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, 2022
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.)**
5857 Owens Drive, Suite 300 Carlsbad, California	**92009**
(Address of principal executive offices)	**(Zip Code)**

(760) 804-1648
(Registrant's telephone number, including area code)
2070 Las Palmas Drive, Carlsbad, California 92011
(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 9, 2022, the registrant had2,161,406 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, 2022	December 31, 2021
ASSETS		
Current Assets		
Cash and cash equivalents	$ 13,657	$ 15,045
Accounts receivable, net	—	21
Inventories	—	986
Prepaid expenses and other current assets	1,885	1,037
Total current assets	15,542	17,089
Property and equipment, net	—	1,809
Operating lease right-of-use assets	1,893	2,110
Other long-term assets	36	36
TOTAL ASSETS	$ 17,471	$ 21,044
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 460	$ 988
Accrued expenses	2,447	4,119
Current portion of operating lease liability	308	283
Total current liabilities	3,215	5,390
Operating lease liability	1,746	1,981
Total liabilities	4,961	7,371
Commitments and contingencies (Note 12)		
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; 1,423 and 140 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	—	—
Additional paid-in capital	209,488	191,945
Accumulated deficit	(196,978)	(178,272)
Total stockholders' equity	12,510	13,673
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 17,471	$ 21,044

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,	
	2022	**2021**	**2022**	**2021**
Revenues				
Product sales	$ —	$ 5	$ 14	$ 17
Cost of revenues				
Product sales	—	68	42	676
Service and other	—	178	119	537
Total cost of revenues	—	246	161	1,213
Gross loss	—	(241)	(147)	(1,196)
Operating expenses				
Selling, general and administrative	3,514	4,211	8,292	11,285
Research and development	727	2,942	6,238	8,521
Restructuring and impairment (Note 13)	542	—	4,069	—
Total operating expenses	4,783	7,153	18,599	19,806
Operating loss	(4,783)	(7,394)	(18,746)	(21,002)
Other income, net	20	16	40	2,028
Loss from continuing operations before income taxes	(4,763)	(7,378)	(18,706)	(18,974)
Income taxes	—	—	—	—
Loss from continuing operations	(4,763)	(7,378)	(18,706)	(18,974)
Discontinued operations				
Income from discontinued operations before income taxes	—	3,080	—	2,191
Income taxes	—	—	—	—
Income from discontinued operations	—	3,080	—	2,191
Net loss	$ (4,763)	$ (4,298)	$ (18,706)	$ (16,783)
Net (loss) income per share, basic and diluted				
Continuing operations	$ (4.36)	$ (57.64)	$ (28.00)	$ (210.82)
Discontinued operations	—	24.06	—	24.34
Total net loss per share, basic and diluted	$ (4.36)	$ (33.58)	$ (28.00)	$ (186.48)
Weighted average number of shares used in computing net (loss) income per share, basic and diluted	1,092	128	668	90

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, 2022	Nine Months Ended September 30, 2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (18,706)	$ (16,783)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash restructuring and impairment	2,943	—
Depreciation and amortization	396	1,250
Stock-based compensation	365	1,967
Loss (gain) on sales and disposals of property and equipment	44	(489)
Gain on sale of discontinued operations	—	(3,473)
Gain on extinguishment of promissory note	—	(2,023)
Changes in operating assets and liabilities:		
Accounts receivable	21	93
Inventories	(14)	(262)
Prepaid expenses and other assets	(826)	9
Accounts payable	(528)	171
Accrued expenses	(3,028)	(1,875)
Other liabilities	(210)	(265)
Deferred revenue	—	(234)
Net cash used in operating activities	(19,543)	(21,914)
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)
Net cash provided by investing activities	—	3,803
CASH FLOWS FROM FINANCING ACTIVITIES		
Net proceeds from issuance of common stock and warrants	13,614	15,430
Payments of offering costs related to the issuance of common stock and warrants	(1,168)	(370)
Net proceeds from exercise of warrants	5,704	—
Proceeds from issuance of common stock in connection with the employee stock purchase plan	5	26
Payments on equipment financing	—	(265)
Net cash provided by financing activities	18,155	14,821
NET CHANGE IN CASH AND CASH EQUIVALENTS	(1,388)	(3,290)
CASH AND CASH EQUIVALENTS, beginning of period	15,045	23,906
CASH AND CASH EQUIVALENTS, end of period	$ 13,657	$ 20,616
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Unpaid offering costs	$ 1,356	$ —
Net proceeds receivable from sales of common stock	$ 379	$ —
Proceeds receivable from sales of property and equipment	$ 38	$ —
Amounts accrued for purchases of property and equipment	$ —	$ 26
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash payments for income taxes	$ —	$ 2
Cash payments for interest	$ —	$ 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 Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at December 31, 2021	140	$ —	$ 191,945	$ (178,272)	$ 13,673
Common stock and warrants issued, net	505	—	9,740	—	9,740
Warrants exercised	1	—	25	—	25
Restricted stock awards cancelled	—	—	—	—	—
Stock-based compensation	—	—	165	—	165
Net loss	—	—	—	(5,495)	(5,495)
Balances at March 31, 2022	646	—	201,875	(183,767)	18,108
Common stock issued pursuant to the vesting of restricted stock units and purchases under the employee stock purchase plan	—	—	5	—	5
Restricted stock awards cancelled	(1)	—	—	—	—
Stock-based compensation	—	—	126	—	126
Net loss	—	—	—	(8,448)	(8,448)
Balances at June 30, 2022	645	—	202,006	(192,215)	9,791
Warrants exercised	445	—	6,236	—	6,236
Common stock and warrants issued, net	333	—	1,172	—	1,172
Stock-based compensation	—	—	74	—	74
Net loss	—	—	—	(4,763)	(4,763)
Balances at September 30, 2022	1,423	$ —	$ 209,488	$ (196,978)	$ 12,510

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at December 31, 2020	63	$ —	$ 174,349	$ (153,202)	$ 21,147
Common stock issued, net	1	—	65	—	65
Stock-based compensation	1	—	1,169	—	1,169
Net loss	—	—	—	(7,236)	(7,236)
Balances at March 31, 2021	65	—	175,583	(160,438)	15,145
Common stock issued, net	52	—	10,645	—	10,645
Common stock issued pursuant to the vesting of restricted stock units and purchases under the employee stock purchase plan	—	—	26	—	26
Stock-based compensation	1	—	696	—	696
Net loss	—	—	—	(5,249)	(5,249)
Balances at June 30, 2021	118	—	186,950	(165,687)	21,263
Common stock issued, net	22	—	4,350	—	4,350
Warrant issued	—	—	132	—	132
Stock-based compensation	—	—	102	—	102
Net loss	—	—	—	(4,298)	(4,298)
Balances at September 30, 2021	140	$ —	$ 191,534	$ (169,985)	$ 21,549

See accompanying notes to unaudited condensed financial statements.

Note 1. Organization

The Company

Ra Medical Systems, Inc. (the "Company") is a medical device company that owns intellectual property related to an advanced excimer laser-based platform for use in the treatment of vascular immune-mediated inflammatory diseases. Its excimer laser and single-use catheter system, together referred to as the DABRA Excimer Laser System, ("DABRA"), is used as a tool in the treatment of peripheral artery disease. The Company was formed on September 4, 2002 in the state of California and reincorporated in Delaware on July 14, 2018.

Pending Merger

On September 12, 2022, the Company announced entering into an Agreement and Plan of Merger (the "Merger Agreement") with a privately-held Delaware corporation, Catheter Precision, Inc. ("Catheter"), a medical device and technology company focused in the field of cardiac electrophysiology. Under the terms of the Merger Agreement, Catheter will become a wholly owned subsidiary of the Company in a stock-for-stock reverse merger transaction (the "Merger"). If completed, the Merger will result in a combined publicly traded company that will focus on the cardiac electrophysiology market. The Company's board of directors and the board of directors of Catheter have approved the Merger, which is currently expected to close before the end of 2022 or early 2023, subject to satisfying certain closing conditions, including the receipt of shareholder approval by both companies.

The Company expects that it will need to raise additional financing in an amount of between $2.0 million and $3.0 million in order to consummate the pending merger with Catheter, in order to meet the $8.0 million "Net Cash" closing requirement under the Merger Agreement and additional original listing requirements of the NYSE American. In addition, the Company needs to meet certain minimum pricing conditions under the Merger Agreement and the listing standards of the NYSE American stock exchange in order for the Merger to close and its shares to continue to be listed on the NYSE American.

Reverse Stock Split

On September 20, 2022, the Company's board of directors approved a reverse stock split ratio of 1-for-50 (the "Reverse Stock Split").On the effective date of October 3, 2022, the number of the Company's issued and outstanding shares of common stock was decreased from 68.2 million shares to 1.4 million shares. The number of authorized shares and par value per common share remained unchanged. No fractional shares were issued as a result of the Reverse Stock Split. Stockholders who would otherwise have been entitled to receive a fractional share received a cash payment in lieu thereof. The financial statements have been retrospectively adjusted to reflect the Reverse Stock Split of the Company's common stock for all periods presented.

NYSE American

On August 31, 2022, the Company received a deficiency letter (the "Letter") from NYSE American indicating that it was not in compliance with NYSE American continued listing standards as set forth in Section 1003(f)(v) of the NYSE American Company Guide because its shares of common stock had been selling for a substantial period of time at a low price per share, which NYSE American determined to be a 30 trading day average price of less than $0.20 per share. The Letter had no immediate effect on the listing or trading of the Company's common stock, and the common stock continues to trade on NYSE American under the symbol "RMED." The Company believes that the aforementioned Reverse Stock Split and accompanying increase in the daily share price of its common stock cured the deficiency, however, the Company had not received confirmation from NYSE American as of the date of this Quarterly Report.

Reduction in Force and Operations

As previously reported, the Company's board of directors approved a reduction in force ("RIF") under which approximately65% of its full-time employees were immediately terminated, effective June 6, 2022, and provided one-time severance payments totaling $0.6 million. In August and September 2022, an additional 20% of the Company's employees were terminated and were provided one-time severance payments totaling $0.3 million. The purpose of the RIF was to preserve capital with the goal of maximizing the opportunities available to the Company while the board of directors' reviewed strategic alternatives. See further discussion in Note 13. *Restructuring and Impairment Charges*.

As a result of the RIF, the discontinuation of enrollment in the clinical study and the board of directors' review of strategic alternatives, the Company has paused all engineering and manufacturing activities, including the development of a version of the DABRA catheter that is compatible with a standard interventional guidewire The Company has also paused research to prove the feasibility of using a DABRA-derived catheter technology to fracture calcium in arteries in a procedure known as lithotripsy. On July 5, 2022, the Company announced the receipt of FDA 510(k) clearance for the DABRA 2.0 catheter as part of the DABRA Excimer Laser System. This catheter includes a braided over jacket to make the catheter more robust and more kink-resistant when navigating tortuous anatomy. This catheter also has a six-month shelf life as a result of multiple design and manufacturing remediations implemented to address prior limitations. The Company has suspended sales of DABRA and currently has no plans to commercialize the DABRA 2.0 pending the closing of the Merger.

Going Concern

The Company has incurred recurring net losses from operations and negative cash flows from operating activities since inception. As of September 30, 2022, the Company had an accumulated deficit of $197.0 million. For the nine months ended September 30, 2022, the Company used cash of $19.5 million in operating activities. As of September 30, 2022, the Company had cash and cash equivalents of $13.7 million.

Management continues to monitor operating costs and seeks to reduce the Company's current liabilities. Such actions may impair the Company's ability to proceed with certain strategic activities, and the Company may be unsuccessful at negotiating existing liabilities to the Company's benefit. If these efforts are unsuccessful, or the Merger is not completed, the Company's cash position could be negatively impacted and the Company may, among other things, be required to seek other sources of financing, consummate another strategic transaction or be required to liquidate its assets and dissolve the Company. If the Merger is completed, the combined entity may not have sufficient cash to fund its operations for next year. Catheter has historically generated negative cash flows from operations. Catheter's expected revenue growth may not be achieved, and expenditures to achieve growth may exceed expectations. Because of the significant uncertainty regarding the Company's future plans, the Company is not able to accurately predict the impact of a potential change in its business strategy and future funding requirements.

Management believes that, based on the Company's liquidity resources and the significant uncertainty regarding its future plans, 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. The Company's independent registered public accounting firm expressed substantial doubt regarding the Company's ability to continue as a going concern in its report on the Company's financial statements as of and for the year ended December 31, 2021.

Although the Company improved its liquidity resources during the nine months ended September 30, 2022 through a private placement, proceeds from warrant exercises and sales of common stock under the At-The-Market Sales Agreement with Ladenburg Thalmann & Co., Inc. (the "ATM Agreement") resulting in total net cash proceeds of $18.2 million, and may receive additional funds from the sale of common stock under the ATM Agreement and exercise of warrants depending on market conditions, management has concluded that the aforementioned conditions 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 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.

COVID-19

The global effects of COVID-19 have created significant volatility, uncertainty and economic disruption. Although restrictions have been recently eased around the world, the COVID-19 pandemic is still ongoing, and the ultimate effects of COVID-19 on the Company's business, operations and financial condition are unknown at this time. The Company expects that patient follow-up in its atherectomy clinical trial may continue to be affected by the uncertainty relating to COVID-19, as patients may continue to elect to postpone follow-up visits and physicians' offices may intermittently close or operate at a reduced capacity in response to COVID-19. The extent to which COVID-19 impacts the Company's 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.

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, 2022 are not necessarily indicative of the results to be expected for the year ending December 31, 2022 or for any other future annual or interim period. The balance sheet as of December 31, 2021 included herein was derived from the audited financial statements as of that date. These unaudited condensed financial statements should be read in conjunction with the Company's audited financial statements included in the Company's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 24, 2022, and as amended on July 13, 2022.

Use of Estimates

The preparation of interim unaudited condensed financial statements in accordance with generally accepted accounting principles in the United States ("GAAP") requires management to make estimates and assumptions that affect the amounts reported in the interim unaudited condensed financial statements and accompanying notes. The amounts reported could differ under different estimates and assumptions. On an ongoing basis, management evaluates its estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may differ from management's estimates.

