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

FORM 10-Q

REGISTRATION STATEMENT
Under
The Securities Act of 1933

(Mark One)

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

For the quarterly period ended September 30, 2021
OR

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

For transition period from to
Commission File Number 001-38847

SILK ROAD MEDICAL, INC.

(Exact name of registrant as specified in its charter)

Delaware	**3841**	**20-8777622**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

1213 Innsbruck Dr. Sunnyvale, CA 94089 (408) 720-9002
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Erica J. Rogers
Chief Executive Officer
1213 Innsbruck Dr. Sunnyvale, CA 94089 (408) 720-9002
(Name, address, including zip code, and telephone number, including area code, of agent for service)

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 7(a)(2)(B) of the Securities Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule12b-2 of the Act). Yes ☐ No ☒

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	SILK	Nasdaq Global Select Market

As of October 31, 2021, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 34,896,409.

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CAUTIONARY NOTES REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business, operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology.

These forward-looking statements include, but are not limited to, statements about:

- our plans to conduct further clinical trials;
- our plans and expected timeline related to our products, or developing new products, to address additional indications or to obtain regulatory approvals or clearances or otherwise;
- the expected use of our products by physicians;
- our expectations regarding the number of procedures that will be performed with our products, the number of physicians we expect to train, and the number of our sales territories;
- our ability to obtain, maintain and expand regulatory clearances for our current products and any new products we create;
- the expected growth of our business and our organization;
- our expectations regarding government and third-party payer coverage and reimbursement;
- our ability to retain and recruit key personnel, including the continued expansion of our sales and marketing infrastructure;
- our ability to obtain an adequate supply of materials and components for our products from our third-party suppliers, most of whom are single-source suppliers;
- our ability to manufacture sufficient quantities of our products with sufficient quality;
- our ability to obtain and maintain intellectual property protection for our products and our business;
- our ability to expand our business into new geographic markets;
- our compliance with extensive Nasdaq requirements and government laws, rules and regulations both in the United States and internationally;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our need for, or ability to obtain, additional financing;
- our ability to identify and develop new and planned products and/or acquire new products;
- our expectations regarding the continued impact of the COVID-19 pandemic on our business;
- developments and projections relating to our competitors or our industry; and
- our intended use of net proceeds from our public offerings.

We believe that it is important to communicate our future expectations to our investors. However, there may be events in the future that we are not able to accurately predict or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. These forward-looking statements are based on management’s current expectations, estimates, forecasts and projections about our business and the industry in which we operate and management’s beliefs and assumptions and are not guarantees of future performance or

development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Quarterly Report on Form 10-Q may turn out to be inaccurate. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q.

These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. We assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Quarterly Report on Form 10-Q to conform these statements to actual results or to changes in our expectations.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed with the SEC as exhibits to this Quarterly Report on Form 10-Q with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

Part I. Financial Information

Item 1: Unaudited Condensed Financial Statements

Silk Road Medical, Inc.
Condensed Balance Sheets
(unaudited)

(in thousands, except share and per share data)	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 105,642	$ 69,466
Short-term investments	17,127	78,016
Accounts receivable, net	10,976	9,070
Inventories	16,049	9,989
Prepaid expenses and other current assets	4,662	6,787
Total current assets	154,456	173,328
Property and equipment, net	5,132	2,844
Restricted cash	232	310
Other non-current assets	5,711	2,832
Total assets	$ 165,531	$ 179,314
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,908	$ 2,598
Accrued liabilities	16,011	16,957
Total current liabilities	20,919	19,555
Long-term debt	48,652	48,533
Other liabilities	7,781	3,726
Total liabilities	77,352	71,814
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.001 par value		
Shares authorized: 5,000,000 at September 30, 2021 and December 31, 2020		
Shares issued and outstanding: none at September 30, 2021 and December 31, 2020		
Common stock, $0.001 par value	—	—
Shares authorized: 100,000,000 at September 30, 2021 and December 31, 2020		
Shares issued and outstanding: 34,854,822 and 34,249,649 at September 30, 2021 and December 31, 2020, respectively	35	34
Additional paid-in capital	362,152	346,318
Accumulated other comprehensive income	1	39
Accumulated deficit	(274,009)	(238,891)
Total stockholders' equity	88,179	107,500
Total liabilities and stockholders' equity	$ 165,531	$ 179,314

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

Silk Road Medical, Inc.
Condensed Statements of Operations and Comprehensive Loss
(unaudited)

(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue	$ 24,701	$ 20,067	$ 73,210	$ 54,093
Cost of goods sold	6,076	5,488	18,213	16,074
Gross profit	18,625	14,579	54,997	38,019
Operating expenses:				
Research and development	6,867	4,711	19,611	11,232
Selling, general and administrative	25,049	19,202	68,792	54,652
Total operating expenses	31,916	23,913	88,403	65,884
Loss from operations	(13,291)	(9,334)	(33,406)	(27,865)
Interest income	42	249	183	951
Interest expense	(633)	(1,215)	(1,884)	(3,620)
Other income (expense), net	(3)	(15)	(11)	(74)
Net loss	(13,885)	(10,315)	(35,118)	(30,608)
Other comprehensive loss:				
Unrealized gain (loss) on investments, net	(2)	(164)	(38)	150
Net change in other comprehensive loss	(2)	(164)	(38)	150
Net loss and comprehensive loss	$ (13,887)	$ (10,479)	$ (35,156)	$ (30,458)
Net loss per share, basic and diluted	$ (0.40)	$ (0.31)	$ (1.02)	$ (0.94)
Weighted average common shares used to compute net loss per share, basic and diluted	34,736,015	33,757,599	34,536,980	32,597,007

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

Silk Road Medical, Inc.
Condensed Statements of Stockholders' Equity
(unaudited)

(in thousands, except share data)	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
	Shares	Amount				
Balances at December 31, 2020	34,249,649	$ 34	$ 346,318	$ (238,891)	$ 39	$ 107,500
Exercise of stock options	163,151	—	848	—	—	848
Issuance of common stock upon release of restricted stock units	25,490	—	—	—	—	—
Stock-based compensation	—	—	3,533	—	—	3,533
Net loss	—	—	—	(10,694)	—	(10,694)
Unrealized loss on investments, net	—	—	—	—	(33)	(33)
Balances at March 31, 2021	34,438,290	34	350,699	(249,585)	6	101,154
Exercise of stock options	155,443	1	1,030	—	—	1,031
Issuance of common stock upon release of restricted stock units	2,792	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	26,884	—	1,086	—	—	1,086
Stock-based compensation	—	—	3,409	—	—	3,409
Net loss	—	—	—	(10,539)	—	(10,539)
Unrealized loss on investments, net	—	—	—	—	(3)	(3)
Balances at June 30, 2021	34,623,409	35	356,224	(260,124)	3	96,138
Exercise of stock options	230,105	—	2,242	—	—	2,242
Issuance of common stock upon release of restricted stock units	1,308	—	—	—	—	—
Stock-based compensation	—	—	3,686	—	—	3,686
Net loss	—	—	—	(13,885)	—	(13,885)
Unrealized loss on investments, net	—	—	—	—	(2)	(2)
Balances at September 30, 2021	34,854,822	$ 35	$ 362,152	$ (274,009)	$ 1	$ 88,179

(in thousands, except share data)	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total
	Shares	Amount				
Balances at December 31, 2019	31,255,267	$ 31	$ 263,384	$ (191,526)	$ 2	$ 71,891
Exercise of stock options	140,370	—	274	—	—	274
Stock-based compensation	—	—	1,293	—	—	1,293
Net loss	—	—	—	(9,941)	—	(9,941)
Unrealized gains on investments, net	—	—	—	—	440	440
Balances at March 31, 2020	31,395,637	31	264,951	(201,467)	442	63,957
Issuance of common stock in connection with public offering, net of underwriting discount, commissions and offering costs of $4,457	1,923,076	2	70,541	—	—	70,543
Exercise of stock options	265,467	1	603	—	—	604
Issuance of common stock under employee stock purchase plan	25,919	—	801	—	—	801
Stock-based compensation	—	—	1,654	—	—	1,654
Net loss	—	—	—	(10,353)	—	(10,353)
Unrealized loss on investments, net	—	—	—	—	(126)	(126)
Balances at June 30, 2020	33,610,099	34	338,550	(211,820)	316	127,080
Exercise of stock options	278,978	—	1,131	—	—	1,131
Stock-based compensation	—	—	2,006	—	—	2,006
Net loss	—	—	—	(10,315)	—	(10,315)
Unrealized loss on investments, net	—	—	—	—	(164)	(164)
Balances at September 30, 2020	33,889,077	$ 34	$ 341,687	$ (222,135)	$ 152	$ 119,738

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

Silk Road Medical, Inc.
Condensed Statements of Cash Flows
(unaudited)

(in thousands)	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities		
Net loss	$ (35,118)	$ (30,608)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	723	563
Stock-based compensation expense	10,628	4,953
Amortization of premiums on investments, net	451	145
Amortization of debt discount and debt issuance costs	119	35
Amortization of right-of-use asset	627	447
Non-cash interest expense	193	249
Loss on disposal of property and equipment	—	51
Change in provision for doubtful accounts receivable	—	(26)
Provision for excess and obsolete inventories	56	109
Changes in assets and liabilities:		
Accounts receivable	(1,906)	(771)
Inventories	(3,744)	(732)
Prepaid expenses and other current assets	(2,014)	(565)
Other assets	(107)	200
Accounts payable	1,304	29
Accrued liabilities	629	(2,054)
Other liabilities	656	176
Net cash used in operating activities	(27,503)	(27,799)
Cash flows from investing activities		
Purchases of property and equipment	(2,006)	(587)
Purchases of investments	—	(58,884)
Proceeds from maturity of investments	60,400	37,180
Net cash provided by (used in) investing activities	58,394	(22,291)
Cash flows from financing activities		
Proceeds from public offerings, net of underwriting discount, commissions and offering costs paid	—	70,568
Proceeds from issuance of common stock	5,207	2,809
Net cash provided by financing activities	5,207	73,377
Net change in cash, cash equivalents and restricted cash	36,098	23,287
Cash, cash equivalents and restricted cash, beginning of period	69,776	39,491
Cash, cash equivalents and restricted cash, end of period	$ 105,874	$ 62,778
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 1,571	$ 3,336
Noncash investing and financing activities:		
Accounts payable and accrued liabilities for purchases of property and equipment	$ 1,298	$ 118
Offering costs in accrued liabilities	—	25
Right-of-use asset obtained in exchange for lease obligation	$ 3,398	$ —

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

Silk Road Medical, Inc.
Notes to Condensed Financial Statements
(unaudited)

1. Formation and Business of the Company

The Company

Silk Road Medical, Inc. (the “Company”) was incorporated in the state of Delaware on March 21, 2007. The Company has developed a technologically advanced, minimally-invasive solution for patients with carotid artery disease who are at risk for stroke. The Company's portfolio of TCAR products enable a new procedure, referred to as transcarotid artery revascularization, or TCAR, that combines the benefits of endovascular techniques and surgical principles. The Company manufactures and sells in the United States its portfolio of TCAR products which are designed to provide direct access to the carotid artery, effective reduction in stroke risk throughout the procedure, and long-term restraint of carotid plaque. The Company commercialized its products in the United States in late 2015.

