to be publicly disclosed, shall be redacted to protect any Confidential Information.

Section 4.02 Non-Solicitation. During the term of this Agreement and for a period of twelve months thereafter and without the written consent of Seller, Purchaser shall not directly or indirectly solicit any of the Seller's employees to terminate such employee's employment with the Seller; provided, however, that the foregoing restrictions shall not prevent Purchaser from hiring any employee whose employment was terminated by Seller.

ARTICLE V
Miscellaneous

Section 5.01 Notices. All Invoices, notices, requests, consents, claims, demands, waivers and other communications hereunder shall be in writing and shall be deemed to have been given: (a) when delivered by hand (with written confirmation of receipt); (b) when received by the addressee if sent by a nationally recognized overnight courier (receipt requested); (c) on the date sent by facsimile or e-mail of a PDF document (with confirmation of transmission) if sent during normal business hours of the recipient, and on the next Business Day if sent after normal business hours of the recipient; or (d) on the third day after the date mailed, by certified or registered mail, return receipt requested, postage prepaid. Such communications

must be sent to the respective parties at the following addresses (or at such other address for a party as shall be specified in a notice given in accordance with this Section 5.01):

(a) if to Seller:

Ra Medical Systems, Inc.
2070 Las Palmas Drive
Carlsbad, California 92011
E-mail: wmcguire@ramed.com
Attention: Chief Executive Officer

with a copy (which shall not constitute notice) to:

Diamond Law, Professional Corporation
5755 Oberlin Drive, Suite 301
San Diego, CA 92121
Attention: Daniel Diamond
Email: dan@diamondlawcorp.com

(b) if to Purchaser:

STRATA Skin Sciences, Inc.
5 Walnut Grove, Suite 140
Horsham, Pennsylvania 19044
E-mail: bmoccia@strataskin.com
Attention: Chief Executive Officer

with a copy (which shall not constitute notice) to:

Stevens & Lee, P.C.
620 Freedom Business Center Drive, Suite 200
King of Prussia, Pennsylvania 19406
E-mail: ssg@stevenslee.com
Attention: Sunjeet S. Gill

Section 5.02 **Headings**. The headings in this Agreement are for reference only and shall not affect the interpretation of this Agreement.

Section 5.03 **Severability**. If any term or provision of this Agreement is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction. Upon such determination that any term or other provision is invalid, illegal or unenforceable, the parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in a mutually acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible.

Section 5.04 **Entire Agreement**. This Agreement, including all Service Exhibits, constitutes the sole and entire agreement of the parties to this Agreement with respect to the subject matter contained herein and supersedes all prior and contemporaneous understandings and agreements, both written and oral, with respect to such subject matter. In the event and to the extent that there is a conflict between the provisions of this Agreement and the provisions of the Purchase Agreement as it relates to the Services hereunder, the provisions of this Agreement shall control.

Section 5.05 **Successors and Assigns**. This Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors and permitted assigns. Subject to the following sentence, neither party may assign its rights or obligations hereunder without the prior written consent of the other party, which consent shall not be unreasonably withheld or delayed. Notwithstanding the foregoing sentence, Purchaser may, without the prior written consent of Seller, assign all or any portion of its right to receive Services to any of its Affiliates that participate in the operation of the Business; *provided*, that such Affiliate shall receive such Services from Seller in the same place and manner as described in the respective Service Exhibit as Purchaser would have received such Service. No assignment shall relieve the assigning party of any of its obligations hereunder.

Section 5.06 **No Third-Party Beneficiaries**. This Agreement is for the sole benefit of the parties hereto and their respective successors and permitted assigns and nothing herein, express or implied, is intended to or shall confer upon any other Person any legal or equitable right, benefit or remedy of any nature whatsoever, under or by reason of this Agreement.

Section 5.07 **Amendment and Modification; Waiver**. This Agreement may only be amended, modified or supplemented by an agreement in writing signed by each party hereto. No waiver by any party of any of the provisions hereof shall be effective unless explicitly set forth in writing and signed by the party so waiving. No failure to exercise, or delay in exercising, any right, remedy, power or privilege arising from this Agreement shall operate or be construed as a waiver thereof; nor shall any single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege.