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.

Fair Value of Financial Instruments

Cash and cash equivalents, trade accounts receivable, accounts payable, accrued expenses and other current assets and liabilities are reported on the balance sheets at carrying value which approximates fair value due to the short-term maturities of these instruments.

Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined on a first-in, first-out basis. 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 excessor obsolete based on changes in customer demand, technological developments or other economic factors.

Prior to June 6, 2022, the Company's catheters were manufactured in-house, and each catheter was tested at various stages of the manufacturing process for adherence to quality standards. Catheters that did not meet functionality specification at each test point were destroyed and immediately written off. Once manufactured, completed catheters that passed quality assurance were 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 was re-tested. If the sample tests were successful, the batch was accepted into finished goods inventory. If the sample tests were unsuccessful, the entire batch was written off.

Impairment of Long-Lived Assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. If such circumstances are determined to exist, an estimate of undiscounted future cash flows produced by the long-lived assets, including its eventual residual values, is compared to the carrying value to determine whether impairment exists. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values.

Segment Information

The Company operates its business in one 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

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2020-06, *Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40)* ("ASU 2020-06"). The new guidance eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, the new guidance requires that the if-converted method is used in computing diluted earnings per share for all convertible instruments. The update is effective for annual reporting periods, including interim periods, beginning after December 15, 2021. The Company adopted ASU 2020-06 on January 1, 2022 using a modified retrospective approach, and the adoption did not impact its financial statements or per share amounts.

Note 3. Discontinued Operations

The Company completed the sale of its Pharos dermatology business (the "Dermatology Business") to STRATA Skin Sciences, Inc. ("Strata") on August 16, 2021 for net proceeds of $3.7 million, resulting in a gain on the sale of the Dermatology Business of $3.5 million which was included as a component of income (loss) from discontinued operations in the statement of operations for the year ended December 31, 2021. The Dermatology Business was previously disclosed as a separate reportable segment of the Company.

The results of the Dermatology Business are reported as loss from discontinued operations in the condensed statements of operations for the three and nine months ended September 30, 2021. Certain overhead costs previously allocated to the Dermatology Business for segment reporting purposes did not qualify for classification as discontinued operations and have been reallocated to continuing operations for the three and nine months ended September 30, 2021.

The following table summarizes the loss from discontinued operations in the condensed statements of operations for the periods presented (in thousands):

	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2021
Revenues	$ 489	$ 2,600
Cost of revenues	396	2,290
Gross income	93	310
Operating expenses	464	1,498
Operating loss	(371)	(1,188)
Other expense, net	(22)	(94)
Gain on sale of Dermatology Business	3,473	3,473
Income from discontinued operations	$ 3,080	$ 2,191

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

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

Note 4. Fair Value Measurements

As of September 30, 2022 and December 31, 2021, cash equivalents of approximately $1.4 million and $15.0 million, respectively, were categorized as Level 1 and consisted of money market funds that were measured at fair value on a recurring basis.

Note 5. Inventories

Inventories consisted of the following (in thousands):

	September 30, 2022	December 31, 2021
Raw materials	$ —	$ 911
Work in process	—	70
Finished goods	—	5
Total inventories	$ —	$ 986

Due to the RIF and the Company’s decision to discontinue enrollment of patients in its clinical trial, the Company suspended manufacturing activities in June 2022 and disposed of substantially all inventories in July 2022, resulting in a write-down of $1.0 million in its inventories to net realizable value. Such expense is included in restructuring and impairment charges in the condensed statements of operations for the nine months ended September 30, 2022. See Note 13. *Restructuring and Impairment Charges.*

Note 6. Property and Equipment

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

	September 30, 2022	December 31, 2021
Furniture and fixtures	$ —	$ 48
Machinery and equipment	—	858
Lasers	—	3,085
Computer hardware and software	—	353
Construction in progress	—	169
Leasehold improvements	—	145
Property and equipment, gross	—	4,658
Accumulated depreciation	—	(2,849)
Total property and equipment, net	$ —	$ 1,809

Depreciation expense was nil and $0.2 million for the three months ended September 30, 2022 and 2021, respectively, and $0.2 million and $0.7 million for the nine months ended September 30, 2022 and 2021, respectively.

Due to the Company's decision to discontinue enrollment of patients in its clinical trial and the RIF, the Company suspended manufacturing activities in June 2022. The Company's property and equipment was determined to be impaired as of June 30, 2022, resulting in an impairment charge of $1.5 million which was based on the actual cash proceeds received upon the disposal of the property and equipment in July 2022. The impairment charge of $1.5 million is included in restructuring and impairment charges in the condensed statements of operations for the nine months ended September 30, 2022. See Note 13. *Restructuring and Impairment Charges.*

Note 7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2022	December 31, 2021
Offering costs	$ 1,356	$ —
Legal expenses	590	1,345
Warranty expenses	192	195
Compensation and related benefits	148	2,004
Other accrued expenses	161	575
Total accrued expenses	$ 2,447	$ 4,119

Note 8. Lease

The Company has an operating lease for office and manufacturing space which requires it to pay base rent and certain utilities. Monthly rent expense is recognized on a straight-line basis over the term of the lease which expires in 2027. At September 30, 2022, the remaining lease term was 5.25 years. The operating lease is 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 an amount equal to the lease payments in a similar economic environment on the lease commencement date, as the lease does not provide an implicit rate. For each of the three months ended September 30, 2022 and 2021, operating lease expense and cash paid for leases was $0.1 million. For the nine months ended September 30, 2022 and 2021, operating lease expense and cash paid for leases was $0.2 million and $0.4 million, respectively. Amortization of operating lease right-of-use assets was $0.1 million for each of the three months ended September 30, 2022 and 2021 and $0.1 million and $0.3 million for the nine months ended September 30, 2022 and 2021, respectively. Variable costs were *de minimis.* See Note 14. *Subsequent Events.*

Maturities of operating lease liabilities consisted of the following as of September 30, 2022 (in thousands):

Years Ending December 31,		
2022 (remaining three months)	$	108
2023		445
2024		459
2025		472
2026		486
Thereafter		501
Total operating lease payments		2,471
Less: imputed interest		(417)
Total operating lease liability	$	2,054

Note 9. Net Loss per Share

Basic net loss per share is calculated by dividing the 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, non-vested restricted stock units and employee stock purchase plan rights.

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, 2022 consisted of warrants of 1,150,686, stock options of 1,427, restricted stock awards of 1,354 and restricted stock units of 75.

Anti-dilutive share equivalents excluded from the computation of diluted net loss per share at September 30, 2021 consisted of warrants of 48,373, stock options of 2,539, restricted stock awards of 6,247, restricted stock units of 916 and Employee Stock Purchase Plan shares of 209.

Note 10. Equity Offerings

At-The-Market Sales Agreement

On September 2, 2022, the Company entered into the ATM Agreement under which the Company could sell its common stock from time to time having an aggregate offering price of up to $7.6 million. The Company sold 333,184 shares of common stock under the offering through September 30, 2022, resulting in net proceeds of $2.5 million, after deducting offering fees. Net proceeds receivable of $0.4 million at September 30, 2022 relates to sales of common stock under the ATM Agreement prior to or on September 30, 2022 that settled after that date. See Note 14. *Subsequent Events*.

Warrant Repricing

On July 22, 2022, the Company reduced the exercise price of all outstanding warrants, consisting of Series A warrants and Series B warrants, that were issued in the public offering on February 8, 2022 (the "Offering") from $25.00 per share to $14.00 per share (the "Warrant Repricing"). Following the Warrant Repricing, the Company entered into warrant inducement offer letters (the "Inducement Letters") with certain investors. In response to the Inducement Letters, investors exercised approximately 0.4 million Series A warrants and no Series B warrants. Investors who exercised their Series A warrants received Series C warrants to purchase 100% of the shares exercised pursuant to the Series A warrants, The Series C warrants have an exercise price of $14.00, are immediately exercisable and expire in five years. The Company received net proceeds of approximately $4.9 million from the exercises of the Series A warrants, after deducting underwriter commissions and fees withheld of $0.6 million and other offering expenses paid or payable of $0.7 million.

The Warrant Repricing resulted in an immediate and incremental increase of approximately $2.3 million in the estimated fair value of the Series A warrants and Series B warrants issued in the Company's February 2022 public offering (the "Offering").

The Series A warrants and Series B warrants were valued on the date of the Warrant Repricing using the Black-Scholes option pricing model ("Black-Scholes model") based on the following assumptions:

	Series A	Series B
Risk-free interest rate	2.97 %	2.85 %
Volatility	137.87 %	90.44 %
Expected dividend yield	0.00 %	0.00 %
Expected life (in years)	0.6	6.6

The Series C warrants were valued at approximately $2.3 million using the Black-Scholes model based on the following assumptions:

Risk-free interest rate	2.87 %
Volatility	96.70 %
Expected dividend yield	0.00 %
Expected life (in years)	5.0

The Company is contractually obligated to pay a former placement agent a cash tail fee equal to7.5% cash compensation for the gross proceeds raised and to issue warrants equal to 7.0% of the number of shares of common stock sold to any investor contacted by the former placement during the term of its engagement with the Company ("Tail Fees"). Thus, the Company is obligated to pay such placement agent Tail Fees related to the Warrant Repricing consisting of cash tail fees of approximately $0.5 million and to issue a warrant to purchase approximately 31,000 shares of common stock with an exercise price of $17.50 per share which represents 125% of the exercise price of the Series C warrants issued pursuant to the Inducement Letters. Such warrant would be immediately exercisable and expire five years from its issuance date. This warrant was valued at approximately $0.2 million on the Warrant Repricing date using the Black-Scholes model based on the following assumptions: expected volatility of96.7%, risk-free interest rate of 2.87%, expected dividend yield of0% and an expected term of 5.0 years. This warrant has not been issued by the Company as of the date of this Quarterly Report. The cash tail fees are included in accrued expenses in the condensed balance sheet as of September 30, 2022.

Public Offering

On February 8, 2022, the Company completed the Offering in which it issued and sold (i)190,700 shares of common stock, (ii) 480,052 warrants to purchase one share of common stock at an exercise price of $25.00 that were immediately exercisable and expireone year from the date of issuance, or Series A warrants, and (iii)480,052 warrants to purchase one share of common stockat an exercise price of $25.00 that were immediately exercisable and expireseven years from the date of issuance, or Series B warrants, and (iv) 289,352 pre-funded warrants to purchase one share of common stockat an exercise price of $0.005 per share that were immediately exercisable and expire twenty years from the date of issuance. In addition, the Company granted the underwriters of the Offering a 45-day option (the "Overallotment Option") to purchase up to (i) 72,000 additional shares of common stock, (ii) 72,000 additional Series A warrants and/or (iii) 72,000 additional Series B warrants, solely to cover overallotments.

The Series A warrants and Series B warrants were valued at approximately $11.6 million using the Black-Scholes model based on the following assumptions:

	Series A	Series B
Risk-free interest rate	0.91 %	1.93 %
Volatility	131.07 %	85.38 %
Expected dividend yield	0.00 %	0.00 %
Expected life (in years)	1.0	7.0

Pursuant to the exercise of the Overallotment Option in February 2022, the Company issued24,902 shares of common stock, 72,000 Series A warrants and 72,000 Series B warrants, net of underwriting discounts. On various dates in February 2022 and March 2022, the Company issued 289,352 shares of common stock upon the exercise of all of the pre-funded warrants issued in the Offering. In addition, in March 2022, the Company issued 1,000 shares of common stock in connection with the exercise of 500 each of Series A warrants and Series B warrants issued in the Offering. In July 2022, the Company issued 800 shares of common stock in connection with the exercise of 800 Series A warrants issued in the Offering.

Net proceeds from the Offering were approximately $9.7 million, after deducting underwriter commissions and fees withheld of approximately $1.1 million and offering expenses paid or payable of $1.8 million.

The Company is contractually obligated to pay a former placement agent Tail Fees related to the Offering consisting of cash tail fees of approximately $0.9 million and a warrant to purchase approximately 33,000 shares of common stock atan exercise price of $31.25 per share, which represents 125% of the exercise price in the Offering. Such warrant would be immediately exercisable and expire five years from its issuance date. This warrant was originally valued at approximately $0.4 million on the date of the Offering using the Black-Scholes model based on the following assumptions: expected volatility of 93.25%, risk-free interest rate of 1.81%, expected dividend yield of 0% and an expected term of 5 years. On the date of the Warrant Repricing, this warrant was revalued at approximately $0.4 million using the Black-Scholes model based on the following assumptions: expected volatility of 98.9%, risk-free interest rate of 2.87%, expected dividend yield of 0% and an expected term of 4.6 years. This warrant had not been issued by the Company as of the date of this Quarterly Report. The cash tail fees are included in accrued expenses in the condensed balance sheet as of September 30, 2022.

Warrants Outstanding

At September 30, 2022, the Company had 1,150,686 shares of common stock reserved for issuance pursuant to the warrants issued by the Company at a weighted average exercise price of $33.67.

Note 11. Stock-Based Compensation

A summary of the activity and related data by award type under the 2018 Equity Incentive Plan and the 2020 Inducement Equity Incentive Plan (collectively, the “Plans”) for the nine months ended September 30, 2022 is set forth below:

Stock Options

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	2,168	$ 17,277		
Canceled/forfeited	(741)	$ 19,266		
Outstanding at September 30, 2022	1,427	$ 16,244	4.07	$ —
Exercisable at September 30, 2022	1,251	$ 18,342	3.60	$ —
Vested and expected to vest at September 30, 2022	1,427	$ 16,244	4.07	$ —

Restricted Stock Units

	Restricted Stock Units	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2021	1,400	$ 219
Vested	(117)	$ 609
Canceled/forfeited	(1,208)	$ 168
Outstanding at September 30, 2022	75	$ 416

Restricted Stock Awards

	Restricted Stock Awards	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2021	3,586	$ 236
Vested	(1,266)	$ 239
Canceled/forfeited	(966)	$ 211
Outstanding at September 30, 2022	1,354	$ 249

The following table summarizes stock-based compensation expense for the Plans included in operating expenses for the periods presented (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Selling, general and administrative	$ 85	$ 78	$ 302	$ 1,551
Research and development	(11)	27	57	251
Stock-based compensation in operating expenses	$ 74	$ 105	$ 359	$ 1,802

Stock-based compensation expense of nil and approximately $5,000 was capitalized to inventory and property and equipment during the three months ended September 30, 2022 and 2021, respectively. Stock-based compensation expense of approximately $6,000 and $0.1 million was capitalized to inventory and property and equipment during the nine months ended September 30, 2022 and 2021, respectively.