Public Offering

In May 2020, the Company completed an underwritten public offering of 6,808,154 shares of its common stock, of which 1,923,076 shares were offered for sale by the Company and the remaining 4,885,078 shares were offered for sale by certain selling stockholders, at a public offering price of $39.00 per share. The Company received cash proceeds of approximately $70,543,000 after deducting underwriting discounts and commissions of approximately $3,750,000 and expenses of approximately $707,000. Also in May 2020, the underwriters fully exercised their option to purchase 1,021,223 additional shares of common stock from the selling stockholders. The Company did not receive any of the proceeds from the sale of the shares of its common stock by the selling stockholders.

2. Summary of Significant Accounting Policies

Basis of Preparation

The accompanying financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America, or U.S. GAAP, and applicable rules and regulations of the Securities and Exchange Commission, or SEC, regarding interim financial reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP have been condensed or omitted, and accordingly the balance sheet as of December 31, 2020, and related disclosures, have been derived from the audited financial statements at that date but does not include all of the information required by U.S. GAAP for complete financial statements. These unaudited condensed financial statements have been prepared on the same basis as the Company’s annual financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for the fair statement of the Company’s condensed financial information. The results of operations for the three and nine months ended September 30, 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2021 or for any other interim period or for any other future year.

The accompanying interim unaudited condensed financial statements and related financial information should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2020 included in the Company's annual report on Form 10-K filed with the SEC on March 1, 2021.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements. Management uses judgment when making estimates related to provisions for accounts receivable and excess and obsolete inventories, the valuation of deferred tax assets, the reserves for sales returns, and stock-based compensation. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Although these estimates are based on the Company’s knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Silk Road Medical, Inc.
Notes to Condensed Financial Statements
(unaudited)

Due to the coronavirus ("COVID-19") pandemic, there has been continued uncertainty and disruption in the global economy and financial markets. While some of the uncertainties began to lift throughout the first half of 2021, new virus variants, and increased infection rates during this period make the current COVID-related environment highly volatile and uncertain. The Company expect these challenges to continue to impact the number of TCAR procedures in 2021, with procedure volumes impacted by increased COVID-19 hospitalizations and hospital capacity constraints due to the COVID-19 Delta variant. The Company is not aware of any specific event or circumstance that would require an update to its estimates or judgments or a revision of the carrying value of its assets or liabilities as of September 30, 2021. The Company has also considered information available to it as of the date of issuance of these financial statements and is not aware of any specific events or circumstances that would require an update to its estimates or judgments, or a revision to the carrying value of its assets or liabilities. These estimates may change as new events occur and additional information becomes available. Actual results could differ materially from these estimates.

Fair Value of Financial Instruments

The Company has evaluated the estimated fair value of its financial instruments as of September 30, 2021 and December 31, 2020. The carrying amounts of certain of the Company's financial instruments, which include cash equivalents, short-term investments, restricted cash, accounts receivable, accounts payable and accrued liabilities approximate their respective fair values because of the short-term nature of these instruments. Management believes that its long-term debt bears interest at the prevailing market rates for instruments with similar characteristics (Level 2 within the fair value hierarchy); accordingly, the carrying value of this instrument approximates its fair value.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with an original maturity of three months or less at the time of purchase to be cash equivalents. Cash equivalents are considered available-for-sale marketable securities and are recorded at fair value, based on quoted market prices. As of September 30, 2021 and December 31, 2020, the Company's cash equivalents are entirely comprised of investments in money market funds.

Restricted cash as of September 30, 2021 and December 31, 2020 consists of a letter of credit of $232,000 and $310,000, respectively, representing collateral for the Company's facility lease in California.

Investments

Short-term investments consist of debt securities classified as available-for-sale and have original maturities greater than 90 days, but less than one year as of the balance sheet date. Long-term investments have maturities greater than one year as of the balance sheet date. All investments are recorded at fair value based on the fair value hierarchy. Money market funds and United States treasury bills with an original maturity less than 90 days are classified within Level 1 of the fair value hierarchy, and commercial paper, corporate bonds/notes, United States Government securities, and asset-backed securities are classified within Level 2 of the fair value hierarchy. Unrealized gains and losses, deemed temporary in nature, are reported as a separate component of accumulated other comprehensive income (loss). The cost of available-for-sale investments sold is based on the specific-identification method. Realized gains and losses are included in earnings and are derived for specific-identification method for determining the costs of investments sold and were insignificant for the three and nine months ended September 30, 2021 and 2020. Amortization of premiums and accretion of discounts are reported as a component of interest income.

A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to earnings and the corresponding establishment of a new cost basis for the investment. The Company evaluates the securities in an unrealized loss position for expected credit losses by considering factors such as historical experience, market data, issuer-specific factors, current economic conditions and credit ratings.

Concentration of Credit Risk, and Other Risks and Uncertainties

The Company is subject to risks related to public health crises such as the global pandemic associated with COVID-19, which has spread to most countries and all 50 states within the United States. The COVID-19 outbreak has negatively impacted, and may continue to negatively impact the Company's operations, its revenue and overall financial condition by

significantly decreasing the number of TCAR procedures performed. The number of TCAR procedures performed, similar to other surgical procedures, has significantly decreased as health care organizations globally prioritized the treatment of patients with COVID-19. In the past governmental authorities have recommended, and in certain cases required, that elective, specialty and other procedures and appointments, be suspended or canceled to focus limited resources and personnel and hospital capacity toward the treatment of COVID-19 and to avoid exposing patients to COVID-19. These measures and challenges will likely continue for the duration of the pandemic, which is uncertain, and will continue to negatively impact the Company's revenue while the pandemic continues. New virus variants, and increased infection rates continue to make the current COVID-related environment highly volatile and uncertain.

Financial instruments that potentially subject the Company to credit risk consist of cash and cash equivalents, investments and accounts receivable to the extent of the amounts recorded on the balance sheet. Cash, cash equivalents, and investments are deposited in financial institutions which, at times, may be in excess of federally insured limits. Cash equivalents are invested in highly rated money market funds and United States treasury bills. The Company invests in a variety of financial instruments, such as, but not limited to, commercial paper, corporate bonds/notes, United States Government securities, asset-backed securities and, by policy, limits the amount of credit exposure with any one financial institution or commercial issuer. The Company has not experienced any material losses on its deposits of cash and cash equivalents or investments during the three and nine months ended September 30, 2021 and 2020.

The Company's accounts receivable are due from a variety of health care organizations in the United States. At September 30, 2021 and December 31, 2020, no customer represented 10% or more of the Company's accounts receivable. For the three and nine months ended September 30, 2021 and 2020, there were no customers that represented 10% or more of revenue.

The Company provides for uncollectible amounts when specific credit problems are identified. In doing so, the Company analyzes historical bad debt trends, customer credit worthiness, current economic trends and changes in customer payment patterns when evaluating the adequacy of the allowance for expected credit losses on customer accounts.

The Company manufactures certain of its commercial products in-house. Certain of the Company's product components and sub-assemblies continue to be manufactured by sole suppliers, the most significant of which is the ENROUTE Transcarotid Stent System, manufactured by Cordis Corporation, or Cordis. Disruption in component or sub-assembly supply from these manufacturers or from in-house production would have a negative impact on the Company's financial position and results of operations.

The Company is subject to certain risks, including that its devices may not be approved or cleared for marketing by governmental authorities or be successfully marketed. There can be no assurance that the Company's products will achieve widespread adoption in the marketplace, nor can there be any assurance that existing devices or any future devices can be developed or manufactured at an acceptable cost and with appropriate performance characteristics. The Company is also subject to risks common to companies in the medical device industry, including, but not limited to, new technological innovations, dependence upon government and third-party payers to provide adequate coverage and reimbursement, dependence on key personnel and suppliers, protection of proprietary technology, product liability claims, and compliance with government regulations.

Existing or future devices developed by the Company may require approvals or clearances from the FDA or international regulatory agencies. In addition, in order to continue the Company's operations, compliance with various federal and state laws is required. If the Company were denied or delayed in receiving such approvals or clearances, it may be necessary to adjust operations to align with the Company's currently approved portfolio. If clearance for the products in the current portfolio were withdrawn by the FDA, this would have a material adverse impact on the Company.

Voluntary Recall

In January and February 2021, the Company announced the voluntary recall of certain lots of its ENROUTE Transcarotid Stent System, manufactured by one of its third-party suppliers, Cordis. The decision to recall these lots was based on complaints received about tips detaching from the stent delivery system as well as internal testing that the Company conducted. The Company believes the root cause of the detachment was a single operator at Cordis, who, over a specific timeframe, produced lots in which a small number of units were not reliably manufactured to specification.

Silk Road Medical, Inc.
Notes to Condensed Financial Statements
(unaudited)

As a result of the voluntary recall the Company reflected a current asset of $4,160,000 on its balance sheet as of December 31, 2020, relating to the replacement lots and other direct costs to be received from Cordis. This amount includes $2,227,000 of recalled ENROUTE stent delivery systems held in the Company's inventory as of December 31, 2020, $1,696,000 of ENROUTE stent delivery systems in the process of being returned from its customers and other direct costs of $237,000. In addition, the Company established an accrual of $1,696,000 relating to its obligation to provide replacement ENROUTE stent delivery systems to its customers as of December 31, 2020. As of September 30, 2021, the Company has a current asset of $334,000 on its balance sheet, relating to other direct costs to be reimbursed from Cordis. In addition, as of September 30, 2021, the Company has a remaining accrual of $15,000 relating to its obligation to provide replacement ENROUTE stent delivery systems to its customers.