Section 5.08 **Governing Law; Submission to Jurisdiction**. This Agreement shall be governed by and construed in accordance with the internal laws of the State of Delaware without giving effect to any choice or conflict of law provision or rule (whether of the State of Delaware or any other jurisdiction) that would cause the application of Laws of any jurisdiction other than those of the State of Delaware. Any legal suit, action or proceeding arising out of or based upon this agreement or the transactions contemplated hereby may be instituted in the federal courts of the United States of America or the courts of the state of Delaware in each case located in the city of Wilmington and county of New Castle, and each party irrevocably submits to the exclusive jurisdiction of such courts in any such suit, action or proceeding. Service of process, summons, notice or other document by mail to such party's address set forth herein shall be effective service of process for any suit, action or other proceeding brought in any such court.

The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or any proceeding in such courts and irrevocably waive and agree not to plead or claim in any such court that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum.

Section 5.09 Waiver of Jury Trial. Each party irrevocably and unconditionally waives any right it may have to a trial by jury in respect of any legal action arising out of or relating to this agreement or the transactions contemplated hereby. Each party to this agreement certifies and acknowledges that (a) no representative of any other party has represented, expressly or otherwise, that such other party would not seek to enforce the foregoing waiver in the event of a legal action, (b) such party has considered the implications of this waiver, (c) such party makes this waiver voluntarily, and (d) such party has been induced to enter into this agreement by, among other things, the mutual waivers and certifications in this Section 5.09.

Section 5.10 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall be deemed to be one and the same agreement. A signed copy of this Agreement delivered by facsimile, e-mail or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date first written above by their respective officers thereunto duly authorized.

STRATA SKIN SCIENCES, INC.

By: /s/ Robert J. Moccia
Name: Robert J. Moccia
Title: Chief Executive Officer

RA MEDICAL SYSTEMS, INC.

By: /s/ Will McGuire
Name: Will McGuire
Title: Chief Executive Officer

TRADEMARK ASSIGNMENT AGREEMENT

This Trademark Assignment Agreement (this "***Assignment***"), dated as of August 16, 2021, is made by and between Ra Medical Systems, Inc., a Delaware corporation ("***Assignor***"), and Strata Skin Sciences, Inc., a Delaware corporation ("***Assignee***").

WHEREAS, Assignor and Assignee have entered into that certain Asset Purchase Agreement, dated as of August 16, 2021 (the "***Purchase Agreement***"); and

WHEREAS, pursuant to the Purchase Agreement, Assignee has agreed to sell, convey, transfer, assign and deliver to Assignor, free and clear of all Liens to Assignor, among other Transferred Assets, the Trademarks of Assignee, and has agreed to execute and deliver this Assignment.

NOW, THEREFORE, in consideration of the mutual representations, warranties, promises, covenants and agreements contained herein and in the Purchase Agreement and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows:

1. **Definitions**. Capitalized terms used but not otherwise defined herein shall have the meanings given to such terms in the Purchase Agreement.

1 . **Assignment**. Assignor hereby irrevocably transfers, assigns and conveys to Assignee, and Assignee hereby accepts, absolutely and forever, throughout the universe, all of Assignor's right, title and interest, whether statutory or at common law, in and to the Trademarks listed on Schedule 1 attached hereto, together with the goodwill of Assignor's business symbolized by the Trademarks, including any assets related thereto, and all corresponding registrations and applications to register the Trademarks, including the registrations listed on Schedule 1, as well as all causes of action for any and all previously occurring infringements of the rights being assigned and the right to receive and retain proceeds relating to those infringements.

2. **Further Actions**. Following the date hereof, Assignee and Assignor agree to execute any further instruments and to do such other acts as may be necessary and proper to vest title in and to the Trademarks and other corresponding rights in Assignee.

3. **Governing Law.** This Assignment shall be governed by, and construed under, the laws of the State of Delaware.

4. **Counterparts.** This Assignment may be executed in multiple counterparts which shall together constitute a single document. Facsimile and electronic signatures shall be deemed to be the equivalent of original signatures for purposes of this Assignment.

IN WITNESS WHEREOF, the parties have duly executed and delivered this Assignment as of the date first above written.

ASSIGNOR:

RA MEDICAL SYSTEMS, INC.

By: /s/ Will McGuire
Name: Will McGuire
Title: Chief Executive Officer

ASSIGNEE:

STRATA SKIN SCIENCES, INC.

By: /s/ Robert J. Moccia
Name: Robert J. Moccia
Title: Chief Executive Officer

SCHEDULE 1 TO TRADEMARK ASSIGNMENT AGREEMENT

Trademarks

PHAROS standard character mark, Registration No. 6050533, registered on May 12, 2020.

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: November 15, 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: November 15, 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 September 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: November 15, 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 September 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: November 15, 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.