Unrecognized stock-based compensation expense by award type and the remaining weighted average recognition period over which such expense is expected to be recognized as of September 30, 2022 was as follows:

	Unrecognized Expense (in thousands)	Remaining Weighted Average Recognition Period (in years)
Stock options	$ 122	1.3
Restricted stock awards	$ 233	1.4
Restricted stock units	$ 20	1.2

Note 12. Commitments and Contingencies

Securities Class Action and Shareholder Derivative Litigation Update

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 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. 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. 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. On March 18, 2022, the Company paid approximately $0.6 million towards the settlement to satisfy its self-insured retention/deductible. The Company's insurers paid the remainder of the settlement. The proposed settlement required both preliminary and final approval by the court. On February 11, 2022, the court granted preliminary approval of the settlement, scheduled a hearing on final approval of the settlement and denied the pending motion to dismiss without prejudice.On May 2, 2022, plaintiffs filed a motion for final approval of the settlement and plan of allocation, and lead counsel filed a motion for an award of attorneys' fees and reimbursement of litigation expenses. On September 23, 2022, the court granted final approval of the settlement, certified the settlement class, granted in part lead counsel's motion for an award of attorneys' fees and reimbursement of litigation expenses, dismissed plaintiffs' claims with prejudice, and entered final judgment.

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. The parties agreed to submit to the court a proposed schedule for the next steps of the litigation within thirty days after the appeal period has run for the order granting final approval of the class action settlement. On November 10, 2022, the plaintiff filed a notice voluntarily dismissing the case without prejudice.

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 and on behalf of the Office of Inspector General, 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.

Filing of Complaint

On September 29, 2022, a purported stockholder of the Company filed a complaint captioned *David Nguyen v. Ra Medical Systems, Inc. et al.* (Civil Action no. 3:22-cv-01470-BEN-MSB) in the U.S. District Court for the Southern District of California against the Company and the Company's current directors (the "Complaint"). The Complaint alleges violations of Sections 14(a) and 20(a) of the Exchange Act based on alleged deficiencies in the Company's preliminary proxy, filed with the SEC on September 23, 2022. The defendants have not been served. The Company has obligations to indemnify and/or advance the directors' legal fees and costs in connection with this lawsuit. The Company is unable to predict the ultimate outcome and is unable to make a meaningful estimate of the amount of range of loss, if any, that could result from any unfavorable outcome.The Company denies the allegations of the Complaint and intends to defend against the Complaint vigorously.

Other Litigation

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.

Note 13. Restructuring and Impairment Charges

Restructuring and impairment charges consisted of the following (in thousands):

	Three Months Ended	Nine Months Ended
	September 30, 2022	
Impairment of property and equipment	$ —	$ 1,548
Inventory obsolescence	—	1,000
Severance expense	326	910
Prepaid expenses	—	395
Contract termination fees	216	216
Total restructuring and impairment charges	$ 542	$ 4,069

The Company's RIF impacted approximately 85% of its full-time employees, resulting in one-time severance payments totaling approximately $0.9 million. In addition, the Company decided to discontinue enrollment of patients in its clinical trial, cease engineering and manufacturing activities, sell or dispose of substantially all of its property and equipment, inventories and research and development supplies, resulting in impairment and inventory obsolescence charges and the write-off of prepaid research and development supplies totaling approximately $2.9 million.

As of September 30, 2022, the accrued liability balance related to severance expense was approximately $28,000 and is included in accrued expenses in the accompanying condensed balance sheet.

Note 14. Subsequent Events

Completion of Offering

On October 7, 2022, pursuant to the ATM Agreement, the Company completed the sale of 1.1 million shares of common stock under the offering, at a weighted average price of $7.09 per share, resulting in net proceeds of approximately $7.4 million, after deducting offering fees of approximately $0.2 million.

Termination of Lease Agreement

On October 24, 2022, the Company entered into a lease termination agreement with Anaya Holdings LLC (the "Landlord") (the "Lease Termination Agreement") pursuant to which it terminated its lease agreement for its corporate headquarters in Carlsbad, California, effective October 28, 2022. In accordance with the terms of the Lease Termination Agreement, the Company has agreed to (i) release its right to the security deposit of approximately $36,000 previously paid to the Landlord and (ii) pay a $0.3 million termination fee to the Landlord.

Entry into Lease Agreement

On October 31, 2022, the Company entered into a month-to-month lease agreement (the "Lease Agreement") with Avanti Workspace for its corporate headquarters in Carlsbad, California, effective November 1, 2022. The rent expense under the Lease Agreement is approximately $1,000 per month.

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", "our", "Ra" and "the Company" refer to Ra Medical Systems, Inc.

Overview

Ra Medical Systems, Inc. is a medical device company that owns intellectual property related to an 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.

The DABRA laser and single-use catheter, together referred to as the DABRA Excimer Laser System, or 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.

As previously disclosed, the board of directors initiated a strategic review of options for increasing shareholder value earlier this year.

Pending Merger

On September 12, 2022, we announced entering into an Agreement and Plan of Merger, or the Merger Agreement, with privately held Catheter Precision, Inc., or Catheter, a medical device and technology company focused in the field of cardiac electrophysiology. Under the terms of the Merger Agreement, Catheter will become a wholly owned subsidiary of Ra Medical in a stock-for-stock reverse merger transaction, or the Merger. If completed, the Merger will result in a combined publicly traded company that will focus on the cardiac electrophysiology market.Our board of directors and the board of directors of Catheter have both approved the Merger, which is currently expected to close before the end of 2022 or early 2023, subject to satisfying certain closing conditions, including the receipt of shareholder approval by both companies.

We expect that we will need to raise additional financing in an amount of between $2.0 million and $3.0 million in order to consummate the pending merger with Catheter in order to meet the $8.0 million "Net Cash" closing requirement under the Merger Agreement and additional original listing requirements of the NYSE American. Our stockholders should carefully read the section of this Quarterly Report and in the amended preliminary proxy statement filed on November 4, 2022, or the Amended Preliminary Proxy, entitled Risk Factors – *We anticipate needing to raise additional funds in order to consummate the Merger with Catheter. 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 are likely to result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. Such financings may have terms or rights superior to those of our shares of common stock and may not be on favorable terms to us, which could adversely affect the market price of our shares of common stock and our business or the rights of our stockholders.* In addition, we need to meet certain minimum pricing conditions under the Merger Agreement and the listing standards of the NYSE American stock exchange in order for the Merger to close and our shares to continue to be listed on the NYSE American. Our stockholders should carefully read the sections of this Quarterly Report and in the Amended Preliminary Proxy entitled Risk Factors – *Because the merger agreement requires that each of (x) the last closing sale price of Ra Medical common stock prior to 4:00 p.m. (New York City time) on the last trading day prior to the closing is equal to or greater than $4.50, and (y) the average of the last closing sale price of Ra Medical common stock prior to 4:00 p.m. (New York City time) on each of the five (5) consecutive full trading days prior to the closing is equal to or greater than $4.50, then we may be unable to consummate the merger should our closing sale price be or continue to be below $4.50, and we may seek to take additional action in order to address the closing sale price of our stock.* and *The initial listing application to be filed with the NYSE American in order to continue the listing of the shares of common stock of the combined company on the NYSE American may not be approved if the combined company does not meet the initial listing standards.*

Reverse Stock Split

On September 20, 2022, our board of directors approved a reverse stock split ratio of 1-for-50, or the Reverse Stock Split. On the effective date of October 3, 2022, the number of our issued and outstanding shares of common stock was decreased from 68.2 million shares to 1.4 million shares. The number of authorized shares and par value per common share remained unchanged. No fractional shares were issued as a result of the Reverse Stock Split. Stockholders who would otherwise have been entitled to receive a fractional share received a cash payment in lieu thereof. The financial statements have been retrospectively adjusted to reflect the Reverse Stock Split of our common stock for all periods presented.

At-The-Market Sales Agreement

On September 2, 2022, we entered into an At-The-Market Sales Agreement, or ATM Agreement, with Ladenburg Thalmann & Co., Inc. Under the ATM Agreement, we could sell our common stock from time to time having an aggregate offering price of up to $7.6 million. We completed sale of 1.1 million shares of common stock under the offering on October 7, 2022, resulting in net proceeds of $7.4 million, after deducting offering fees.

NYSE American

On August 31, 2022, we received a deficiency letter, or the Letter, from NYSE American indicating that we are not in compliance with NYSE American continued listing standards as set forth in Section 1003(f)(v) of the NYSE American Company Guide because our shares of common stock have been selling for a substantial period of time at a low price per share, which NYSE American determined to be a 30 trading day average price of less than $0.20 per share. The Letter has no immediate effect on the listing or trading of our common stock, and the common stock continues to trade on NYSE American under the symbol "RMED." We believe that the aforementioned Reverse Stock Split and accompanying increase in the daily share price of our common stock cured this deficiency, however, we have not received confirmation from NYSE American as of the date of this Quarterly Report.

Clinical Study

As previously reported, our strategy was to pursue an atherectomy indication for use, which the FDA defines to include a prespecified improvement in luminal patency. We received an Investigational Device Exemption, or IDE, approval in January 2020, and the study was approved for up to 10 clinical sites and 100 subjects. In January 2022, primarily due to subject fallout for follow-up visits due to COVID-19, we filed a protocol amendment with the FDA to add up to an additional 25 subjects to the study. The protocol amendment was approved by the FDA in February 2022, raising the enrollment limit from a maximum of 100 subjects to 125 subjects.

We enrolled the first subject in the atherectomy clinical study in February 2020. Throughout much of 2021 and 2020, the COVID-19 pandemic substantially impacted our ability to activate new sites and enroll additional subjects. Many sites or potential sites have been or are currently operating at a reduced capacity, and some have been closed from time to time.

On June 6, 2022, we made the decision to stop enrollment at 108 subjects in the atherectomy clinical study, and we believe we have enough subjects to eventually satisfy the FDA's data requirements to support an atherectomy indication. Although the COVID-19 pandemic has had and will continue to have an unpredictable impact on subject follow-up in this study, we currently aim to complete the six-month follow-up before the end of 2022 or early 2023.

Reduction in Force and Operations

As previously reported, the board of directors approved a reduction in force, or RIF, under which approximately 65% of our full-time employees were immediately terminated, effective June 6, 2022, and provided one-time severance payments totaling approximately $0.6 million. In August and September 2022, an additional 20% of our employees were terminated and were provided one-time severance payments totaling approximately $0.3 million. The purpose of the RIF was to preserve capital with the goal of maximizing the opportunities available to us during the board of directors' review of strategic alternatives.

As a result of the RIF and the board of directors' review of strategic alternatives, we have paused all engineering activities, including the development of a version of the DABRA catheter that is compatible with a standard interventional guidewire as well as research to prove the feasibility of using a DABRA-derived catheter technology to fracture calcium in arteries in a procedure known as lithotripsy. On July 5, 2022, we announced the receipt of FDA 510(k) clearance for the DABRA 2.0 catheter as part of the DABRA Excimer Laser System. This catheter includes a braided over jacket to make the catheter more robust and more kink-resistant when navigating tortuous anatomy. This catheter also has a six-month shelf life as a result of multiple design and manufacturing remediations implemented to address prior limitations. We currently have no plans to commercialize the DABRA 2.0, pending the closing of the Merger.

As a result of the RIF, the discontinuation of both the enrollment in the clinical study and engineering activities and the board of directors' ongoing review of strategic alternatives, we have suspended all manufacturing activities and are no longer supplying catheters to any sites.

Warrant Repricing

On July 22, 2022, we reduced the exercise price of all outstanding warrants, consisting of Series A and Series B warrants that were issued in the February 2022 public offering, from $25.00 per share to $14.00 per share, or the Warrant Repricing. Following the Warrant Repricing, we entered into warrant inducement offer letters, or the Inducement Letters, with certain investors to immediately exercise all of the Series A and Series B warrants held by such investors. In response to the Inducement Letters, investors exercised approximately 0.4 million Series A warrants and no Series B warrants. Investors who exercised their Series A warrants received Series C warrants to purchase 100% of the shares exercised pursuant to the Series A warrants with an exercise price of $14.00 per share and a term of five years. We received net proceeds of approximately $4.9 million from the exercises of the Series A warrants, after deducting underwriter commissions and fees withheld of $0.6 million and other offering expenses paid or payable of $0.7 million. The Series C warrants and the shares underlying the Series C warrants are unregistered and were issued in a private placement pursuant to Section 4(a)(2) of the Securities Act of 1933, or the Securities Act.

The Warrant Repricing resulted in an immediate and incremental increase of approximately $2.3 million in the estimated fair value of the Series A warrants and Series B warrants. The estimated fair value of the Series C warrants issued in the Warrant Repricing was approximately $2.3 million.

We are contractually obligated to pay a former placement agent tail fees on the proceeds received from the Series A warrant exercises and the issuance of the Series C warrants. The tail fees consist of cash tail fees equal to 7.5% cash compensation for the gross proceeds raised in the exercises of the Series A warrants in response to the Inducement Letters and the issuance of warrants equal to 7% of the number of shares of common stock issued, or the Tail Fees, to any investor contacted by the former placement agent during the term of its engagement with us. Therefore, the Tail Fees we are contractually obligated to pay related to the exercises of the Series A warrants in response to the Inducement Letters consist of a cash fee of approximately $0.5 million and the issuance of a warrant to purchase approximately 31,000 shares of common stock at an exercise price of $17.50 per share which represents 125% of the exercise price of the Series C warrants. The warrants were valued at approximately $0.2 million on the Warrant Repricing date and would be immediately exercisable and expire five years from their issuance date. We had not issued this warrant as of the date of this Quarterly Report.