Leases

The Company accounts for leases in accordance with Accounting Standards Codification (“ASC”) 842, "Leases." The Company considers if an arrangement is a lease at inception if it obtains the right to control the use of an identified asset under a leasing arrangement with an initial term greater than twelve months. The Company determines whether a contract conveys the right to control the use of an identified asset for a period of time if the contract contains both the right to obtain substantially all of the economic benefits from the use of the identified asset and the right to direct the use of the identified asset. The Company also evaluates the nature of each lease to determine whether it is an operating or financing lease and recognizes the right-of-use asset and lease liabilities based on the present value of future minimum lease payments over the expected lease term. The Company’s leases do not generally contain an implicit interest rate and therefore the Company uses the incremental borrowing rate it would expect to pay to borrow on a similar collateralized basis over a similar term in order to determine the present value of its lease payments. The Company considers renewal options in the determination of the lease term if the option to renew is reasonably certain. Variable lease costs represent payments that are dependent on usage, a rate or index. Variable lease costs, which consists primarily of taxes, insurance and common area maintenance costs, are expensed as incurred, as the Company has elected to account separately for contracts that contain lease and non-lease components, consistent with its historical practice. The Company does not have any finance leases.

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606, "Revenue from Contracts with Customers." Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the entity satisfies a performance obligation.

As of September 30, 2021 and December 31, 2020, the Company recorded $164,000 and $71,000, respectively, of unbilled receivables, which are included in accounts receivable, net on the condensed balance sheet, as the Company has an unconditional right to payment as of the end of the applicable period.

The Company’s revenue is generated from the sale of its products to hospitals and medical centers in the United States through direct sales representatives. Revenue is recognized when obligations under the terms of a contract with customers are satisfied, which occurs with the transfer of control of the Company’s products to its customers, either upon shipment of the product or delivery of the product to the customer under the Company’s standard terms and

conditions. The Company's products are readily available for usage as soon as the customer possesses it. Upon receipt, the customer controls the economic benefits of the product, has significant risks and rewards, and the legal title. The Company has present right to payment; therefore, the transfer of control is deemed to happen at a point in time. Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring the goods.

For sales where the Company's sales representative hand delivers product directly to the hospital or medical center from the sales representative's trunk stock inventory, the Company recognizes revenue upon delivery, which represents the point in time when control transfers to the customer. Upon delivery there are legally-enforceable rights and obligations between the parties which can be identified, commercial substance exists and collectability is probable. For sales which are sent directly from the Company to hospitals and medical centers, the transfer of control occurs at the time of shipment or delivery of the product. There are no further performance obligations by the Company or the sales representative to the customer after delivery under either method of sale. As allowed under the practical expedient, the Company does not disclose the value of unsatisfied performance obligations for (i) contracts with an original expected length of one year or less and (ii) contracts for which it recognizes revenue at the amount to which it has the right to invoice for services performed.

The Company is entitled to the total consideration for the products ordered by customers as product pricing is fixed according to the terms of customer contracts and payment terms are short. Payment terms fall within the one-year guidance for the practical expedient which allows the Company to forgo adjustment of the promised amount of consideration for the effects of a significant financing component. The Company excludes taxes assessed by governmental authorities on revenue-producing transactions from the measurement of the transaction price.

Costs associated with product sales include commissions and royalties. The Company applies the practical expedient and recognizes commissions and royalties as expense when incurred because the expense is incurred at a point in time and the amortization period is less than one year. Commissions are recorded as selling expense and royalties are recorded as cost of goods sold in the condensed statements of operations and comprehensive loss.

The Company accepts product returns at its discretion or if the product is defective as manufactured. The Company establishes estimated provisions for returns based on historical experience and considers other factors that it believes could significantly impact its expected returns, which provisions are classified within accrued liabilities on the condensed balance sheet. The Company elected to expense shipping and handling costs as incurred and includes them in the cost of goods sold. In those cases where the Company bills shipping and handling costs to customers, it will classify the amounts billed as a component of revenue.

Cost of Goods Sold

The Company manufactures certain of its portfolio of TCAR products at its California facility and purchases other products from third party manufacturers. Cost of goods sold consists primarily of costs related to materials, components and subassemblies, manufacturing overhead costs, direct labor, reserves for excess, obsolete and non-sellable inventories as well as distribution-related expenses. A significant portion of the Company's cost of goods sold currently consists of manufacturing overhead costs. These overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. Cost of goods sold also includes depreciation expense for production equipment and certain direct costs such as shipping costs and royalties.

Stock–Based Compensation

The Company accounts for stock-based compensation in accordance with Financial Accounting Standards Board ("FASB") ASC 718, "Compensation-Stock Compensation." ASC 718 requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based payments including stock options, restricted stock units and shares issued under its employee stock purchase plan. ASC 718 requires companies to estimate the fair value of all share-based payment option awards on the date of grant using an option pricing model. The fair value of stock options is recognized over the period during which an optionee is required to provide services in exchange for the option award, known as the requisite service period (usually the vesting period), on a straight-line basis. For performance-based stock options, the Company will assess the probability of performance conditions being achieved in each reporting period. The amount of stock-based compensation expense recognized in any one period related to performance-based stock

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options can vary based on the achievement or anticipated achievement of the performance conditions. The Company accounts for option forfeitures as they occur.

The Company accounts for stock-based compensation for restricted stock units at their fair value, based on the closing market price of the Company's common stock on the date of grant. These costs are recognized on a straight-line basis over the requisite service period, which is usually the vesting period.

The Company accounts for stock-based compensation for its employee stock purchase plan based on the estimated fair value of the options on the date of grant. The Company estimates the grant date fair value using an option pricing model for each purchase period. These costs are recognized on a straight-line basis over the offering period.

Income Taxes

The Company accounts for income taxes under the liability method, whereby deferred tax assets and liabilities are determined based on the difference between the condensed financial statements and tax bases of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to affect taxable income. A valuation allowance is established when necessary to reduce deferred tax assets to the amounts expected to be realized. As the Company has historically incurred operating losses, it has established a full valuation allowance against its net deferred tax assets, and there is no provision for income taxes.

The Company also follows the provisions of ASC 740-10, "Accounting for Uncertainty in Income Taxes." ASC 740-10 prescribes a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken or expected to be taken on a tax return. No liability related to uncertain tax positions is recorded on the condensed financial statements. It is the Company's policy to include penalties and interest expense related to income taxes as part of the provision for income taxes.

Comprehensive Loss

Comprehensive loss consists of net loss and changes in unrealized gains and losses on investments classified as available-for-sale. For the three and nine months ended September 30, 2021 and 2020, the Company's unrealized gains and losses on available-for-sale investments represent the only component of other comprehensive loss that are excluded from the reported net loss and that are presented in the condensed statements of operations and comprehensive loss. Accumulated other comprehensive income or loss is presented in the accompanying condensed balance sheets as a component of stockholders' equity.

Net Loss per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the period, without consideration for potential dilutive common shares. Diluted net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, common stock options, and restricted stock units are considered to be potentially dilutive securities. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share as the inclusion of all potential dilutive common shares would have been anti-dilutive.

Net loss per share was determined as follows (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss	$ (13,885)	$ (10,315)	$ (35,118)	$ (30,608)
Weighted average common stock outstanding used to compute net loss per share, basic and diluted	34,736,015	33,757,599	34,536,980	32,597,007
Net loss, basic and diluted	$ (0.40)	$ (0.31)	$ (1.02)	$ (0.94)

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The following potentially dilutive securities outstanding have been excluded from the computation of diluted weighted average shares outstanding because such securities have an antidilutive impact due to the Company's net loss:

	September 30,	
	2021	2020
Common stock options	3,930,140	4,451,768
Restricted stock units	350,249	44,109
	4,280,389	4,495,877

Segment and Geographical Information

The Company operates and manages its business as one reportable and operating segment. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. Primarily all of the Company's long-lived assets are based in the United States. Long-lived assets are comprised of property and equipment and the Company's right-of-use assets. All of the Company's revenue was in the United States for the three and nine months ended September 30, 2021 and 2020, based on the shipping location of the external customer.

3. Recent Accounting Pronouncements

Effective January 1, 2021, the Company adopted ASU 2016-13, Financial Instruments-Credit Losses (Topic 326):"Measurement of Credit Losses on Financial Instruments," which requires measurement and recognition of expected credit losses for most financial assets and certain other instruments. Unrealized losses on available-for-sale debt securities that are attributed to credit risk are recorded through earnings rather than to other comprehensive income. Credit losses relating to available-for-sale debt securities are now recorded through an allowance for credit losses. In addition, Topic 326 also provides new guidance related to the measurement of expected credit losses on the Company's allowance for bad debt for accounts receivable, which is estimated upon assessment of various factors including historical collection experience, current and future economic market conditions and a review of the current aging status and financial condition of the Company's customers. The Company adopted the new standard using a modified retrospective transition method, which required a cumulative-effect adjustment, if any, to the opening balance of accumulated deficit to be recognized on the date of adoption. The Company did not have any cumulative-effect adjustments as of the date of adoption.

Effective January 1, 2021, the Company adopted ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, which enhances and simplifies various aspects of the income tax accounting guidance related to intra-period tax allocation, interim period accounting for enacted changes in tax law, and the year-to-date loss limitation in interim period tax accounting. ASU 2019-12 also amends other aspects of the guidance to reduce complexity in certain areas. The adoption did not have a material impact on the Company's financial statements and related disclosures.

4. Fair Value Measurements

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents and investments. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. A three-tier fair value hierarchy is established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value:

- Level 1 – quoted prices in active markets for identical assets or liabilities;
- Level 2 – observable inputs other than quoted prices in active markets for identical assets and liabilities;
- Level 3 – unobservable inputs.

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Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. The Company's cash equivalents are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. The corporate bonds/notes, commercial paper, asset-backed securities and U.S. government securities are classified as Level 2 as they are valued based upon quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets.

The following tables sets forth by level within the fair value hierarchy the Company's assets that are reported at fair value as of September 30, 2021 and December 31, 2020, using the inputs defined above (in thousands):

	September 30, 2021			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 105,629	$ —	$ —	$ 105,629
Commercial paper	—	2,000	—	2,000
U.S. government securities	—	15,127	—	15,127
	$ 105,629	$ 17,127	$ —	$ 122,756

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$ 60,295	$ —	$ —	$ 60,295
Commercial paper	—	39,577	—	39,577
Corporate bonds/notes	—	7,969	—	7,969
U.S. government securities	—	38,470	—	38,470
	$ 60,295	$ 86,016	$ —	$ 146,311

There were no transfers between fair value hierarchy levels during the three and nine months ended September 30, 2021 and 2020.