Going Concern

As of the date of this Quarterly Report, we concluded that there is substantial doubt regarding our ability to continue as a going concern for the twelve months from the date of filing of this Quarterly Report. Substantial doubt about a company's ability to continue as a going concern is generally viewed unfavorably by current and prospective investors, as well as by analysts and creditors and potential strategic partners. As a result, it may be more difficult for us to consummate any strategic transactions and/or raise the additional financing necessary to continue to operate our business. If the Merger is not consummated, we may be forced to refocus or rebuild around a different core or strategic technology, consummate another strategic transaction or be required to liquidate our assets and dissolve the Company.If the Merger is completed, the combined entity may not have sufficient cash to fund its operations for next year. Catheter has historically generated negative cash flows from operations. Catheter's expected revenue growth may not be achieved, and expenditures to achieve growth may exceed expectations.

COVID-19

The global effects of COVID-19 have created significant volatility, uncertainty and economic disruption. Although restrictions have been recently eased around the world, the COVID-19 pandemic is still ongoing, and the ultimate effects of COVID-19 on our business, operations and financial condition are unknown at this time. We expect that patient follow-up in our atherectomy clinical trial may continue to be affected by the uncertainty relating to COVID-19, as patients may continue to elect to postpone follow-up visits and physicians' offices may intermittently close or operate at a reduced capacity in response to COVID-19. However, the extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain it or treat its impact, among others.

Components of our Results of Operations

Net Revenue

Product sales consist of the sales of catheters for use with the DABRA laser. We are no longer selling commercial product or catheters for use in our atherectomy clinical trial.

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 owned.

Selling, General and Administrative Expenses

Selling, general and administrative, or SG&A, expenses primarily consist of employee-related expenses, including salaries, benefits and stock-based compensation expense. Other SG&A expenses include professional services fees, including legal, audit and tax fees, insurance costs, general corporate expenses and facility related expenses.

Research and Development Expenses

Research and development, or R&D, expenses primarily consist of employee-related expenses, including salaries, benefits and stock-based compensation expense. Other R&D expenses include the cost of clinical studies and trials, supplies used for internal R&D and clinical activities and the cost of outside consultants who assist with technology development and clinical affairs.

Results of Continuing 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,		
	2022	2021	Change	2022	2021	Change
Net revenue	$ —	$ 5	$ (5)	$ 14	$ 17	$ (3)
Cost of revenue	—	246	(246)	161	1,213	(1,052)
Selling, general and administrative expenses	3,514	4,211	(697)	8,292	11,285	(2,993)
Research and development expenses	727	2,942	(2,215)	6,238	8,521	(2,283)
Restructuring and impairment charges	542	—	542	4,069	—	4,069
Other income, net	20	16	4	40	2,028	(1,988)

Net Revenue

We had no revenue during the three months ended September 30, 2022, due to the decision to cease manufacturing activities in June 2022. Net revenue decreased during the nine months ended September 30, 2022 as compared to the corresponding period in the prior year since we were only selling catheters to clinical trial sites while we focused our efforts on remedying the inconsistencies in our DABRA catheter performance and obtaining an atherectomy indication.

Cost of Revenue

The decreases in cost of revenue of $0.2 million and $1.1 million for the three and nine months ended September 30, 2022, respectively, as compared to the corresponding periods in the prior year were primarily due to the discontinuation of manufacturing activities in June 2022.

Selling, General and Administrative Expenses

The decrease in SG&A expenses of $0.7 million for the three months ended September 30, 2022 as compared to the corresponding period in the prior year was due to decreases of $0.6 million in personnel and consulting expenses, primarily due to the RIF, and $0.1 million in legal expenses. SG&A expenses for the three months ended September 30, 2022 of $3.5 million primarily consisted of legal expenses of $1.5 million, personnel and consulting expenses of $1.0 million and insurance costs of $0.4 million.

The decrease in SG&A expenses of $3.0 million for the nine months ended September 30, 2022 as compared to the corresponding period in the prior year was due to decreases of $1.2 million in stock-based compensation expense, $0.9 million in legal expenses, $1.1 million in personnel and consulting expenses, $0.2 million in insurance expense and $0.1 million in other costs, partially offset by a gain on sale of assets of $0.5 million. SG&A expenses for the nine months ended September 30, 2022 of $8.3 million primarily consisted of personnel and consulting expenses of $3.5 million, legal expenses of $1.5 million and insurance costs of $1.4 million.

Research and Development Expenses

The decrease in R&D expenses of $2.2 million for the three months ended September 30, 2022 as compared to the corresponding period in the prior year was due to the decreases in personnel and consulting expenses of $1.5 million, $0.5 million in R&D supplies and $0.2 million in clinical study expenses due to the RIF and the decrease in R&D activity.

The decrease in R&D expenses of $2.3 million for the nine months ended September 30, 2022 as compared to the corresponding period in the prior year was due to decreases of $2.0 million in personnel and consulting expenses, $0.2 million in stock-based compensation expense and $0.2 million in R&D supplies, partially offset by an increase of $0.1 million in other expenses.

Restructuring and Impairment Charges

Restructuring and impairment charges of $0.5 million and $4.1 million for the three and nine months ended September 30, 2022, respectively, include the one-time severance expenses incurred due to the RIF, as well as impairment and inventory obsolescence charges and other expenses due to our decision to discontinue enrollment of patients in our clinical trial, cease manufacturing activities, sell or dispose of substantially all of our property and equipment and inventories and expense prepaid R&D supplies.

Other Income, Net

Other income, net remained flat for the three months ended September 30, 2022 as compared to the corresponding period in the prior year. The decrease in other income, net of $2.0 million for the nine months ended September 30, 2022 as compared to the corresponding period in the prior year was primarily due to the forgiveness of the Paycheck Protection Plan promissory note in 2021.

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 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, restructuring and impairment charges, loss (gain) on sales and disposals of property and equipment and gain on extinguishment of promissory note.

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,	
	2022	2021	2022	2021
Loss from continuing operations	$ (4,763)	$ (7,378)	$ (18,706)	$ (18,974)
Depreciation and amortization	74	319	396	974
Interest income	(24)	—	(41)	(2)
Interest expense	—	—	—	12
EBITDA	(4,713)	(7,059)	(18,351)	(17,990)
Stock-based compensation	80	110	365	1,887
Restructuring and impairment	542	—	4,069	—
Loss (gain) on sales and disposals of property and equipment	—	4	44	(489)
Gain on extinguishment of promissory note	—	—	—	(2,023)
Adjusted EBITDA	$ (4,091)	$ (6,945)	$ (13,873)	$ (18,615)

The decrease in negative Adjusted EBITDA of $2.9 million and $4.7 million for the three and nine months ended September 30, 2022, respectively, as compared to the corresponding periods in the prior year were primarily due to the decreases in personnel and consulting expenses, primarily due to the RIF, of $2.1 million and $3.1 million for the three and nine months ended September 30, 2022, respectively. In addition, legal expenses decreased by approximately $0.9 million for the nine months ended September 30,2022 as compared to the corresponding period in the prior year primarily due to lower legal expenses related to the securities litigation and prior investigation.

Liquidity and Capital Resources

As of September 30, 2022, we had cash and cash equivalents of $13.7 million. We will continue to monitor our operating costs and seek to reduce our current liabilities. Such actions may impair our ability to proceed with certain strategic activities, and we may be unsuccessful at negotiating existing liabilities to our benefit. If these efforts are unsuccessful or the Merger is not completed, our cash position could be negatively impacted and we may, among other things, be required to seek other sources of financing, consummate another strategic transaction or be required to liquidate ourassets and dissolve the Company. Because of the significant uncertainty regarding our future plans, we are not able to accurately predict the impact of a potential change in our business strategy and future funding requirements.

Management believes that, based on the Company's liquidity resources and the significant uncertainty regarding its future plans, 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. The Company's independent registered public accounting firm expressed substantial doubt regarding the Company's ability to continue as a going concern in its report on the Company's financial statements as of and for the year ended December 31, 2021.

Although we improved our liquidity resources during 2022 with proceeds from a private placement, warrant exercises and the ATM financing, resulting in total net proceeds of $23.5 million, and we may receive additional funds from the exercise of warrants depending on market conditions, management has concluded that the aforementioned conditions 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. We expect that we will need to raise additional financing in an amount of between $2.0 million and $3.0 million in order to consummate the potential merger with Catheter in order to meet the $8.0 million "Net Cash" closing requirement under the Merger Agreement and additional original listing requirements of the NYSE American. Our stockholders should carefully read the section of this Quarterly Report and the Adjusted Preliminary Proxy entitled Risk Factors – *We anticipate needing to raise additional funds in order to consummate the Merger with Catheter. 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 are likely to result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. Such financings may have terms or rights superior to those of our shares of common stock and may not be on favorable terms to us, which could adversely affect the market price of our shares of common stock and our business or the rights of our stockholders*. 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 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.

Further, SEC regulations limit the amount of funds we can raise during any 12-month period pursuant to our effective 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.

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,	
	2022	2021
Net cash used in operating activities	$ (19,543)	$ (21,914)
Net cash provided by investing activities	—	3,803
Net cash provided by financing activities	18,155	14,821

Net Cash Used in Operating Activities

Net cash used in operating activities of $19.5 million for the nine months ended September 30, 2022 consisted of a net loss of $18.7 million and non-cash adjustments of $3.7 million, consisting primarily of non-cash restructuring and impairment charges of $2.9 million and stock-based compensation and depreciation and amortization of $0.4 million each. In addition, we experienced changes in operating assets and liabilities of $4.5 million.

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 of $2.8 million, consisting of gains on the sale of the Dermatology Business of $3.5 million, extinguishment of promissory note of $2.0 million and sales of property and equipment of $0.5 million, partially offset by stock-based compensation of $2.0 million and depreciation and amortization of $1.3 million. In addition, we experienced changes in operating assets and liabilities of $2.4 million.

Net Cash Provided by Investing Activities

We had no cash flows related to investing activities for the nine months ended September 30, 2022. Net cash provided by investing activities of $3.8 million for the nine months ended September 30, 2021 consisted primarily of proceeds from the sale of the Dermatology Business.

Net Cash Provided by Financing Activities

Net cash provided by financing activities of $18.2 million for the nine months ended September 30, 2022 consisted of net proceeds of $13.6 million from the February 2022 public offering and September 2022 ATM financing and $5.7 million from the exercises of Series A warrants in conjunction with the July 2022 Warrant Repricing. In addition, we paid $1.1 million in offering costs related to the financing activities.

Net cash provided by financing activities of $14.8 million for the nine months ended September 30, 2021 primarily consisted of net proceeds from our ATM financing.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial position and results of operations is based on our interim unaudited 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, 2021 filed with the Securities and Exchange Commission, or SEC, on March 24, 2022, and as amended on July 13, 2022, other than the change in the estimated useful life of our lasers which was changed to eight years effective January 1, 2022, as more fully described in Note 2. *Summary of Significant Accounting Policies* in our December 31, 2021 financial statements included in our Annual Report.

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.

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 $13.7 million as of September 30, 2022. 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 and/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 interim 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, 2022. 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 interim 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 interim Chief Financial Officer concluded that, as of September 30, 2022, 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, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

The former Chief Financial Officer of the Company resigned effective May 25, 2022. On July 8, 2022, the board of directors appointed the Company's Chief Executive Officer to act as the interim Chief Financial Officer effective immediately. On July 14, 2022, the board of directors appointed a new interim Chief Financial Officer effective immediately. These changes in personnel, along with the changes in personnel resulting from the Company's RIF, did not necessitate material changes in internal control process design or operation.

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 Class Action and Shareholder Derivative Litigation Update

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 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, or 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, or 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. 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. On March 18, 2022, the Company paid approximately $0.6 million towards the settlement to satisfy its self-insured retention/deductible. The Company's insurers paid the remainder of the settlement. The proposed settlement required both preliminary and final approval by the court. On February 11, 2022, the court granted preliminary approval of the settlement, scheduled a hearing on final approval of the settlement and denied the pending motion to dismiss without prejudice. On May 2, 2022, plaintiffs filed a motion for final approval of the settlement and plan of allocation, and lead counsel filed a motion for an award of attorneys' fees and reimbursement of litigation expenses. On September 23, 2022, the court granted final approval of the settlement, certified the settlement class, granted in part lead counsel's motion for an award of attorneys' fees and reimbursement of litigation expenses, dismissed plaintiffs' claims with prejudice, and entered final judgment.

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. The parties agreed to submit to the court a proposed schedule for the next steps of the litigation within thirty days after the appeal period has run for the order granting final approval of the class action settlement. On November 10, 2022, the plaintiff filed a notice voluntarily dismissing the case without prejudice.

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.

Filing of Complaint

On September 29, 2022, a purported stockholder of the Company filed a complaint captioned *David Nguyen v. Ra Medical Systems, Inc. et al.* (Civil Action no. 3:22-cv-01470-BEN-MSB) in the U.S. District Court for the Southern District of California against us and our current directors (the "Complaint"). The Complaint alleges violations of Sections 14(a) and 20(a) of the Exchange Act based on alleged deficiencies in our preliminary proxy, filed with the SEC on September 23, 2022. The defendants have not been served. We have obligations to indemnify and/or advance the directors' legal fees and costs in connection with this lawsuit. We are unable to predict the ultimate outcome and are unable to make a meaningful estimate of the amount of range of loss, if any, that could result from any unfavorable outcome. We deny the allegations of the Complaint and intend to defend against the Complaint vigorously.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Quarterly Report on Form 10-Q, as well as in Part I, Item IA of our Annual Report on Form 10-K for the year ended December 31, 2021, or the 2021 Annual Report, in Part II, Item 1A – Risk Factors contained in our Quarterly Report on Form 10-Q for the quarter ended June 30 2022, or the Q2 2022 Quarterly Report, Exhibits 99.7 and 99.8 to our Current Report on Form 8-K filed on September 12, 2022, or the September 12 8-K and in our Amended Preliminary Proxy Statement filed on November 4, 2022, or the Amended Preliminary Proxy Statement, before making an investment decision. The risks and uncertainties described below, in our 2021 Annual Report, the Q2 2022 Quarterly Report, the September 12 8-K and the Amended Preliminary Proxy Statement 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.

We have entered into an Agreement and Plan of Merger with Catheter Precision, Inc. ("Catheter" or "Catheter Precision") dated September 9, 2022 (the "Merger Agreement" and such transaction, the "Merger"). We cannot be certain that the Merger will be consummated or that all of the conditions precedent will be satisfied or waived in a timely manner or at all. Other than with respect to the risks entitled "Risks Related to the Merger with Catheter," or as set forth below, the risks set forth below are with respect to us as a standalone company and our current business, prospects and operations. Should the Merger be effected, the combined company could face similar risks.

Risk Factor Summary

Risks Related to the Merger with Catheter

- Failure to complete, or delays in completing, the Merger could materially and adversely affect our results of operations, business, financial results and/or stock price.
- We cannot be sure if or when the Merger will be completed.
- Because the Merger Agreement provides for the issuance to Catheter stakeholders of Ra Medical shares representing a fixed percentage of the combined company, subject to limited adjustments, we may face risks as a result of changes in our stock price during the pendency of the Merger.
- Because of requirements in the Merger Agreement with respect to our stock price at and around the closing date, we may be unable to consummate the Merger should our closing sale price be or continue to be below $4.50, and we may seek to take additional action in order to address the closing sale price of our stock.
- We anticipate needing to raise additional funds in order to consummate the Merger. 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 are likely to result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. Such financings may have terms or rights superior to those of our shares of common stock and may not be on favorable terms to us, which could adversely affect the market price of our shares of common stock and our business or the rights of our stockholders.
- We are substantially dependent on our remaining employees to facilitate the consummation of the Merger.
- If we do not successfully consummate a strategic transaction with Catheter or otherwise, our board of directors may decide to pursue a dissolution and liquidation of our company.
- The market price of our common stock following the Merger may decline as a result of the Merger.
- We may be targeted by securities class action and derivative lawsuits that could result in substantial costs and may delay or prevent the Merger from being completed.
- Litigation against us and Catheter, or the members of the board of directors of the Company or Catheter, could prevent or delay the completion of the Merger or result in the payment of damages following completion of the Merger.

- Our and Catheter's equity holders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger.
- Some of our and Catheter's executive officers and directors have interests in the Merger that are different from yours and that may influence them to support or approve the Merger without regard to your interests.
- The ownership of the post-Merger public company's common stock will be highly concentrated, and it may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause the company stock price to decline.
- Our and Catheter's security holders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the post-Merger public company following the closing of the Merger as compared to their current ownership and voting interest in the respective companies.
- The initial listing application to be filed with the NYSE American in order to continue the listing of the shares of common stock of the combined company on the NYSE American may not be approved if the combined company does not meet the initial listing standards.
- Upon the consummation of the Merger, the Company may be a "controlled company" within the meaning of NYSE American rules and, as a result, the Company may qualify for, and may choose to rely on, exemptions from certain corporate governance requirements.
- Our exploration of strategic alternatives for our legacy assets may not result in a successful transaction, and the process of exploring strategic alternatives or its conclusion could adversely impact our business and stock price.

Risks Related to Our Financial Position and Need for Additional Capital

- We require additional capital to finance our operations which may not be available on acceptable terms or at all.
- We have determined that there is substantial doubt about our ability to continue as a going concern, and we will need to develop a business plan for the combined company to execute following the Merger, should it be consummated. We may require additional capital in order to execute the business plan and fund the operations of the combined company or, if the Merger is not consummated, in order to continue the operations of our current business as a standalone company. We may not be able to obtain such funding on a timely basis, or on commercially reasonable terms, or at all. Any capital-raising transaction we are able to complete may result in substantial dilution to our existing stockholders, require us to relinquish significant rights, or restrict our operations.

Risks Related to Our Business and Products as a Standalone Company

- Our ability to continue as a standalone company and to successfully conduct our current business is highly dependent upon us attracting and retaining highly qualified personnel.
- We may be unable to successfully 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 follow-up may continue to be hindered or delayed by the effects of the COVID-19 pandemic.
- We are required to devote significant resources to complying with the terms and conditions of our Settlement Agreement and Corporate Integrity Agreement (as described below) 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 products that we currently offer.
- The military action launched by Russian forces in Ukraine, and the actions that have been and could be taken by other countries, including new and stricter sanctions and actions taken in response to such sanctions, have impacted and may continue to impact, our business and results of operations, including the supply chain for the products we currently offer.

Risks Related to Government Regulation and our Industry for our Legacy Business

- 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 for our Legacy Business

- 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 for our Legacy Business

- 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 and 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, or any other applicable listing standard, 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 Merger with Catheter

Failure to complete, or delays in completing, the Merger could materially and adversely affect our results of operations, business, financial results and/or stock price.

On September 9, 2022, we entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Catheter, Rapid Merger Sub 1, Inc., a newly-created wholly-owned subsidiary of the Company (“First Merger Sub”), and Rapid Merger Sub 2, LLC, a newly-created wholly-owned subsidiary of the Company (“Second Merger Sub”), pursuant to which, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, the First Merger Sub will merge with and into Catheter, with Catheter being the surviving corporation (the “Post-Merger Surviving Company”) and a wholly-owned subsidiary of the Company (the “First Effective Time”), and then, immediately following the First Effective Time, and as part of the same overall transaction, the Post-Merger Surviving Company will merge with and into the Second Merger Sub (the “Second Effective Time”), with the Second Merger Sub being the surviving limited liability company (the “Post-Merger Combined Company”) (such transactions collectively, the “Merger”). Consummation of the Merger is subject to certain closing conditions, a number of which are not within our control. Any failure to satisfy these required conditions to closing may prevent, delay or otherwise materially adversely affect the completion of the transaction. We cannot predict with certainty whether or when any of the required closing conditions will be satisfied or if another uncertainty may arise and cannot assure you that we will be able to successfully consummate the Merger as currently contemplated under the Merger Agreement or at all.

Our efforts to complete the Merger has caused and could continue to cause substantial disruptions in, and has created and may continue to create uncertainty surrounding, our business, which may materially adversely affect our results of operation and our business. Uncertainty as to whether the Merger will be completed has affected and may continue to affect our ability to recruit prospective employees or to retain and motivate existing employees. Employee retention has and may continue to be particularly challenging while the transaction is pending because employees may experience uncertainty about their roles following the transaction. Uncertainty as to our future could adversely affect our business and our relationship with collaborators, suppliers, vendors, regulators and other business partners. For example, vendors, collaborators and other counterparties may defer decisions about working with us or seek to change existing business relationships with us. Changes to, or termination of, existing business relationships could adversely affect our results of operations and financial condition, as well as the market price of our common stock. The adverse effects of the pendency of the transaction could be exacerbated by any delays in completion of the transaction or termination of the Merger Agreement.

Risks related to the failure of the proposed Merger to be consummated include, but are not limited to, the following:

- we would not realize any or all of the potential benefits of the Merger, including any synergies that could result from combining our financial and proprietary resources with those of Catheter, which could have a negative effect on our stock price;
- we will remain liable for significant transaction costs, including legal, accounting, financial advisory and other costs relating to the Merger regardless of whether the Merger is consummated;
- the trading price of our common stock may decline to the extent that the current market price for our stock reflects a market assumption that the Merger will be completed;
- the attention of our management and employees has and will continue to be diverted to the Merger rather than to our own operations and the pursuit of other opportunities that could have been beneficial to us;
- we could be subject to litigation related to any failure to complete the Merger;
- the potential loss of additional key personnel during the pendency of the Merger as employees and other service providers may experience uncertainty about their future roles with us following completion of the Merger; and
- under the Merger Agreement, we are subject to certain restrictions on the conduct of our business prior to completing the Merger, which restrictions could adversely affect our ability to conduct our business as we otherwise would have done if we were not subject to these restrictions.

The occurrence of any of these events individually or in combination could materially and adversely affect our results of operations, business, and our stock price.

We cannot be sure if or when the Merger will be completed.

The consummation of the Merger is subject to the satisfaction or waiver of various conditions, including the authorization of the Merger and/or related transactions by our shareholders and Catheter's shareholders. In addition, in connection with the Merger Agreement and as a condition to closing, we are required to furnish to Catheter Net Cash (as defined in the Merger Agreement) greater than $8,000,000, which may require us to raise additional capital in the public markets through the sale of our securities. We cannot guarantee that the closing conditions set forth in the Merger Agreement will be satisfied. If we are unable to satisfy the closing conditions in Catheter's favor or if other mutual closing conditions are not satisfied, Catheter will not be obligated to complete the Merger.

If the Merger is not completed, our board of directors, in discharging its fiduciary obligations to our shareholders, will evaluate other strategic alternatives or financing options that may be available, which alternatives may not be as favorable to our shareholders as the Merger. Any future sale or merger, financing or other transaction may be subject to further shareholder approval. We may also be unable to find, evaluate or complete other strategic alternatives, which may have a materially adverse effect our business.

Our efforts to complete the Merger has caused and could continue to cause substantial disruptions in, and has created and may continue to create uncertainty surrounding, our business, which may materially adversely affect our results of operation and our business. Uncertainty as to whether the Merger will be completed has affected and may continue to affect our ability to recruit prospective employees or to retain and motivate existing employees. Employee retention has and may continue to be particularly challenging while the transaction is pending because employees may experience uncertainty about their roles following the transaction. Uncertainty as to our future could adversely affect our business and our relationship with collaborators, suppliers, vendors, regulators and other business partners. For example, vendors, collaborators and other counterparties may defer decisions about working with us or seek to change existing business relationships with us. Changes to, or termination of, existing business relationships could adversely affect our results of operations and financial condition, as well as the market price of our common stock. The adverse effects of the pendency of the transaction could be exacerbated by any delays in completion of the transaction or termination of the Merger Agreement.

Until the Merger is completed, the Merger Agreement restricts Catheter and us from taking specified actions without the consent of the other party, and, in regards to us, except as expressly permitted by the Merger Agreement or by applicable laws, to carry on our business in accordance with good commercial practice and in substantially the same manner as heretofore conducted. These restrictions may prevent Catheter and us from making appropriate changes to our respective businesses or pursuing attractive business opportunities that may arise prior to the completion of the Merger.

Because the Merger Agreement provides for the issuance to Catheter stakeholders of Ra Medical shares representing a fixed percentage of the combined company, subject to limited adjustments, we may face risks as a result of changes in our stock price during the pendency of the Merger.

The Merger Agreement provides for Catheter stakeholders to receive Ra Medical shares representing a fixed percentage of the combined company, with only limited adjustments. If the public trading value of shares of our common stock changes over the period of time required to satisfy the Merger's closing conditions, including but not limited to as a result of the impact of our financings needed to satisfy the Net Cash condition, the consideration to be issued to Catheter's shareholders at the time of the Merger may be different from the public trading value of shares of our common stock when we entered into the Merger Agreement.

Because the Merger Agreement requires that each of (x) the last closing sale price of Ra Medical common stock prior to 4:00 p.m. (New York City time) on the last trading day prior to the closing is equal to or greater than $4.50, and (y) the average of the last closing sale price of Ra Medical common stock prior to 4:00 p.m. (New York City time) on each of the five (5) consecutive full trading days prior to the closing is equal to or greater than $4.50, then we may be unable to consummate the Merger should our closing sale price be or continue to be below $4.50, and we may seek to take additional action in order to address the closing sale price of our stock.

The Merger Agreement requires that each of (x) the last closing sale price of Ra Medical common stock prior to 4:00 p.m. (New York City time) on the last trading day prior to the closing is equal to or greater than $4.50, and (y) the average of the last closing sale price of Ra Medical common stock prior to 4:00 p.m. (New York City time) on each of the five (5) consecutive full trading days prior to the closing is equal to or greater than $4.50. If our stock is trading or continues to trade at or below $4.50, then we will not be able to consummate the potential Merger with Catheter without taking additional action, such as, but not limited to, seeking a waiver from Catheter for this closing condition, having Catheter amend the terms of its Debt Settlement Agreement, and/or amending the Merger Agreement. In each of these situations, Ra Medical and its stockholders could be asked in exchange to approve, among other terms, a modification to the Merger consideration under the Merger Agreement in order to increase the consideration to be paid to Catheter securityholders, which would reduce the equity ownership of Ra Medical stockholders in the combined entity.

We anticipate needing to raise additional funds in order to consummate the Merger with Catheter. 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 are likely to result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. Such financings may have terms or rights superior to those of our shares of common stock and may not be on favorable terms to us, which could adversely affect the market price of our shares of common stock and our business or the rights of our stockholders.

We anticipate needing to raise additional funds of between $2,000,000 to $3,000,000 in order to consummate the Merger with Catheter. 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 are likely to result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. 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, which may be at substantial discounts to the current trading price of our common stock. If we sell common stock, convertible securities or other equity securities, our stockholders are expected to be diluted by subsequent sales, and such dilution may be material to our existing stockholders.

We may not be able to obtain financing on favorable terms, if at all. If we raise additional funds by issuing equity securities, the percentage ownership of our then-current shareholders will be reduced. Further, we may have to offer new investors in our equity securities rights that are superior to the holders of common stock, which could adversely affect the market price and the voting power of shares of our common stock, or affect the distribution amount that our stockholders would be able to receive in the event that we do not consummate the Merger and decide to liquidate the company and could cause our stock price to fall.

We are substantially dependent on our remaining employees to facilitate the consummation of the Merger.

As of October 31, 2022, we had only 6 full-time employees. Our ability to successfully complete the Merger depends in large part on our ability to retain certain remaining personnel. Despite our efforts to retain these employees, one or more may terminate their employment with us on short notice. The loss of the services of certain employees could potentially harm our ability to consummate the Merger, to run our day-to-day business operations, as well as to fulfill our reporting obligations as a public company.