5. Balance Sheet Components

Investments

The fair value of the Company's available-for-sale investments as of September 30, 2021 and December 31, 2020 are as follows (in thousands):

	September 30, 2021			
		Gross Unrealized		Estimated
	Amortized Cost	Gains	Losses	Fair Value
Money market funds	$ 105,629	$ —	$ —	$ 105,629
Commercial paper	2,000	—	—	2,000
U.S. government securities	15,126	1	—	15,127
	$ 122,755	$ 1	$ —	$ 122,756
Classified as:				
Cash equivalents				$ 105,629
Short-term investments				17,127
				$ 122,756

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	December 31, 2020			
		Gross Unrealized		Estimated
	Amortized Cost	Gains	Losses	Fair Value
Money market funds	$ 60,295	$ —	$ —	$ 60,295
Commercial paper	39,577	—	—	39,577
Corporate bonds/notes	7,970	—	(1)	7,969
U.S. government securities	38,430	42	(2)	38,470
	$ 146,272	$ 42	$ (3)	$ 146,311
Classified as:				
Cash equivalents				$ 68,295
Short-term investments				78,016
				$ 146,311

All of the Company's cash equivalents and short-term investments mature within one year as of September 30, 2021 and December 31, 2020. Available-for-sale investments held as of September 30, 2021 had a weighted average days to maturity of 41 days.

The following table presents the Company's available-for-sale investments that were in an unrealized loss position as of September 30, 2021 and December 31, 2020 (in thousands):

	September 30, 2021		December 31, 2020	
	Less than 12 months		Less than 12 months	
Assets:	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate bonds/notes	$ —	$ —	$ 5,369	$ (1)
U.S. government securities	—	—	10,128	(2)
	$ —	$ —	$ 15,497	$ (3)

Inventories

Components of inventories were as follows (in thousands):

	September 30, 2021	December 31, 2020
Raw materials	$ 2,195	$ 1,785
Finished products	13,876	10,599
	16,071	12,384
Less: Reserve for excess and obsolete	(23)	(2,395)
	$ 16,049	$ 9,989

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As of September 30, 2021 and December 31, 2020, there were no work-in-process inventories. The reserve for excess and obsolete inventory at September 30, 2021 and December 31, 2020, included $5,000 and $2,377,000, respectively, associated with the Company's voluntary product recall.

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2021	December 31, 2020
Accrued payroll and related expenses	$ 10,228	$ 9,573
Provision for sales returns	410	820
Accrued professional services	1,909	2,520
Recall replacement obligation	15	1,696
Operating lease liability	1,003	850
Accrued royalty expense	608	518
Deferred revenue	448	206
Accrued travel expenses	552	237
Accrued clinical expenses	150	113
Accrued other expenses	688	424
Total	$ 16,011	$ 16,957

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6. Long-term Debt

CRG

In October 2015, the Company entered into a term loan agreement with CRG. The term loan agreement provides for up to $30,000,000 in term loans split into two tranches as follows: (i) the Tranche A Loans provided for $20,000,000 in term loans, and (ii) the Tranche B Loans provided for up to $10,000,000 in term loans. The Company drew down the Tranche A Loans on October 13, 2015. The Tranche B Loans were available to be drawn prior to March 29, 2017. In January 2017, the term loan agreement was amended to extend the commitment period of the Tranche B Loans to April 28, 2017. In April 2017, the Company drew down $5,000,000 of the available Tranche B Loans.

In September 2018, the term loan agreement was amended to provide for additional term loans in an aggregate principal amount of up to $25,000,000. In September 2018, the Company drew down an additional $15,000,000 under the amended term loan agreement with CRG, no additional draw was taken. Under the terms of the amended term loan agreement, the related fixed interest rate was 10.0%, 8.0% of the interest was due and payable in cash and at the election of the Company, 2.0% of the interest due and payable may be paid in kind. All unpaid principal, and accrued and unpaid interest, was due and payable in full on December 31, 2022.

On October 29, 2020, in connection with the consummation of the Loan and Security agreement with Stifel Bank as noted below, the Company repaid all amounts outstanding under the term loan with CRG.

Stifel Bank

In October 2020, the Company entered into a Loan and Security Agreement, or Loan Agreement, with Stifel Bank which provides for a $50,000,000 loan facility, comprised of a $50,000,000 secured revolving credit facility, with a $2,000,000 subfacility for the issuance of letters of credit and other ancillary banking services, and a $50,000,000 secured term loan facility, provided that amounts outstanding under both facilities may not exceed an aggregate principal amount of $50,000,000 at any time. Any borrowings under the revolving loan facility mature on October 29, 2022, or October 29, 2023 if as of October 29, 2022, no event of default has occurred and we are in compliance with the terms of the Loan Agreement. Borrowings under the term loan facility mature on October 29, 2024. Interest under the revolving credit facility is the greater of a) 0.5% above the "Prime Rate" as published by The Wall Street Journal or b) 4.75%.

Also in October 2020, the Company drew down $49,000,000 under the term loan facility and used the majority of the proceeds to pay off and terminate the prior term loan agreement with CRG totaling $46,674,000, which included a prepayment premium of $305,000, a final interest payment of $365,000 and a facility fee of $2,191,000. The Company recognized a loss on debt extinguishment of $1,119,000 in connection with the early termination of the term loan agreement with CRG. The principal amount of outstanding term loans under the Loan Agreement with Stifel Bank shall be repaid in equal monthly installments beginning on May 29, 2022, or November 29, 2022 if the Company achieves revenue for the year ending December 31, 2021 of at least 80% of the board-approved financial projections for such fiscal year. Interest under the term loan facility is the greater of a) 0.75% above the "Prime Rate" as published by The Wall Street Journal or b) 4.75%. The term loan may not be reborrowed once repaid, but the Company may prepay the term loan at any time without premium or penalty.

The Company also concurrently entered in a Success Fee Agreement in October 2020 with Stifel Bank, which requires that the Company pay Stifel Bank the lesser of 0.75% of the original principal amount of all credit extensions made under the Loan Agreement or $375,000 in the event the Company completes a Liquidity Event (liquidation, merger, sale of the Company or change in control). The Success Fee Agreement terminates on October 29, 2025. The Company has determined the probability of a Liquidity Event to be remote and accordingly, has not recognized a liability as of September 30, 2021.

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Obligations under the Loan Agreement are secured by substantially all of the Company's assets. Beginning on January 15, 2021, the Loan Agreement required that the Company maintain unrestricted cash and cash equivalents with Stifel Bank or at Stifel Bank Affiliates of at least $20,000,000. In addition, for any fiscal quarter where the Company's unrestricted cash and cash equivalents maintained with Stifel Bank or at Stifel Bank Affiliates are less than $60,000,000 for any day during such fiscal quarter, the Company must comply with a minimum revenue covenant. Additionally, the Loan Agreement contains customary affirmative and negative covenants, including covenants limiting the Company's ability and the ability of the Company's subsidiaries to, among other things, dispose of assets, effect certain mergers, incur debt, grant liens, pay dividends and distributions on capital stock, make investments and acquisitions, and enter into transactions with affiliates, in each case subject to customary exceptions for a loan facility of this size and type.

The events of default under the Loan Agreement include, among others, payment defaults, material misrepresentations, breaches of covenants, cross defaults with certain other material indebtedness, bankruptcy and insolvency events, and judgment defaults. The occurrence of an event of default could result in the acceleration of our obligations under the Loan Agreement, the termination of the lender's commitments, a 5% increase in the applicable rate of interest and the exercise by the lender of other rights and remedies provided for under the Loan Agreement.

As of September 30, 2021, the aggregate outstanding principal balance under the Loan Agreement was $49,000,000 and the annual interest rate was 4.75%. As of September 30, 2021, the Company was in compliance with all applicable financial covenants. As of September 30, 2021, management does not believe that it is probable that the above events of default will be triggered within the next twelve months, therefore, the debt is classified as long-term on the condensed balance sheet.

Future maturities under the Loan Agreement as of September 30, 2021 are as follows (in thousands):

Period Ending December 31:	**Amount**
2021	$ 588
2022	6,257
2023	25,749
2024	21,457
	54,051
Less: Amount representing interest	(5,051)
Less: Amount representing debt discount and debt issuance costs	(348)
Present value of minimum payments	$ 48,652

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7. Commitments and Contingencies

Operating Lease and Rights-of-Use

The Company's operating lease obligation at its corporate headquarters in California consists of leased office, laboratory, and manufacturing space under a non-cancellable operating lease that expires in October 2024. The lease agreement includes a renewal provision allowing the Company to extend this lease for an additional period of five years.

In May 2021, the Company entered into a new, non-cancelable operating lease for additional office, laboratory and manufacturing space in Minnesota that expires in November 2029. The lease agreement includes a renewal provision allowing the Company to extend this lease for two additional five year terms. In connection with the lease, the Company recognized a right-of-use asset and lease liability of $3,398,000.

Operating lease costs were $369,000 and $217,000 for the three months ended September 30, 2021 and 2020, respectively, and $875,000 and $652,000 for the nine months ended September 30, 2021 and 2020, respectively. Cash paid (net of tenant improvement allowances receivable) for amounts included in the measurement of operating lease liabilities was $(1,043,000) and $197,000 for the three months ended September 30, 2021 and 2020, respectively, and $(650,000) and $569,000 for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, the weighted average discount rate was approximately 6.50% and the weighted average remaining lease term was 6.15 years. Balance sheet information as of September 30, 2021 and December 31, 2020 consists of the following (in thousands):

Operating Lease:	September 30, 2021	December 31, 2020
Operating lease right-of-use assets in other non-current assets	$ 5,569	$ 2,798
Operating lease liabilities in accrued liabilities	$ 1,003	$ 850
Operating lease liabilities in other liabilities	6,574	2,850
Total operating lease liabilities	$ 7,577	$ 3,700

The following table summarizes the Company's operating lease maturities as of September 30, 2021 (in thousands):

Period Ending December 31:	Amount
2021	$ (300)
2022	1,576
2023	1,970
2024	1,767
2025	886
2026 and thereafter	3,686
Total lease payments	$ 9,585
Less: interest	(2,008)
Total lease liabilities	$ 7,577

Purchase Obligations

Purchase obligations consist of agreements to purchase goods and services entered into in the ordinary course of business. As of September 30, 2021, the Company had non-cancellable purchase obligations to suppliers of $11,471,000.