If we do not successfully consummate a strategic transaction with Catheter or otherwise, our board of directors may decide to pursue a dissolution and liquidation of our company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that our agreement with Catheter will result in a successfully consummated transaction. If the Merger is not completed, our board of directors, in discharging its fiduciary obligations to our shareholders, will evaluate other strategic alternatives or financing options that may be available. There is no guarantee that we will achieve any such alternatives. If no transaction is completed, our board of directors may decide to pursue a dissolution and liquidation of our Company. In such an event, the amount of cash available for distribution to our shareholders will depend heavily on the timing of such decision and, ultimately, such liquidation since the amount of cash available for distribution continues to decrease as we fund our operations while we evaluate our strategic alternatives. In addition, if our board of directors were to approve and recommend, and our shareholders were to approve, a dissolution and liquidation of our Company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our shareholders. Our commitments and contingent liabilities may include (i) obligations under our employment and related agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control of our Company; (ii) potential litigation against us, and other various claims and legal actions arising in the ordinary course of business; and (iii) non-cancelable facility lease obligations. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of our Company. If a dissolution and liquidation were pursued, our board of directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up of our company.

The market price of our common stock following the Merger may decline as a result of the Merger.

The market price of our common stock may decline as a result of the Merger for a number of reasons including, but not limited to, if:

- investors react negatively to the prospects of the post-Merger public company’s business and prospects from the Merger;
- the effect of the Merger on the post-Merger public company’s business and prospects is not consistent with the expectations of financial or industry analysts;
- the post-Merger public company does not achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts; or
- Catheter is a private company and there is no readily determinable market value for its shares; thus, valuation of the company is inherently difficult and as a result the value ascribed to Catheter may differ from its value if there was a ready market.

Shareholder lawsuits challenging the Merger and our disclosures concerning the Merger have been filed, and may continue to be filed, that could result in substantial costs and may delay or prevent the Merger from being completed.

Shareholder lawsuits are often brought against public companies that have entered into merger agreements. As of the date of this filing of our Quarterly Report, there is one pending lawsuit challenging the Merger, as set forth in Note 12. *Commitments and Contingencies* of this Quarterly Report. However, shareholders may file additional lawsuits challenging the Merger. The outcome of any current or future litigation is uncertain. Even if the lawsuits are without merit, defending against these claims can result in substantial costs and divert management time and resources. An adverse judgment could result in monetary damages, which could have a negative impact on our liquidity and financial condition. In addition, if a plaintiff is successful in obtaining an injunction prohibiting completion of the Merger, then that injunction may delay or prevent the Merger from being completed, or from being completed within the expected timeframe, which may adversely affect our and Catheter’s respective businesses, financial positions and results of operation.

Litigation against us and Catheter, or the members of the board of directors of the Company or Catheter, could prevent or delay the completion of the Merger or result in the payment of damages following completion of the Merger.

While we and Catheter believe that any claims that may be asserted by purported shareholder or stockholder plaintiffs related to the Merger would be without merit, the results of any such potential legal proceedings are difficult to predict and could delay or prevent the Merger from becoming effective in a timely manner. The existence of litigation related to the Merger could affect the likelihood of obtaining any approvals that are required from our stockholders or Catheter's stockholders. Moreover, any litigation could be time consuming and expensive, could divert our and Catheter's management's attention away from their regular business and, if any lawsuit is adversely resolved against either us, Catheter or members of the respective board of directors of the Company or Catheter (each of whom we or Catheter are respectively required to indemnify pursuant to indemnification agreements), could have a material adverse effect on our or Catheter's financial condition.

Our and Catheter's security holders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger.

The post-Merger public company may not be able to realize the full strategic and financial benefits currently anticipated from the Merger and if such benefits are not fully realized as a result of the Merger, then our and Catheter's equity holders will have experienced dilution of their ownership interests in their respective companies without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the post-Merger public company.

Some of our and Catheter's executive officers and directors have interests in the Merger that are different from yours and that may influence them to support or approve the Merger without regard to your interests.

Some of our and Catheter's officers and directors are parties to arrangements that provide them with interests in the Merger that are different from the respective stockholders of the Company and Catheter, including, among others, service as an officer or director of the post-Merger public company following the closing of the Merger, severance and retention benefits, the acceleration of equity award vesting, the conversion of debt instruments at a preferential price, and continued indemnification.

The ownership of the post-Merger public company's common stock will be highly concentrated, and it may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause the company stock price to decline.

Executive officers and directors of the post-Merger public company and their affiliates and persons that are related to such officers and directors are expected to beneficially own or control, in the aggregate, in excess of 50% of the outstanding shares of common stock of the post-Merger public company following the completion of the Merger. Accordingly, these executive officers, directors and their affiliates, acting as a group, will have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of the post-Merger public company assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of the post-Merger public company, even if such a change of control would benefit the other stockholders of the post-Merger public company. The significant concentration of stock ownership may adversely affect the trading price of the post-Merger public company's common stock due to investors' perception that conflicts of interest may exist or arise, and may adversely affect the liquidity of the post-Merger public company's common stock. As a result, it is possible that the post-Merger combined company will satisfy the controlled company provisions of the NYSE American, in which case the combined company would not be required to satisfy all of the corporate governance requirements of the NYSE American, including without limitation, requirements that a majority of the Board be independent and that the combined company have independent compensation and nominating committees. See "--Upon the consummation of the Merger, the Company may be a "controlled company" within the meaning of NYSE American rules and, as a result, the Company may qualify for, and may choose to rely on, exemptions from certain corporate governance requirements".

Our and Catheter's security holders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the post-Merger public company following the closing of the Merger as compared to their current ownership and voting interest in the respective companies.

After the completion of the Merger, the current security holders of the Company and Catheter will own a smaller percentage of the post-Merger public company than their ownership in their respective companies prior to the Merger. Immediately after the Merger, it is currently estimated that Catheter stockholders, option holders and noteholders as of immediately prior to the Merger will own approximately 79.3% of the capital stock of the post-Merger public company (including the assumption of Catheter options), with our stockholders as of immediately prior to the Merger, whose shares of our Common Stock will remain outstanding after the Merger, owning approximately 20.63% of the common stock of the post-Merger public company on a fully-diluted pro forma basis calculated via the treasury stock method. These estimates are based on the anticipated exchange ratio and are subject to adjustment as provided in the Merger Agreement, including a downwards adjustment for the Catheter stockholders, option holders and noteholders and an upwards adjustment for our stockholders, each to the extent that, and by the amount in which, we deliver Net Cash (as defined in the Merger Agreement) greater than $8,000,000.

In addition, it is a condition to the closing of the Merger that David Jenkins be appointed to our board of directors and also as our Executive Chair and Chief Executive Officer, with Will McGuire resigning from his position as our current Chief Executive Officer, and one to-be-determined current board member who will resign from our board of directors, such that our board of directors will be David Jenkins and four other of the current directors. Consequently, security holders of the Company and Catheter will be able to exercise less influence over the management, the board of directors and policies of the post-Merger public company following the closing of the Merger than they currently exercise over the management, the board of directors and policies of their respective companies.

Because the Merger will likely result in an ownership change under Section 382 of the Code for the Company, the Company's pre-Merger net operating loss carryforwards and certain other tax attributes will be subject to limitation. The net operating loss carryforwards and certain other tax attributes of the post-Merger public company may also be subject to limitations as a result of ownership changes.

If a corporation undergoes an "ownership change" within the meaning of Section 382 of the Code, the Company's net operating loss carryforwards and certain other tax attributes arising from before the ownership change are subject to limitations on use after the ownership change. In general, an ownership change occurs if there is a cumulative change in the corporation's equity ownership by certain stockholders that exceeds fifty percentage points over a rolling three-year period. Similar rules may apply under state tax laws. The Merger will likely result in an ownership change for the Company and, accordingly, the Company's net operating loss carryforwards and certain other tax attributes will be subject to limitations on their use after the Merger. Additional ownership changes in the future could result in additional limitations on the Company's and the post-Merger public company's net operating loss carryforwards. Consequently, even if the post-Merger public company achieves profitability, it may not be able to utilize a material portion of the Company's or the post-Merger public company's net operating loss carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations.

The initial listing application to be filed with the NYSE American in order to continue the listing of the shares of common stock of the combined company on the NYSE American may not be approved if the combined company does not meet the initial listing standards.

In order to continue the listing of the shares of common stock of the combined company on the NYSE American, the combined company must meet the NYSE American's initial listing standards and the NYSE American must approve an initial listing application that the Company will file with the NYSE American.

The NYSE American initial listing standards require that issuers meeting one of the following tests: (1) $750,000 of pre-tax income (in either the last fiscal year or two of the three most recent years), $3 million of public float, $4 million of stockholders' equity and a minimum share price of $3 per share; (2) $15 million of public float, $4 million of stockholders' equity, a $3 per share price and 2 years of operating history; (3) a $50 million market cap; $15 million of public float, $4 million of stockholders' equity, and a $2 per share price; (4) a $75 million market cap; $20 million of public float and a $3 per share price; or (5) $75 million in total assets and total revenue (in either the last fiscal year or two of the three most recent years); $20 million of public float and a $3 per share price, plus in each case either (a) 800 public stockholders and 500,000 shares of total public float; (b) 400 public stockholders and 1,000,000 shares of total public float; or (c) 400 public stockholders, 500,000 shares of total public float and a 2,000 share daily trading volume (over the past six months). In addition, the NYSE American may impose any other requirements that it deems appropriate, including without limitation, requirements as to the projected liquidity and cash flow of the combined company.

Although no assurances can be given that the combined company will meet such initial listing standards or that the NYSE American will approve such application, the Company intends for the combined company to meet the initial listing standard of the NYSE American that requires that the Company have $15 million of public float, $4 million of stockholders' equity, a $3 per share price and 2 years of operating history. If any initial listing standard or other NYSE American requirement is not met, the NYSE American will not approve the initial listing application and the shares of common stock of the combined company will not be listed on the NYSE American upon consummation of the Merger. The Reverse Stock Split was approved by the Company's stockholders at a special meeting on September 20, 2022, at a ratio of one new share for every 50 shares outstanding as determined by the Company's board of directors on September 20, 2022, which was effective at 4:01 p.m. Eastern time on September 30, 2022. As a result of the Reverse Stock Split, the Company's stock is currently trading above $3 per share, although there can be no guarantee that it will continue to do so.

If the NYSE American does not approve the initial listing application upon consummation of the Merger, the failure of the common stock of the combined company to be listed on a national securities exchange could have a material adverse effect on the combined company and its stockholders. The common stock of the combined company would be expected to trade on an over-the-counter market, which could, among other things, substantially impair the ability of the combined company to raise additional capital, result in a loss of institutional investor interest and fewer financing opportunities for the combined company, materially impair the ability of stockholders to buy and sell shares of the common stock of the combined company, and could have an adverse effect on the market price of, and the efficiency of the trading market for, the common stock of the combined company.

Upon the consummation of the Merger, the Company may be a "controlled company" within the meaning of NYSE American rules and, as a result, the Company may qualify for, and may choose to rely on, exemptions from certain corporate governance requirements.

Upon the consummation of the Merger, it is anticipated that David Jenkins, including his affiliates and affiliated entities will beneficially own more than 50% of the voting power of all of the Company's outstanding capital stock. If such stockholder maintains that beneficial ownership, the Company will be a "controlled company" as defined in Section 801 of the NYSE American Company Guide. Under the NYSE American rules, a company of which more than 50% of the voting power is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain NYSE American corporate governance requirements, including:

- the requirement that a majority of the Company's board of directors consists of independent directors;
- the requirement that the Company's directors must be nominated by a Nominating Committee composed by a majority of independent directors; and
- the requirement that executive compensation must be determined or recommended to the Company's board of directors for determination, by a Compensation Committee comprised of independent directors or by a majority of the independent directors on the Company's board.

Accordingly, if the Company qualifies as a controlled company, it will elect to be treated as such and its stockholders will not be afforded the same protections generally as stockholders of other NYSE American-listed companies and will be considered "controlled" for other purposes under the Delaware General Corporation Law including Section 203, for so long as any stockholder controls more than 50% of our voting power and the Company relies upon such exemptions.

Risks Related to Our Evaluation of Strategic Alternatives for our Legacy Assets

We cannot assure you that our exploration of strategic alternatives for our legacy assets will result in a transaction or that any such transaction would be successful, and the process of exploring strategic alternatives or its conclusion could adversely impact our business and our stock price.

In March 2022, we engaged Ladenburg Thalmann & Co. Inc. to assist us in identifying and evaluating a range of potential strategic alternatives, including an acquisition, company sale, merger, business combination, asset sale, in-license, out-license or other strategic transaction. On September 9, 2022, we entered into a definitive agreement for a merger transaction with Catheter as described in our Current Report on Form 8-K, filed with the SEC on September 9, 2022. However, we are continuing to explore strategic options for our legacy assets. There can be no assurance that this exploration of strategic alternatives will result in us entering or completing any transaction with respect to those assets or that any resulting plans or transactions will yield additional value for shareholders. Any potential transaction would be dependent on a number of factors that may be beyond our control, including, among other things, market conditions, industry trends, the interest of third parties in a potential transaction with us and the availability of financing to potential buyers on reasonable terms.

The process of exploring strategic alternatives could adversely impact our business, financial condition and results of operations. We could incur substantial expenses associated with identifying and evaluating potential strategic alternatives, including those related to equity compensation, severance pay and legal, accounting and financial advisory fees. In addition, the process may be time consuming and disruptive to our business operations, could divert the attention of management and the board of directors from our business, could negatively impact our ability to attract, retain and motivate key employees, and could expose us to potential litigation in connection with this process or any resulting transaction. Further, speculation regarding any developments related to the review of strategic alternatives and perceived uncertainties related to the future of the Company could cause our stock price to fluctuate significantly.

If we do not consummate the Merger, we will continue to face risks related to our legacy business as described herein. There can be no assurance that we will succeed in such activities.

Risks Related to Our Financial Position and Need for Additional Capital

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

Although management believes the Company has adequate resources to operate as a going concern, our current cash resources may not ultimately be sufficient to fund operations at the expected level of activity beyond the twelve months from the date of this Quarterly Report. We will need additional capital to continue operations at the current level and to continue our atherectomy indication trial and engineering efforts.

Our operations have consumed substantial amounts of cash since inception, primarily due to our research and development and commercialization efforts. As of September 30, 2022, we had cash and cash equivalents of $13.7 million and an accumulated deficit of $197.0 million. For the nine months ended September 30, 2022, we used cash of $19.5 million in operating activities. 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. On June 6, 2022, we initiated a reduction in force (a "**RIF**"), in which approximately 65% of our full-time employees were immediately terminated and the non-terminated employees were offered conditional retention arrangements pursuant to which it was expected that they would continue to provide services into the third quarter of 2022. On September 2, 2022, we completed the RIF, pursuant to which an additional 20% of our employees were terminated, with effective dates ranging from August 1, 2022 to September 2, 2022. We have suspended sales of DABRA catheters. We sold or disposed of most of our inventories and property and equipment, including lasers. As a further cost savings initiative, in late October 2022, we terminated the lease at our premises at 2070 Las Palmas Drive, Carlsbad, California 92011, and entered into a month-to-month lease for a smaller space located at 5857 Owens Drive, Suite 300, Carlsbad, California 92009. Although we are continuing the follow-up for our atherectomy clinical trial, we stopped enrollment in June 2022. We have decreased or deferred capital expenditures, development and engineering activities and implemented further operating expense reduction measures. Such measures are likely to 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 compliance with, and payments under, the terms of our Settlement Agreement and Corporate Integrity Agreement associated with our settlements with the Department of Justice (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 the government investigation, we are unable to predict when we will become profitable, and we may never become profitable.

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

- our ability to restart engineering efforts and resume manufacturing operations;
- our ability to develop a larger diameter catheter to facilitate treatment of larger vessels more commonly seen in above-the-knee procedures;
- the timing for completing follow-up 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;
- 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 its 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 continue to delay, reduce the scope of our future 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 effects of the COVID-19 pandemic and Russia's invasion of Ukraine to have a negative impact on our ability to secure additional financing in a timely manner or on favorable terms, if at all.

We have determined that there is substantial doubt about our ability to continue as a going concern, and we will need to develop a business plan for the combined company to execute following the Merger, should it be consummated. We may require additional capital in order to execute the business plan and fund the operations of the combined company or, if the Merger is not consummated, in order to continue the operations of our current business as a standalone company. We may not be able to obtain such funding on a timely basis, or on commercially reasonable terms, or at all. Any capital-raising transaction we are able to complete may result in substantial dilution to our existing stockholders, require us to relinquish significant rights, or restrict 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. We have concluded and disclosed in the footnotes to our condensed financial statements, included elsewhere within this Quarterly Report, that we do not have sufficient cash to fund our operations through 12 months from the date of issuance of the most recent financial statements. 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. If we do not consummate the Merger and are unable to successfully raise additional funds, then we may have to refocus or rebuild around a different core or strategic technology, consummate another strategic transaction or be required to liquidate our assets and dissolve the Company. 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.

We are developing a business plan for the combined company to execute should we consummate the proposed Merger. Management currently believes that it will be necessary for us to raise additional funding in the form of an equity financing from the sale of common stock or the issuance of debt or to pursue and consummate one or more strategic transactions, whether related or unrelated. There can be no guarantee that we will successfully raise all the funding we require or be able to consummate any strategic transaction and, even if so, that we would be able to continue as a going concern. However, substantial doubt about a company's ability to continue as a going concern is generally viewed unfavorably by current and prospective investors, as well as by analysts and creditors. As a result, it may be more difficult for us to raise the additional financing necessary to continue to operate our business, and we may be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether.

If our board of directors decides to dissolve the Company and liquidate its assets, we would be required to pay all of our debts and contractual obligations, and to set aside certain reserves for potential future claims, and there can be no assurance as to the amount or timing of available cash left to distribute to our stockholders after paying our debts and other obligations and setting aside funds for potential future claims.

Risks Related to Our Business and Products as a Standalone Company

The risks set forth below related to Ra Medical are with respect to Ra Medical as a standalone company and the operation of its legacy business should we restart our operations and resume our legacy business. Should the merger be effected, some of these risks may also apply to the combined company.

Our ability to continue as a standalone company and to successfully conduct our business is highly dependent upon us attracting and retaining highly qualified 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. Our success as a standalone company and to successfully conduct our current business is highly dependent on attracting and retaining a highly qualified management team. Will McGuire, our Chief Executive Officer, has been diagnosed with a serious illness not caused by COVID-19 and has been undergoing treatment for his illness. He continues to fulfill all of his duties and responsibilities and has stated his desire to continue in such roles. We do not expect our Chief Executive Officer to relinquish any of his responsibilities or duties in the short term as a result of this diagnosis, however, his condition may change and prevent him from doing so. The Board has discussed a plan of succession and will continue to evaluate and monitor our options on an ongoing basis should Mr. McGuire need to relinquish any of his responsibilities or duties at any time as a result of his illness or otherwise.

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. Members of our management, scientific and development teams have and may continue to terminate their employment with us, either as a result of further reductions in force initiated by us or voluntarily on their own. 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, and have left, 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.

We may be unable to successfully 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 penetrate our target markets and increase sales of our products and any new product indications that we introduce, which will, in turn, depend in part on our success in growing our installed unit base and driving continued use of our systems, including long-term adoption by physicians. In 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.

If we are to continue as a standalone company, our success will depend in large part on DABRA. If we are unable to successfully manufacture, market and sell DABRA, our business prospects will be significantly harmed.

If we are to continue as a standalone company, our future financial success will depend substantially on our ability to effectively and profitably manufacture, market and sell DABRA. We have recently significantly reduced the component of our workforce that was responsible for the manufacturing, marketing and sales of DABRA. The commercial success of DABRA will depend on a number of factors, including the following:

- our ability to hire and attract highly qualified manufacturing, marketing and sales personnel;
- 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 follow-up in a timely manner or at all, which may be affected by reductions in voluntary medical procedures during the ongoing COVID-19 pandemic;
- our ability to receive FDA clearance for an atherectomy indication for use;
- 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;
- whether we are required by the FDA or comparable non-U.S. regulatory authorities to conduct additional clinical trials for future or current indications; and
- our ability to restart engineering efforts and resume manufacturing operations.

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 continue to be hindered or delayed by the effects of the COVID-19 pandemic.

The effects of the COVID-19 pandemic and the DABRA catheter performance limitations have impacted our ability to complete our atherectomy study in a timely manner. For example, follow up with our atherectomy clinical trial, and patients' completion of our atherectomy trial, may be further delayed or slowed by any increases in COVID-19 cases or other effects of the COVID-19 pandemic, 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. Accordingly, we cannot predict whether or when we will be able to successfully complete our atherectomy indication trial follow-up. 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 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 Office of Inspector General, or 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 or any potential strategic transaction, such as a sale of one or more of our assets, a license to our technology, a business combination or other partnership transaction.

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. 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 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 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;
- 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 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 incurred losses in recent periods and may be unable to achieve profitability in the future.

We incurred losses from continuing operations of $4.8 million and $18.7 million for the three and nine months ended September 30, 2022, respectively. As of September 30, 2022, we had an accumulated deficit of $197.0 million. If we restart our operations, we expect to continue to incur significant manufacturing, product development, regulatory and other expenses 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 any of our products, and to defend, cooperate and resolve pending lawsuits and government investigation, as applicable. In addition, our general and administrative expenses have increased due to legal proceedings, 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 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 we restart manufacturing operations and our manufacturing facilities become damaged or inoperable, or we are required to vacate the facilities, our ability to manufacture and sell our products and to pursue our research and development efforts may be jeopardized.

Our facilities 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 facility 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 recent 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 was characterized as a global pandemic and how long and how extensive the economic effects will last, has not been determined. The extent to which the effects of COVID-19 impact our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge regarding COVID-19 and the actions to contain it or treat its impact, among others. 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 effects of the pandemic could also adversely affect our ability to secure additional financing in a timely manner or on favorable terms, if at all.

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 we renew our legacy business and DABRA is not cleared or approved for new indications, our commercial opportunity will be limited.

As part of our legacy business, we marketed and sold 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, if we renew our legacy business, one of our strategies in the future may be to pursue additional vascular indications for DABRA. Submitting the required applications for additional indications will require substantial additional funding beyond our cash and cash equivalents as of September 30, 2022. 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, or may be of a strategic nature with a focus on a new direction focused on the combined company and the business that we may acquire. 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. 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. As discussed above, we are currently conducting a clinical study intended to support our FDA regulatory application for the atherectomy indication for use.

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 previously disclosed and 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, 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. Whether actions will be commenced, whetheran investigation can be settled before or after actions are commenced, and the terms on whichany 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 have previously been a party to securities class action and shareholder derivative litigation and other litigation as set forth in *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 management's attention and resources and significant defense costs and other professional fees. Any violation of the FCPA, other applicable anti-bribery, anti-corruption laws, healthcare laws, and anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could have a material and adverse effect on our reputation, business, financial condition, and results of operations for years after these investigations are resolved.

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

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

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

In addition to selling our products in the U.S., we 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.

The impact of the military action in Ukraine, and the actions that have been and could be taken by other countries, including new and stricter sanctions and actions taken in response to such sanctions, have affected, and may continue to affect, our business and results of operations, including our supply chain.

On February 24, 2022, Russian forces launched significant military action against Ukraine, and sustained conflict and disruption in the region is possible. The impact to Ukraine, as well as actions taken by other countries, including new and stricter sanctions imposed by Canada, the United Kingdom, the European Union, the U.S. and other countries and companies and organizations against officials, individuals, regions and industries in Russia and Ukraine, and actions taken by Russia in response to such sanctions, and each country's potential response to such sanctions, tensions and military actions could have a material adverse effect on our operations. Any such material adverse effect from the conflict and enhanced sanctions activity may disrupt our supply chains and affect the delivery of our products and services or impair our ability to complete financial or banking transactions.

We also cannot predict the impact of any heightened geopolitical instability or the results that may follow, including reductions in consumer confidence, heightened inflation, cyber disruptions or attacks, higher natural gas costs, higher manufacturing costs and higher supply chain costs. The impact of Russia's invasion of Ukraine could cause our results to differ materially from the outlook presented in this Quarterly Report.

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.

In addition to current and proposed economic sanctions on Russia, which may increase or continue for an indefinite period of time as a result of Russia's invasion of Ukraine, 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.

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.

As previously disclosed, in 2019, 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.

If we pursue our legacy business, 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 October 31, 2022, we had six full-time employees. In the second quarter of 2022, we initiated a RIF, in which approximately 65% of our full-time employees were immediately terminated, and the non-terminated employees were offered conditional retention arrangements pursuant to which it was expected that they would continue to provide services through the third quarter of 2022. The RIF was completed on September 2, 2022, resulting in an additional 20% of our employees being terminated, with effective dates ranging from August 1, 2022 to September 2, 2022.

The future financial performance of our legacy business and our ability to successfully market and sell our products depends, in part, on our ability to hire and retain qualified personnel and 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.

Employment of social media as part of our marketing strategy 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.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we may become exposed to, or collect and store sensitive data, including procedure-based information and legally protected health information, credit card, and other financial information, insurance information, and other potentially personally identifiable information. We also store sensitive intellectual property and other proprietary business information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology, or IT, and infrastructure, and that of our third-party billing and collections provider and other technology partners, may be vulnerable to cyber-attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. We rely extensively on IT systems, networks and services, including internet sites, data hosting and processing facilities and tools, physical security systems and other hardware, software and technical applications and platforms, some of which are managed, hosted, provided and/or used by third-parties or their vendors, to assist in conducting our business. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems or infrastructure, by our workforce, others with authorized access to our systems or unauthorized persons could negatively impact operations. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our or our third-party providers' systems, portable media or storage devices. We could also experience a business interruption, theft of confidential information or reputational damage from industrial espionage attacks, malware or other cyber-attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature and expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and becoming more prevalent in the industry. We are investing in protections and monitoring practices of our data and IT to reduce these risks and continue to monitor our systems on an ongoing basis for any current or potential threats. There can be no assurance, however, that our efforts will prevent breakdowns or breaches to our or our third-party providers' databases or systems that could adversely affect our business.

Risks Related to Government Regulation and our Industry for our Legacy Business

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 applicable 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 disclosed above, we have entered into the Settlement Agreement, and the agreements with the participating states, resolving a DOJ civil investigation concerning certain Covered Conduct (as defined in the Settlement Agreement), 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," Class II medical devices are also subject to "special controls," including, in many cases, 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. 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, such as the

Merger with Catheter. 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. On December 28, 2020, we 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 are also 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 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, 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, and the Company received notice in February 2022 that the FDA has terminated 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.

The failure by us to properly identify reportable events or to file timely reports with the FDA can subject us to sanctions and penalties, including warning letters and recalls. Physicians, hospitals and other healthcare providers may make similar reports to regulatory authorities. Any such reports may trigger an investigation by the FDA or similar foreign regulatory bodies, which could divert managerial and financial resources, harm our reputation and have a material adverse effect on our business, financial condition, and results of operations.

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

Material modifications to the intended use or technological characteristics of our devices will require new 510(k) clearances or premarket approvals or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on FDA published guidelines, the FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement, or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA-cleared device that would significantly affect its safety or efficacy or that would constitute a major change in its intended use would constitute a material modification and would require a new 510(k) clearance or possibly a premarket approval. If required, we may not be able to obtain additional 510(k) clearances or premarket approvals for new devices or for modifications to, or additional indications for, our devices in a timely fashion, or at all. Delays in obtaining required future clearances would harm our ability to introduce new or enhanced devices in a timely manner, which in turn would harm our future growth. We have made modifications to our devices in the past and will make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop selling or marketing our devices as modified, which could harm our operating results and require us to redesign our platform devices. In these circumstances, we may also be subject to significant enforcement actions such as significant regulatory fines or penalties. Furthermore, the FDA's ongoing review of the 510(k) program may make it more difficult for us to modify our previously cleared products, either by imposing stricter requirements on when a new 510(k) for a modification to a previously cleared product must be submitted or applying more onerous review criteria to such submissions.