Indemnification

In the normal course of business, the Company enters into contracts and agreements with suppliers and other parties that contain a variety of representations and warranties and may provide for indemnification of the counterparty. The Company's exposure under these agreements is unknown because it involves claims that may be made against it in the future but have not yet been made. To date, the Company has not been subject to any claims or been required to defend any action related to its indemnification obligations.

The Company indemnifies each of its directors and officers for certain events or occurrences, subject to certain limits, while the director is or was serving at the Company's request in such capacity, as permitted under Delaware law and in accordance with its certificate of incorporation and bylaws. The term of the indemnification period lasts as long as a director may be subject to any proceeding arising out of acts or omissions of such director in such capacity. The maximum amount of potential future indemnification is unlimited; however, the Company currently holds director liability insurance. The Company believes that the fair value of these indemnification obligations is minimal. Accordingly, the Company has not recognized any liabilities relating to these obligations as of September 30, 2021.

Contingencies

The Company is not involved in any pending legal proceedings that it believes could have a material adverse effect on its financial condition, results of operations or cash flows. From time to time, the Company may pursue litigation to assert its legal right and such litigation may be costly and divert the efforts and attention of its management and technical personnel which could adversely affect its business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. There were no contingent liabilities requiring accrual at September 30, 2021 and December 31, 2020.

8. Stockholders' Equity

Preferred Stock

At September 30, 2021, the Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 5,000,000 shares of preferred stock with $0.001 par value per share, of which no shares were issued and outstanding.

Common Stock

At September 30, 2021, the Company's certificate of incorporation, as amended and restated, authorizes the Company to issue up to 100,000,000 shares of common stock with $0.001 par value per share, of which 34,854,822 shares were issued and outstanding. The holders of common stock are also entitled to receive dividends whenever funds are legally available, when and if declared by the Board of Directors. As of September 30, 2021, no dividends have been declared to date. Each share of common stock is entitled to one vote.

9. Stock Option Plans

In March 2019, the Company's Board of Directors approved the adoption of the 2019 Equity Incentive Plan, or the 2019 Plan, which became effective immediately prior to the Company's initial public offering in April 2019. The 2019 Plan replaced the 2007 Stock Option Plan which was terminated immediately prior to consummation of the Company's initial public offering, collectively the "Plans." The 2019 Plan provides for the grant of incentive stock options, or ISOs, to employees and for the grant of nonqualified stock options, or NSOs, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to employees, directors and consultants. A total of 2,317,000 shares of common stock were initially reserved for issuance pursuant to the 2019 Plan. In addition, the shares reserved for issuance under the 2019 Plan will also include shares reserved but not issued under the 2007 Stock Option Plan, plus any share awards granted under the 2007 Stock Option Plan that expire or terminate without having been exercised in full or that are forfeited or repurchased. In addition, the number of shares available for issuance under the 2019 Plan includes an annual increase on the first day of each fiscal year beginning fiscal 2020, equal to the lesser of (i) 3,000,000 shares; (ii) 4.0% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (iii) an amount as determined by the Board of Directors. As of September 30, 2021, the Company has reserved 5,015,486 shares of common stock for issuance under the 2019 Plan.

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A summary of the shares available for issuance under the 2019 Plan is as follows:

	Number of Shares
Balances, December 31, 2020	1,790,687
Authorized	1,369,985
Granted / Awarded	(643,960)
Cancelled	91,506
Balances, September 30, 2021	2,608,218

The exercise price of ISOs and NSOs shall not be less than 100% and 85%, respectively, of the estimated fair value of the shares on the date of grant as determined by the Board of Directors. The exercise price of ISOs and NSOs granted to a 10% stockholder shall not be less than 110% of the estimated fair value of the shares on the date of grant as determined by the Board of Directors. To date, options have a term of 10 years and generally vest over 4 years from the date of grant.

Stock option activity under the Company's Plans is set forth below:

	Options Outstanding			
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balances, December 31, 2020	4,237,828	$ 16.56	7.38	$ 197,407
Options granted	323,057	53.94		
Options exercised	(548,699)	7.46		
Options cancelled	(82,046)	37.61		
Balances, September 30, 2021	3,930,140	$ 20.47	6.97	$ 137,958
Vested and exercisable at September 30, 2021	2,660,361	$ 12.41	6.28	$ 113,810
Vested and expected to vest at September 30, 2021	3,930,140	$ 20.47	6.97	$ 137,958

The aggregate intrinsic value of options exercised during the nine months ended September 30, 2021 was $25,146,000. The aggregate intrinsic value was calculated as the difference between the exercise prices of the underlying options and the estimated fair value of the common stock on the date of exercise.

Restricted Stock Units

In March 2020, the Company began granting restricted stock units, or RSUs, under the 2019 Plan. RSUs generally vest over four years in annual equal increments. The fair value of RSUs is based on the Company's closing stock price on the date of grant. A summary of RSUs activity for the nine months ended September 30, 2021 is as follows:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Balances, December 31, 2020	68,396	$ 46.16
Awards granted	320,903	53.30
Awards vested	(29,590)	46.32
Awards canceled	(9,460)	55.21
Balances, September 30, 2021	350,249	$ 52.45
Expected to vest at September 30, 2021	350,249	$ 52.45

2019 Employee Stock Purchase Plan

In March 2019, the Company's Board of Directors adopted the 2019 Employee Stock Purchase Plan, or 2019 ESPP, under which eligible employees are permitted to purchase common stock at a discount through payroll deductions. A total

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of 434,000 shares of common stock were initially reserved for issuance and is increased on the first day of each fiscal year, beginning in 2020, by an amount equal to the lesser of (i) 1,200,000 shares (ii) 1.0% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year; or (iii) an amount as determined by the Board of Directors. As of September 30, 2021, the Company has reserved 1,089,048 shares of common stock for issuance under the 2019 ESPP. The price of the common stock purchased will be the lower of 85% of the fair market value of the common stock at the beginning of an offering period or at the end of a purchase period. The 2019 ESPP was effective upon adoption by the Company's Board of Directors but was not in use until the completion of the Company's initial public offering in April 2019. The 2019 ESPP is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Internal Revenue Code of 1986, as amended.

As of September 30, 2021, 141,059 shares of common stock have been issued to employees participating in the 2019 ESPP and 947,989 shares were available for future issuance under the 2019 ESPP.

Stock-Based Compensation

The Company estimated the fair value of stock options using the Black–Scholes option pricing model. The fair value of employee and nonemployee stock options is being amortized on a straight–line basis over the requisite service period of the awards. The fair value of employee and nonemployee stock options was estimated using the following assumptions for the three and nine months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Expected term (in years)	5.25 - 6.00	5.25 - 6.25	5.25 - 6.25	5.25 - 6.25
Expected volatility	46.7% - 47.3%	48.0% - 49.1%	45.0% - 50.4%	43.0% - 49.1%
Risk-free interest rate	0.75% - 0.82%	0.32% - 0.42%	0.41% - 1.08%	0.32% - 1.41%
Dividend yield	—%	—%	—%	—%

The fair value of the shares to be issued under the Company's 2019 ESPP was estimated using the Black-Scholes valuation model with the following assumptions for the three and nine months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Expected term (in years)	0.50	0.50	0.50	0.50
Expected volatility	51.5%	76.4%	44.4% - 76.4%	44.4% - 76.4%
Risk-free interest rate	0.03%	0.14%	0.03% - 1.58%	0.14% - 1.58%
Dividend yield	—%	—%	—%	—%

Total stock-based compensation expense relating to the Company's stock options, RSUs and 2019 ESPP during the three and nine months ended September 30, 2021 and 2020 is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cost of goods sold	$ 144	$ 91	$ 452	$ 244
Research and development expenses	695	304	2,020	726
Selling, general and administrative expenses	2,847	1,611	8,156	3,983
	$ 3,686	$ 2,006	$ 10,628	$ 4,953

As of September 30, 2021, there was total unrecognized compensation costs of $19,994,000 related to stock options expected to be recognized over a period of approximately 2.60 years, a total of $15,830,000 of unrecognized compensation costs related to unvested RSUs expected to be recognized over a period of approximately 3.18 years and $105,000 of unrecognized compensation costs related to the ESPP, which the Company will recognize over 0.13 years.

Silk Road Medical, Inc.
Notes to Condensed Financial Statements
(unaudited)

10. 401(k) Plan

The Company has a qualified retirement plan under section 401(k) of the Internal Revenue Code (“IRC”) under which participants may contribute up to 90% of their eligible compensation, subject to maximum deferral limits specified by the IRC. Beginning in January 2020, the Company started matching employees' contributions to the 401(k) plan at 50% of the first 5% of compensation deferred to the 401(k) plan. The Company's matching contributions were $308,000 and $195,000 for the three months ended September 30, 2021 and 2020, respectively, and $1,003,000 and $717,000 for the nine months ended September 30, 2021 and 2020, respectively.

Item 2: Management Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with the section entitled "Selected financial data" and our condensed financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q. This discussion and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions, that are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this Quarterly Report on Form 10-Q entitled "Risk Factors."

Overview

We are a medical device company focused on reducing the risk of stroke and its devastating impact. We believe a key to stroke prevention is minimally-invasive and technologically advanced intervention to safely and effectively treat carotid artery disease, one of the leading causes of stroke. We have pioneered a new approach for the treatment of carotid artery disease called transcarotid artery revascularization, or TCAR, which we seek to establish as the standard of care. We manufacture and sell in the United States our portfolio of TCAR products, which are designed to provide direct access to the carotid artery, effective reduction in stroke risk throughout the procedure, and long-term restraint of carotid plaque.

We began commercializing our products in the United States in late 2015. Our products are currently the only devices cleared and approved by the FDA specifically for transcarotid use. While our current commercial focus is on the U.S. market, our products have obtained CE Mark approval, allowing us to commercialize in Europe in the future. We are also pursuing regulatory clearances in select international markets. TCAR is reimbursed based on established current procedural technology, or CPT, codes and International Classification of Diseases, or ICD-10, codes related to carotid stenting that track to Medicare Severity Diagnosis Related Group, or MS-DRG, classifications.

We designed our commercial strategy and built our direct sales force with a particular focus on vascular surgery practices. Vascular surgeons are skilled in endovascular procedures, and our sales and marketing efforts are focused on driving adoption and supporting their practice development by offering them an innovative, safe, effective and minimally-invasive alternative for treating carotid artery disease. We also market to other specialists with experience in CEA or CAS with the appropriate skill set for TCAR, including neurosurgeons, cardiothoracic surgeons and non-surgical interventionalists in radiology, neuroradiology and cardiology. We also work on developing strong relationships with physicians and hospitals that we have identified as key opinion leaders. We consider the hospitals and medical centers where the procedure is performed to be our customers, as they typically are responsible for purchasing our products.

We manufacture and distribute the ENROUTE NPS at our facility in Sunnyvale, California, using components and sub-assemblies manufactured both in-house and by third party manufacturers and suppliers. We purchase our other products from third-party contract manufacturers, including our ENROUTE stent. Many of these third-party manufacturers and outside vendors are currently single-source suppliers. While we expect that our existing manufacturing facility will be sufficient to meet our anticipated growth through at least the next three years, we supplement our distribution operations with a third-party logistics and warehousing service and during the second quarter of 2021 have expanded operations to include additional facilities in Minnesota.

In April 2019, we completed our initial public offering by issuing 6,000,000 shares of common stock, at a public offering price of $20.00 per share, for net proceeds of approximately $109.1 million after deducting underwriting discounts and commissions and expenses. In August 2019, we completed a secondary public offering of 4,200,000 shares of common stock by selling stockholders, and the exercise in full of the underwriters' option to purchase 630,000 additional shares of common stock from selling stockholders, at a public offering price of $39.50 per share. We received no proceeds from the sale of our common stock by the selling stockholders.

Prior to our initial public offering in April 2019, our primary sources of capital were private placements of convertible preferred stock, debt financing arrangements and revenue from sales of our products

In May 2020, we completed an underwritten public offering of 6,808,154 shares of our common stock, of which we offered 1,923,076 shares for sale and the remaining 4,885,078 shares were offered for sale by certain selling stockholders, at a public offering price of $39.00 per share. From the public offering, we received cash proceeds of approximately $70.5 million, net of underwriting discounts and commissions and offering costs which were paid by us.

Also, in May 2020, the underwriters fully exercised their option to purchase 1,021,223 additional shares of common stock from the selling stockholders. We did not receive any of the proceeds from the sale of the shares of common stock by the selling stockholders. As of September 30, 2021, we had cash and cash equivalents of $105.6 million, investments of $17.1 million, long-term debt of $48.7 million and an accumulated deficit of $274.0 million.

COVID-19 Pandemic

The global COVID-19 pandemic presents significant risks to us and has had, and continues to have impacts on our business, operations, and financial results and condition, directly and indirectly, including, without limitation, impacts on: the health of our management and employees; our manufacturing, distribution, marketing and sales operations; our research and development activities, including clinical activities; and customer and patient behaviors. COVID-19 and its variants have negatively impacted, and may continue to negatively impact our operations and revenue and overall financial condition by significantly decreasing the number of TCAR procedures performed. The pandemic has also reduced our expectations for the growth rate in the number of TCAR procedures to be performed in the future. The number of TCAR procedures performed, similar to other surgical procedures, has significantly decreased as many health care organizations globally have prioritized the treatment of patients with COVID-19. These measures and challenges will likely continue for the duration of the pandemic, which is uncertain, and will significantly reduce our expected revenue while the pandemic continues. As well, due to presumed fear and anxiety, some patients are not accessing routine or emergency health care which may impact our expected procedures and revenue.

Numerous state and local jurisdictions have imposed, and others in the future may impose, “shelter-in-place” orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Such orders or restrictions have resulted in our facilities periodically closing, work stoppages, slowdowns and delays, travel restrictions and cancellation of events, among other effects, thereby negatively impacting our operations.

Other disruptions or potential disruptions include restrictions on our personnel to travel and access customers for selling, marketing, training, case support and product development feedback; delays in approvals by regulatory bodies; delays in product development efforts; and additional government requirements or other incremental mitigation efforts that may further impact our capacity to manufacture, sell and support the use of our products.

While some of these restrictions began to lift throughout the first half of 2021, new virus variants, and increased infection rates during this period continue to make the current COVID-related environment highly volatile and uncertain. The ultimate extent of the impact of the COVID-19 pandemic on us remains highly uncertain and will depend on future developments and factors that continue to evolve, including the ability of various regions to effectively manage COVID-19, the extent of the continuing resurgence of COVID-19, the efficacy and extent of distribution of vaccines, and the impact of mutations of COVID-19. Most of these developments and factors are outside of our control and could exist for an extended period of time even after the pandemic might end.

Components of our Results of Operations

Revenue

We currently derive all of our revenue from the sale of our portfolio of TCAR products to hospitals and medical centers in the United States. Each of our products is purchased individually, and the majority of our revenue is derived from sales of the ENROUTE NPS and ENROUTE stent. No single customer accounted for 10% or more of our revenue during the three and nine months ended September 30, 2021 and 2020. We expect revenue to increase in absolute dollars as we expand our sales territories and trained physician base, add new accounts and as existing physicians perform more TCAR procedures. However, we anticipate continued headwinds related to the rapid spread of Covid-19 variants and their nearer term impact on hospital capacity and patient behavior.

We expect our revenue to fluctuate from quarter-to-quarter due to a variety of factors, including seasonality. For example, in the first quarter, our results can be harmed by adverse weather and by resetting of annual patient healthcare insurance plan deductibles, both of which may cause patients to delay elective procedures. Holiday and summer vacations by physicians and/or their patients can also affect procedure volumes that in turn affect hospital ordering patterns. We have also seen procedure volumes moderate during major medical conferences when significant portions of our customer base are attending the conferences.

Cost of Goods Sold and Gross Margin

We manufacture the ENROUTE NPS in California at our facility in Sunnyvale. We purchase our other products from third party manufacturers. Cost of goods sold consists primarily of costs related to materials, components and sub-assemblies, direct labor, manufacturing overhead, reserves for excess, obsolete and non-sellable inventories as well as distribution-related expenses. Overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management. Cost of goods sold also includes depreciation expense for production equipment and certain direct costs such as those incurred for shipping our products and royalties related to the sale of our ENROUTE stent. We record adjustments to our inventory valuation for estimated excess, obsolete and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes and overall market conditions. We expense all inventory provisions as cost of goods sold. We expect cost of goods sold to increase in absolute dollars to the extent more of our products are sold.

We calculate gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily average selling prices, product sales mix, production and ordering volumes, manufacturing costs, product yields, replacement of expired product, headcount and cost-reduction strategies. We expect our gross margin to increase over the long-term as our production and ordering volumes increase and as we spread the fixed portion of our overhead costs over a larger number of units produced, potentially offset by any investments in additional operational infrastructure in both California and our new facilities in Minnesota. We intend to use our design, engineering and manufacturing know-how and capabilities to further advance and improve the efficiency of our manufacturing processes, which we believe will reduce costs and have a positive long-term impact on our gross margin. However, our gross margin could fluctuate from quarter to quarter as we introduce new products, due to the timing of certain manufacturing engineering projects, as we adopt new manufacturing processes and technologies and as we expand our distribution operations and infrastructure to support long term growth and risk mitigation. In addition, COVID-19 and its variants may continue to negatively impact our gross margin in the near term due to unfavorable production variances as a result of lower production and lower demand.

Research and Development Expenses

Research and development, or R&D, expenses consist primarily of engineering, product development, clinical studies to develop and support our products, regulatory expenses, medical affairs, and other costs associated with products and technologies that are in development. These expenses include employee compensation, including stock-based compensation, supplies, consulting, prototyping, testing, materials, travel expenses, depreciation and an allocation of facilities overhead expenses. Additionally, R&D expenses include costs associated with our clinical studies, including clinical trial design, clinical trial site initiation and study costs, data management, related travel expenses and the cost of products used for clinical trials, internal and external costs associated with our regulatory compliance and quality assurance functions and overhead costs. We expect R&D expenses as a percentage of revenue to vary over time depending on the level and timing of our new product development efforts, as well as our clinical development, clinical trial and other related activities. While some of these restrictions began to lift throughout the first half of 2021, due to new virus variants and increased infections, we anticipate various COVID-19 related policies and restrictions to continue to delay or affect our product development efforts and clinical and regulatory matters at least through the remainder of 2021.

Selling, General and Administrative Expenses

Selling, general and administrative, or SG&A, expenses consist primarily of compensation for personnel, including stock-based compensation, related to selling and marketing functions, physician education programs, commercial operations and analytics, reimbursement, finance, information technology and human resource functions. Other SG&A expenses include sales commissions, training, travel expenses, promotional activities, marketing initiatives, market research and analysis, conferences and trade shows, professional services fees (including legal, audit and tax fees), insurance costs, general corporate expenses and allocated facilities-related expenses. We expect SG&A expenses to continue to increase in absolute dollars as we expand our infrastructure to both drive and support anticipated growth in revenue, due to additional legal, accounting, insurance and other expenses associated with being a public company, and as we expand our presence in Minnesota. In addition, we will continue exploring sales and marketing expansion opportunities in international geographies.

While some of these restrictions began to lift throughout the first half of 2021 and allowed for the resumption in certain employee and physician travel, tradeshow and other expenses, due to new virus variants and increased infections, we expect the COVID-19 pandemic to continue to modulate our SG&A expenses over the short term. The outbreak and persistence of COVID-19 in international markets that we have targeted for our international expansion may also delay preparation for and launch of such expansion efforts.

Interest Income (Expense), net

Interest income (expense), net consists primarily of cash interest incurred on our outstanding indebtedness and non-cash interest related to the amortization of debt discount and issuance costs associated with our debt agreements. Our interest expense was partially offset by interest income earned on our investments. We expect our interest expense to decline due to the refinancing of our debt obligations in October 2020 and the associated decrease in interest rate.

Results of Operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2021**	**2020**	**2021**	**2020**
Revenue	$ 24,701	$ 20,067	$ 73,210	$ 54,093
Costs of goods sold	6,076	5,488	18,213	16,074
Gross profit	18,625	14,579	54,997	38,019
Operating expenses:				
Research and development	6,867	4,711	19,611	11,232
Selling, general and administrative	25,049	19,202	68,792	54,652
Total operating expenses	31,916	23,913	88,403	65,884
Loss from operations	(13,291)	(9,334)	(33,406)	(27,865)
Interest income (expense), net	(591)	(966)	(1,701)	(2,669)
Other income (expense), net	(3)	(15)	(11)	(74)
Net loss	$ (13,885)	$ (10,315)	$ (35,118)	$ (30,608)

Comparison of Three Months Ended September 30, 2021 and 2020

Revenue. Revenue increased $4.6 million, or 23%, to $24.7 million during the three months ended September 30, 2021, compared to the three months ended September 30, 2020. The increase in revenue was attributable to an increase in the number of products sold as we expanded our sales territories, increased the number of new accounts, trained more physicians in TCAR and as physicians performed more TCAR procedures as compared to the prior period. Although revenue increased during the three months ended September 30, 2021, as compared with the prior year period, the COVID-19 pandemic continued to impact revenue as resurgences due to the Delta variant adversely effected hospital capacity and patient behaviors.