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

We and our suppliers are required to comply with the FDA's QSR, which delineates, among other things, the design controls, document controls, purchasing controls, identification and traceability, production and process controls, acceptance activities, nonconforming product requirements, corrective and preventive action requirements, labeling and packaging controls, handling, storage, distribution and installation requirements, complaint handling, records requirements, servicing requirements, and statistical techniques potentially applicable to the production of our medical devices. We and our suppliers are also subject to the regulations of foreign jurisdictions regarding the manufacturing process if we market products overseas. The FDA enforces the QSR through periodic and announced or unannounced inspections of manufacturing facilities. Our facility has 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 facility 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, the 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, 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 have been reported to us and retrospectively filed three MDRs with the FDA.

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

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

There have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control or manage the increasing costs of healthcare and, more generally, to reform the U.S. healthcare system.

Certain of these proposals could limit the prices we are able to charge for our products or the coverage and reimbursement available for our products and could limit the acceptance and availability of our products on the market. The adoption of proposals to control costs could have a material adverse effect on our business, financial condition, and results of operations.

For example, in the U.S., in March 2010, the 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.

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 June 2021, the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the PPACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the PPACA. Thus, the PPACA will remain in effect in its current form. Further, legislative and regulatory changes under the PPACA remain possible, although the new federal administration under President Biden has signaled that it plans to build on the PPACA and expand the number of people who are eligible for health insurance under it. It is unclear how future litigation and healthcare measures promulgated by the Biden administration will impact the implementation of the PPACA and our business, financial condition and results of operations. Complying with any new legislation or reversing changes implemented under the PPACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

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 2031, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2022, unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of the sequester. 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. As a result of reform of the U.S. healthcare system, changes in reimbursement policies or healthcare cost containment initiatives may limit or restrict coverage and reimbursement for procedures using our products and cause our revenue to decline. 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 procedural technology, or 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 Centers for Medicare and Medicaid Services, or 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 if 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, 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 incurred, 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 applicable 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) to non-physician healthcare professionals (defined to include physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetistsand anesthesiologist assistants, and certified nurse-midwives) and teaching hospitals, as well as information regarding ownership and investment interests held by the physicians described above and their immediate family members; 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.

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. As disclosed above, we entered into a Settlement Agreement with the DOJ to resolve a civil investigation and related civil complaint concerning Covered Conduct. 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.

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 for our Legacy Business

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 for our Legacy Business

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 have experienced inconsistencies in our DABRA catheter performance. We may encounter unforeseen situations that would result in delays or shortfalls in manufacturing, including as a result of the ongoing military conflict between Russia and Ukraine. Key components and sub-assemblies of DABRA would be provided by a limited number of suppliers, and we may not maintain large inventory levels of these components and sub-assemblies. For example, we would 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 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 have historically obtained 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 have sourced 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 suppliers' 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.

We rely on third parties to conduct our clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies, or failing to comply with regulatory requirements.

We do not have the ability to independently conduct our clinical trials. We currently rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct clinical trials and we would expect to continue to rely upon third parties to conduct clinical trials of our investigational products. Third parties have a significant role in the conduct of our clinical trials and the subsequent collection and analysis of data. These third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we have limited ability to control the amount or timing of resources that any such third party will devote to our clinical trials. The third parties we rely on for these services may also have relationships with other entities, some of which may be our competitors. Some of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements with a third party, it would delay our development activities.

Our reliance on these third parties for such medical device development activities will reduce our control over these activities but will not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP standards, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are reliable and accurate and that the rights, integrity and confidentiality of trial participants are protected. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials substantially comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under current cGMP or quality system regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the marketing authorization process.

Misconduct by our CROs or other third-party contractors could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by third parties we contract with, and the precautions we take to detect and prevent this activity 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 comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, damages, reputational harm, and the curtailment or restructuring of our operations, among others.

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 New York Stock Exchange 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 Quarterly 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 shareholder 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 management's 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.

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, 2021, we had net operating loss carryforwards, or NOLs, of approximately $39.2 million for federal income tax purposes, and $41.2 million for state income tax purposes. 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 $20.8 million. The tax expense was offset by a 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 U.S federal income tax and state income tax obligations. In addition, as a result of the Tax Cuts and Jobs Act of 2017, as modified by the 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, however, the deductibility of our federal NOLs generated in such years will be limited to 80% of taxable income if utilized in taxable years beginning after December 31, 2020. Federal net operating losses incurred in years beginning before January 1, 2018 are subject to a twenty-year carryforward but are not limited to 80% of taxable income. See Risk Factors — *Because the Merger will likely result in an ownership change under Section 382 of the Code for the Company, the Company's pre-Merger net operating loss carryforwards and certain other tax attributes will be subject to limitation. The net operating loss carryforwards and certain other tax attributes of the post-Merger public company may also be subject to limitations as a result of ownership changes.*

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 IPO, 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 IPO, (b) in which we have total annual gross revenue of at least $1.235 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 GAAP, 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 IPO. 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, 2022, we had 1,423,367 outstanding shares of our common stock.

In connection with our February 2022 equity offering, July 2022 warrant repricing and 2020 equity offerings, we issued warrants to investors and our placement agents and, in connection with the sale of the Dermatology Business in 2021, we issued a warrant to the broker. We had an aggregate 1,150,686 warrants outstanding as of September 30, 2022. We have an effective shelf registration statement and had an ATM offering thereunder until January 18, 2022 and a second effective ATM offering thereunder from September 2, 2022 through October 7, 2022. During the year ended December 31, 2021, we sold 76,223 shares of common stock under the first ATM offering. No shares were sold under the first ATM offering during 2022. As of September 30, 2022, we had sold 333,184 shares of common stock under the second ATM offering. In addition, pursuant to our 2018 Equity Incentive Plan, or 2018 Plan, equity incentive awards representing up to an aggregate of 8,207 shares of our common stock were available for issuance to our employees, directors and consultants as of September 30, 2022. 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, no shares were available for sale under our ESPP as of September 30, 2022. The ESPP was paused after the end of the contribution period in May 2022. The ESPP 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 2022 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, 640 shares of common stock were reserved solely for the granting of inducement stock options, restricted stock, restricted stock units and other awards and 180 shares were available for issuance as of September 30, 2022. 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 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. 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.

We are subject to the continued listing requirements of the NYSE American. If we are unable to comply with such requirements, our common stock would be delisted from the NYSE American, which would limit investors' ability to effect transactions in our common stock and subject us to additional trading restrictions.

Shares of our common stock are currently listed on the NYSE American. In order to maintain our listing, we must maintain certain share prices, financial and share distribution targets, including maintaining a minimum amount of stockholders' equity and a minimum number of public stockholders. In addition to these objective standards, the NYSE American may delist the securities of any issuer if, in its opinion, the issuer's financial condition and/or operating results appear unsatisfactory; 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; if the issuer sells or disposes of principal operating assets or ceases to be an operating company; if an issuer fails to comply with the NYSE American's listing requirements; if an issuer's common stock sells at what the NYSE American considers a "low selling price" (generally trading below $0.20 per share for an extended period of time); or if any other event occurs or any condition exists which makes continued listing on the NYSE American, in its opinion, inadvisable. On August 31, 2022, we received a deficiency letter from the NYSE American indicating that we are not in compliance with Section 1003(f)(v) of the NYSE American Company Guide, because shares of our common stock have been selling for a low price per share for a substantial period time. If we fail to regain compliance with the NYSE American continued listing standards by February 28, 2023, the NYSE American will commence delisting proceedings.

If the NYSE American delists our shares of common stock from trading on its exchange and we are not able to list our securities on another national securities exchange, we expect our common stock would qualify to be quoted on an over-the-counter market. If this were to occur, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage;
- a decreased ability to issue additional securities or obtain additional financing in the future.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as "covered securities." Because our shares of common stock are listed on the NYSE American, our shares of common stock qualify as covered securities under such statute. Although the states are preempted from regulating the sale of our securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. If we were no longer listed on the NYSE American, our securities would not be covered securities and we would be subject to regulation in each state in which we offer our securities.

We may be required to raise additional financing by issuing new securities, which may have terms or rights superior to those of our shares of common stock, which could adversely affect the market price of our shares of common stock and our business.

We will require additional financing to fund research, development and commercialization of our technology, to obtain and maintain patents and other intellectual property rights in our technology, and for working capital and other purposes. We may not be able to obtain financing on favorable terms, if at all. If we raise additional funds by issuing equity securities, the percentage ownership of our then-current shareholders will be reduced. Further, we may have to offer new investors in our equity securities rights that are superior to the holders of common stock, which could adversely affect the market price and the voting power of shares of our common stock. If we raise additional funds by issuing debt securities, the holders of these debt securities would similarly have some rights senior to those of the holders of shares of common stock, and the terms of these debt securities could impose restrictions on operations and create a significant interest expense for us which could have a materially adverse effect on our business.

We have not paid dividends in the past and have no immediate plans to pay dividends.

We plan to reinvest all of our earnings, to the extent we have earnings, in order to market our products and to cover operating costs and to otherwise become and remain competitive. We do not plan to pay any cash dividends with respect to our securities in the foreseeable future. We cannot assure you that we would, at any time, generate sufficient surplus cash that would be available for distribution to the holders of our common stock as a dividend.

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

Recent Sales of Unregistered Securities

On July 22, 2022, we reduced the exercise price of all Series A Common Stock Purchase Warrants and Series B Common Stock Purchase Warrants, or the Existing Warrants, that were issued in our February 2022 underwritten public offering from $25.00 per share to $14.00, or the Warrant Repricing. Following the Warrant Repricing, we entered into warrant inducement offer letters, or the Inducement Letters, with certain investors to immediately exercise up to approximately 0.4 million of the Existing Warrants held by such investors, or the Inducement Offer. In consideration for exercising the Existing Warrants, pursuant to the terms of the Inducement Letters, we issued to the investors a new Series C Common Stock Purchase Warrant, or the Series C Warrant, if the investor exercised a Series A Warrant or a new Series D Common Stock Purchase Warrant, or the

Series D Warrant, and together with the Series C Warrants, collectively the New Warrants, if the investor exercised a Series B Warrant, in each case, to purchase up to a number of shares of common stock equal to 100% of the number of shares of common stock issued pursuant to the immediate exercise of the corresponding Series A Warrants and Series B Warrants, as applicable. The Series C Warrants have an exercise price of $14.00 and a term of five years, and the Series D Warrants have an exercise price of $14.00 and a term of seven years. We received aggregate gross proceeds of approximately $6.2 million from the exercise of the Series A Warrants which resulted in the issuance of an aggregate of approximately 0.4 million shares of common stock, together with the corresponding issuance of Series C Warrants exercisable for approximately 0.4 million shares of common stock. None of the Series B Warrants were exercised pursuant to the Inducement Offer. The New Warrants and the shares underlying the New Warrants were issued in a private placement pursuant to Section 4(a)(2) of the Securities Act and were unregistered at the time of issuance. The shares issued upon exercise of the Series A Warrants were registered in our February 2022 underwritten public offering. While the shares underlying the Series C Warrants were registered following the Inducement Offer, the Series C Warrants themselves have not been registered.

The terms of the Warrant Repricing, the Inducement Offer and the New Warrants are complex and are only briefly summarized above. For further information regarding these agreements and the financing, please refer to our Current Report on Form 8-K filed with the SEC on July 22, 2022. The discussion herein is qualified in its entirety by reference to such filed transaction documents.

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
2.1	Agreement and Plan of Merger, dated September 9, 2022, by and among Ra Medical Systems, Inc., Rapid Merger Sub 1, Inc., Rapid Merger Sub 2, LLC and Catheter Precision, Inc. (incorporated by reference to Exhibit 2.1 of the Company's Form 8-K filed on September 12, 2022).
3.1	Bylaws Amendment (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K filed on August 17, 2022).
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Ra Medical Systems, Inc., dated as of September 20, 2022 (incorporated by reference to Exhibit 3.1 of Company's Form 8-K filed on September 20, 2022).
4.1	Form of Series C Warrant offered in July 2022 (incorporated by reference to Exhibit 4.1 of Company's Form 8-K filed on July 22, 2022).
4.2	Form of Series D Warrant offered in July 2022 (incorporated by reference to Exhibit 4.2 of Company's Form 8-K filed on July 22, 2022).
10.1	Consulting Agreement by and between the Company and Brian Conn dated as of May 25, 2022 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K file on July 18, 2022).
10.2	Form of Warrant Inducement Offer Letter Form (incorporated by reference to Exhibit 10.1 of Company's Form 8-K filed on July 22, 2022).
10.3	Non-Binding Summary of Proposed Terms by and between Ra Medical Systems, Inc. and Catheter Precision, Inc. dated as of July 18, 2022 (incorporated by reference to Exhibit 10.2 of Company's Form 8-K filed on July 22, 2022).
10.4	Amendment to Letter Agreement by and between the Company and Brian Conn dated as of August 10, 2022 (incorporated by reference to Exhibit 10.1 of Company's Form 8-K filed on August 12, 2022).
10.5	At Market Issuance Sales Agreement by and between the Company and Ladenburg Thalmann & Co. Inc. (incorporated by reference to Exhibit 10.1 of Company's Form 8-K filed on September 2, 2022).
10.6	Form of Support Agreement, by and among the Company, Catheter Precision, Inc. and directors, officers and certain shareholders of the Company (incorporated by reference to Exhibit 10.1 of Company's Form 8-K filed on September 12, 2022).
10.7	Form of Lock-Up Agreement, by and among the Company, Catheter Precision, Inc. and directors, officers and certain shareholders of the Company and certain stockholders of Catheter Precision, Inc. (incorporated by reference to Exhibit 10.2 of Company's Form 8-K filed on September 12, 2022).
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 14, 2022

By: /s/ Brian Conn
Brian Conn
Interim Chief Financial Officer

Exhibit 31.1

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

I, Jonathan Will McGuire, certify that:

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures(as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f))for the registrant and have:

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

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

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2022

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, Brian Conn, 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 fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures(as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f))for the registrant and have:

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

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

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2022

By: /s/ Brian Conn
Brian Conn
Interim 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, 2022 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 14, 2022

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, 2022 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 14, 2022

By: /s/ Brian Conn
Brian Conn
Interim 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.