Cost of Goods Sold and Gross Margin. Cost of goods sold increased $0.6 million, or 11%, to $6.1 million during the three months ended September 30, 2021, compared to the three months ended September 30, 2020. This increase was attributable to the increase in the number of products sold. Gross margin for the three months ended September 30, 2021 increased to 75%, compared to 73% in the three months ended September 30, 2020. Gross margin in the prior year period included unfavorable production variances as a result of temporarily idled manufacturing operations and lower than anticipated demand due to COVID-19.

Research and Development Expenses. R&D expenses increased $2.2 million, or 46%, to $6.9 million during the three months ended September 30, 2021, compared to $4.7 million during the three months ended September 30, 2020. The increase in R&D expenses was driven by growth in personnel and investment in new and ongoing R&D programs. The increase in R&D expenses was primarily attributable to an increase of $1.7 million in personnel-related expenses, including stock-based compensation, an increase of $0.3 million in product development materials and costs, and an increase of $0.2 million related to the allocated costs of facilities and other related expenses.

Selling, General and Administrative Expenses. SG&A expenses increased $5.8 million, or 30%, to $25.0 million during the three months ended September 30, 2021, compared to $19.2 million during the three months ended September 30, 2020. The increase in SG&A costs was due to the continued expansion of our sales team and commercial efforts,and general corporate and other costs associated with operating as a public company, compared to the third quarter of 2020. The increase in SG&A expenses is primarily attributable to an increase of $4.2 million in payroll and personnel-related expenses, an increase of $0.9 million in physician training and travel related costs, an increase of $0.3 million in consulting, legal and professional fees, an increase of $0.2 million in marketing and tradeshow expenses, and an increase of $0.2 million in software related expense. Personnel-related expenses included stock-based compensation expense of $2.8 million and $1.6 million for the three months ended September 30, 2021 and 2020, respectively.

Interest Income (Expense), Net. Interest income (expense), net decreased $0.4 million, or 39%, to an expense of $0.6 million during the three months ended September 30, 2021, compared to an expense of $1.0 million during the three months ended September 30, 2020. This decrease in net interest expense was attributable to the reduction in interest rate resulting from the October 2020 refinancing of our debt obligations, partially offset by a decrease in interest income due to both lower interest rates and a decrease in our cash and investments balances during the three months ended September 30, 2021 as compared with the prior period.

Other Income (Expense), Net. There were no significant changes within other income (expense), net during the three months ended September 30, 2021, compared to the three months ended September 30, 2020.

Comparison of Nine Months Ended September 30, 2021 and 2020

Revenue. Revenue increased $19.1 million, or 35%, to $73.2 million during the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020. The increase in revenue was attributable to an increase in the number of products sold as we expanded our sales territories, increased the number of new accounts, trained more physicians in TCAR and as physicians performed more TCAR procedures as compared to the prior period. Although revenue increased during the nine months ended September 30, 2021, as compared with the prior year period, the COVID-19 pandemic continued to impact our revenue as resurgences due to the Delta and other variants adversely effected hospital capacity and patient behaviors.

Cost of Goods Sold and Gross Margin. Cost of goods sold increased $2.1 million, or 13%, to $18.2 million during the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020. This increase was attributable to the increase in the number of products sold. Gross margin for the nine months ended September 30, 2021 increased to 75%, compared to 70% in the nine months ended September 30, 2020. Gross margin in the prior year period included unfavorable production variances as a result of temporarily idled manufacturing operations and lower than anticipated demand due to COVID-19.

Research and Development Expenses. R&D expenses increased $8.4 million, or 75%, to $19.6 million during the nine months ended September 30, 2021, compared to $11.2 million during the nine months ended September 30, 2020. The increase in R&D expenses was driven by growth in personnel and investment in new and ongoing R&D programs. The increase in R&D expenses was primarily attributable to an increase of $4.6 million in personnel-related expenses, including stock-based compensation, as a result of increased headcount, an increase of $2.0 million in product development materials and costs, an increase of $1.0 million in clinical and regulatory expense, and an increase of $0.7 million in outside services. The remaining increase related to the allocated costs of facilities and other related expenses partially offset by a decrease in educational grants.

Selling, General and Administrative Expenses. SG&A expenses increased $14.1 million, or 26%, to $68.8 million during the nine months ended September 30, 2021, compared to $54.7 million during the nine months ended September 30, 2020. The increase in SG&A costs was due to the continued expansion of our sales team and commercial efforts, and general corporate and other costs associated with operating as a public company, compared to the prior period. The increase in SG&A expenses is primarily attributable to an increase of $11.2 million in payroll and personnel-related expenses, an increase of $0.7 million in consulting, legal and professional fees, an increase of $1.2 million in physician training and travel related costs, an increase of $0.6 million in software related expense, an increase of $0.2 million in marketing and tradeshow expenses and an increase of $0.2 million in insurance costs. Personnel-related expenses included stock-based compensation expense of $8.2 million and $4.0 million for the nine months ended September 30, 2021 and 2020, respectively.

Interest Income (Expense), Net. Interest income (expense), net decreased $1.0 million, or 36%, to an expense of $1.7 million during the nine months ended September 30, 2021, compared to an expense of $2.7 million during the nine months ended September 30, 2020. This decrease in net interest expense was attributable to the reduced interest rate as a result of the October 2020 refinancing of our debt obligations, partially offset by a decrease in interest income due to lower interest rates during the nine months ended September 30, 2021 as compared with the prior period.

Other Income (Expense), Net. There were no significant changes within other income (expense), net during the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020.

Liquidity and Capital Resources

As of September 30, 2021, we had cash and cash equivalents of $105.6 million, investments of $17.1 million, an accumulated deficit of $274.0 million and $48.7 million outstanding under our Loan Agreement, net of issuance costs.

On October 29, 2020, we entered into a Loan and Security Agreement, or Loan Agreement, with Stifel Bank which provides for a $50.0 million loan facility, comprised of a $50.0 million secured revolving credit facility, with a $2.0 million subfacility for the issuance of letters of credit and other ancillary banking services, and a $50.0 million secured term loan facility, provided that amounts outstanding under both facilities may not exceed an aggregate principal amount of $50.0 million at any time. Any borrowings under the revolving loan facility mature on October 29, 2022, or October 29, 2023 if as of October 29, 2022, no event of default has occurred and we are in compliance with the terms of the Loan Agreement. Borrowings under the term loan facility mature on October 29, 2024. Also on October 29, 2020, we drew down $49.0 million under the term loan facility and used the majority of the proceeds to pay off and terminate our prior loan agreement with CRG.

In May 2020, we completed an underwritten public offering of 6,808,154 shares of our common stock, of which we offered 1,923,076 shares for sale and the remaining 4,885,078 shares were offered for sale by certain selling stockholders, at a public offering price of $39.00 per share. From the public offering, we received cash proceeds of approximately $70.5 million, net of underwriting discounts and commissions and offering costs which were paid by us. Also, in May 2020, the underwriters fully exercised their option to purchase 1,021,223 additional shares of common stock from the selling stockholders. We did not receive any of the proceeds from the sale of the shares of common stock by the selling stockholders.

Prior to our public offerings, our primary sources of capital were private placements of convertible preferred stock, debt financing agreements and revenue from the sale of our products.

We believe that our cash and cash equivalents and available-for-sale investments as of September 30, 2021, together with our expected revenue will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months.

Cash Flows

The following table summarizes our cash flows for each of the periods presented below:

	Nine Months Ended September 30,	
(in thousands)	**2021**	**2020**
Net cash (used in) provided by:		
Operating activities	$ (27,503)	$ (27,799)
Investing activities	58,394	(22,291)
Financing activities	5,207	73,377
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 36,098	$ 23,287

Net Cash Used in Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2021 was $27.5 million, consisting primarily of a net loss of $35.1 million and an increase in net operating assets of $5.2 million, partially offset by non-cash charges of $12.8 million. The increase in net operating assets was primarily due to increases in accounts receivable and inventories to support the growth of our operations, an increase in prepaid expenses and other current assets primarily due to timing of insurance premium payments and decreases in accounts payable, accrued and other liabilities, due to timing of payments. The non-cash charges primarily consisted of stock-based compensation, depreciation and amortization, amortization of premiums on investments and of right-of-use assets, non-cash interest expense and provision for excess and obsolete inventories.

Net cash used in operating activities for the nine months ended September 30, 2020 was $27.8 million, consisting primarily of a net loss of $30.6 million and an increase in net operating assets of $3.7 million, partially offset by non-cash charges of $6.5 million. The increase in net operating assets was primarily due to increases in accounts receivable, inventories and prepaid expenses and other current assets to support the growth of our operations, partially offset by decreases in other assets and increases in accounts payable, due to timing of payments and growth of our operations. The non-cash charges primarily consisted of stock-based compensation, depreciation and amortization, provision for excess and obsolete inventories, non-cash interest expense and other charges related to our term loan agreement with CRG.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities in the nine months ended September 30, 2021 was $58.4 million. Cash provided by investing reflected maturities of investments of $60.4 million offset by purchases of property and equipment of $2.0 million.

Net cash used in investing activities in the nine months ended September 30, 2020 was $22.3 million. Cash used in investing reflected purchases of purchases of property and equipment of $0.6 million and net purchases of investments of $21.7 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities in the nine months ended September 30, 2021 was $5.2 million consisting of proceeds from stock option exercises and purchases under our employee stock purchase plan.

Net cash provided by financing activities in the nine months ended September 30, 2020 was $73.4 million, consisting of proceeds of $70.6 million from our public offering in May 2020, net of issuance costs paid, and proceeds of $2.8 million from stock option exercises and purchases under our employee stock purchase plan.

Off-Balance Sheet Arrangements

We currently have no off-balance sheet arrangements, such as structured finance, special purpose entities, or variable interest entities.

Contractual Obligations and Commitments

As of September 30, 2021, our principal obligations consist of the operating leases for our facilities, our Loan Agreement with Stifel Bank and non-cancellable inventory purchase commitments. The non-cancellable purchase commitments primarily consist of ENROUTE stents and other inventory components.

In May 2021, we entered into a lease agreement for approximately 63,118 square feet of office space located in Plymouth, Minnesota for a period beginning in May 2021 and ending in November 2029, with an initial annual base rent payment of approximately $0.8 million, increasing to $1.0 million annually in the final year of the lease term.

On October 29, 2020, we drew down $49.0 million under the term loan facility with Stifel Bank using the majority of the proceeds to pay off outstanding amounts under our loan agreement with CRG and to terminate the CRG loan agreement. The principal amount of outstanding term loans under the Loan Agreement with Stifel Bank shall be repaid in equal monthly installments beginning on May 29, 2022, or November 29, 2022 if we achieve revenue for the year ending December 31, 2021 of at least 80% of our board-approved financial projections for such fiscal year. The term loan may not be reborrowed once repaid, but we may prepay the term loan at any time without premium or penalty. We are also obligated to pay a fee to the lender upon the occurrence of certain liquidity events, along with other customary fees for a loan facility of this size and type.

Our obligations under the Loan Agreement are secured by substantially all of our assets. The Loan Agreement requires that we maintain unrestricted cash and cash equivalents with Stifel Bank or at Stifel Bank Affiliates of at least $20.0 million. In addition, for any fiscal quarter where our unrestricted cash and cash equivalents maintained with Stifel Bank or at a Stifel Bank Affiliates are less than $60.0 million for any day during such fiscal quarter, we must comply with a minimum revenue covenant. Additionally, the Loan Agreement contains customary affirmative and negative covenants, including covenants limiting our ability and the ability of our subsidiaries to, among other things, dispose of assets, effect certain mergers, incur debt, grant liens, pay dividends and distributions on capital stock, make investments and acquisitions, and enter into transactions with affiliates, in each case subject to customary exceptions for a loan facility of this size and type.

The events of default under the Loan Agreement include, among others, payment defaults, material misrepresentations, breaches of covenants, cross defaults with certain other material indebtedness, bankruptcy and insolvency events, and judgment defaults. The occurrence of an event of default could result in the acceleration of our obligations under the Loan Agreement, the termination of the lender's commitments, a 5% increase in the applicable rate of interest and the exercise by the lender of other rights and remedies provided for under the Loan Agreement.

There have been no other material changes to our contractual obligations from those described in our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on March 1, 2021.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. 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. There have been no significant and material changes in our critical accounting policies during the three and nine months ended September 30, 2021, as compared to those disclosed in "Management's Discussion and Analysis of Financial Conditions and Results of Operations - Critical Accounting Policies and Estimates" in our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on March 1, 2021.

Recently Issued Accounting Pronouncements

See Note 3 to our condensed financial statements included elsewhere in this Quarterly Report on Form 10-Q for new accounting pronouncements not yet adopted as of the date of this Quarterly Report on Form 10-Q.

Item 3: Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include risk related to interest rate sensitivities and foreign currency exchange rate sensitivity.

Interest Rate Risk

We had cash, cash equivalents and investments of $122.8 million as of September 30, 2021 which consisted of bank deposits, money market funds, U.S. government securities and commercial paper. The primary objectives of our investment activities are the preservation of capital and support of our liquidity requirements. Our investments are exposed to market risk due to fluctuations in interest rates, which may affect our income and the fair market value of our investments.

We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate risk exposure. A hypothetical 10% change in interest rates would not have a material impact on the value of our cash and cash equivalents or our investments as of September 30, 2021.

Credit Risk

As of September 30, 2021 and December 31, 2020, our cash and cash equivalents were maintained with two financial institutions in the United States, and our current deposits are likely in excess of insured limits. We have reviewed the financial statements of these institutions and believe each to have sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us. Our cash equivalents and investments are invested in highly rated money market funds, U.S. treasury bills, U.S. government securities, corporate bonds/notes, asset-backed securities and commercial paper.

Our accounts receivable primarily relate to revenue from the sale of our products to hospitals and medical centers in the United States. No customer represented 10% or more of our accounts receivable as of September 30, 2021 or December 31, 2020.

Foreign Currency Risk

Our business is primarily conducted in U.S. dollars. Any transactions that may be conducted in foreign currencies are not expected to have a material effect on our results of operations, financial position or cash flows.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our President and Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) prior to the filing of this quarterly report. Based on that evaluation, our President and Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the most recent fiscal quarter covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Part II. Other Information

Item 1. Legal Proceedings

From time to time we may become involved in 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.

Item 1A. Risk Factors

We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition, results of operations and future growth prospects. Our business could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. The occurrence of any of the following risks or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition, results of operations and future prospects. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Quarterly Report on Form 10-Q, including our condensed financial statements and related notes. Please also see “Cautionary Notes Regarding Forward-Looking Statements.”

Summary of Principal Risk Factors

The following risks and uncertainties are among the most significant we face. However, the risks and uncertainties identified in this subsection are not the only ones we face, and are qualified in their entirety by reference to all of the risk factors described in Item 1A.

General Risks Related to Our Business

- Our business is dependent upon the broad adoption of TCAR by hospitals and physicians.
- Adoption of TCAR depends upon positive clinical data and medical society recommendations, and negative clinical data or medical society recommendations would adversely affect our business.
- If we are not able to maintain adequate levels of third-party coverage and reimbursement for the procedures using our products, if third parties rescind or modify their coverage, or if patients are left with significant out-of-pocket costs, it would have a material adverse effect on our business, financial condition and results of operations.

- The COVID-19 pandemic and efforts to reduce its spread have impacted, and, with the spread of new variants, continue to negatively impact, our business and operations.
- We rely on Cordis Corporation, formerly a Cardinal Health Company, or Cordis, to supply the ENROUTE stent, and if Cordis fails to supply the ENROUTE stent in sufficient quantities or at all, it will have a material adverse effect on our business, financial condition and results of operations.
- We depend on a limited number of single source suppliers to manufacture our components, sub-assemblies and materials, including Cordis, which makes us vulnerable to supply shortages and price fluctuations that could have a material adverse effect on our business, financial condition and results of operations.
- We have a history of net losses, we expect to incur operating losses in the future and we may not be able to achieve or sustain profitability.
- The failure of third parties to meet their contractual, regulatory, and other obligations could adversely affect our business.

Intellectual Property Risks

- We may become a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell and market our products.
- Our success will depend on our ability to obtain, maintain and protect our intellectual property rights.
- We may not be able to protect our intellectual property rights throughout the world.

Regulatory Risks

- Our products have in the past and could in the future be subject to product recalls that could harm our reputation or increase the probability of inspection by, or additional scrutiny from, the FDA or other relevant regulatory bodies.
- Changes in the CMS fee schedules may harm our revenue and operating results.
- If we fail to comply with broad based healthcare and other governmental regulations, we could face substantial fines and penalties and our business, results of operations and financial condition could be adversely affected.
- If we fail to obtain and maintain necessary regulatory clearances or approvals for our products, or if clearances or approvals for future products and indications are delayed or not issued, our commercial operations would be harmed.
- Our clinical trials may fail to demonstrate competent and reliable evidence of the safety and effectiveness of our products, which would prevent or delay commercialization of our products in development.

Risks Related to Our Business

We have a history of net losses, we expect to incur operating losses in the future and we may not be able to achieve or sustain profitability.

We have incurred net losses since our inception in March 2007. For the nine months ended September 30, 2021, we had a net loss of $35.1 million, and we expect to continue to incur additional losses in the future. As of September 30, 2021, we had an accumulated deficit of $274.0 million. To date, we have financed our operations primarily through equity and debt financings and from sales of our portfolio of TCAR products that enable transcarotid artery revascularization. The losses and accumulated deficit have primarily been due to the substantial investments we have made to develop our products, as well as for costs related to general research and development, including clinical and regulatory initiatives to obtain marketing approval, sales and marketing efforts and infrastructure improvements.

Over the next several years, we expect to continue to devote a substantial amount of our resources to expand commercialization efforts and increase adoption of TCAR using our products, improve and expand reimbursement for TCAR, expand the labeled indications for our products and develop additional products. In addition, as a public company, we incur significant legal, accounting, director & officer liability insurance and other expenses that we did not incur as a private company, all of which continue to increase. Accordingly, we expect to continue to incur operating losses for the foreseeable future and we cannot assure you that we will achieve profitability in the future or that, if we do become profitable, we will sustain profitability. Our failure to achieve and sustain profitability in the future will make it more difficult

to finance our business and accomplish our strategic objectives, which would have a material adverse effect on our business, financial condition and results of operations and cause the market price of our common stock to decline. In addition, failure of our products to significantly penetrate the target markets would negatively affect our business, financial condition and results of operations.

We rely on, and currently sell products to enable, TCAR, which is our only product offering.

To date, all of our revenue has been derived, and we expect it to continue to be derived in the near term, from sales of our products that enable TCAR. TCAR is a relatively new treatment option for certain patients diagnosed with carotid artery disease and, as a result, physician awareness of TCAR and our products, and experience with TCAR and our products, is limited. A number of factors that are outside of our control may contribute to fluctuations in our financial results, including:

- Physician and hospital demand for our products and the extent of adoption of TCAR, including the rate at which physicians recommend our products and TCAR to their patients;
- Positive or negative media coverage, or public, patient and/or physician perception, of our products and TCAR or competing products and procedures;
- Any safety or effectiveness concerns that arise regarding our products or TCAR;
- Unanticipated delays in product development or product launches;
- Our ability to maintain our current or obtain further regulatory clearances or approvals;
- Delays in, or failure of, product, component and material deliveries by our third-party suppliers; and
- Introduction of new products or procedures for treating carotid artery disease that compete with our products and the TCAR procedure.

It is therefore difficult to predict our future financial performance and growth, and such forecasts are inherently limited and subject to a number of uncertainties. If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, our operating and financial results could differ materially from our expectations and our business could suffer.

In addition, because we devote substantially all of our resources to our products that enable TCAR and rely on our products and the adoption of TCAR as our sole source of revenue, any factors that negatively impact our products or TCAR, or result in a decrease in sales of products, could have a material adverse effect on our business, financial condition and results of operations.

Our business is dependent upon the broad adoption of TCAR by hospitals and physicians.

Our future growth and profitability largely depends on our ability to increase physician awareness of TCAR and on the willingness of physicians to adopt our products and TCAR, and to recommend the procedure to their patients. Physicians may not use our products unless they are able to determine, based on experience, clinical data, medical society recommendations and other analyses, that our products provide a safe and effective treatment alternative for carotid artery disease. Even if we are able to raise awareness among physicians, physicians tend to be slow in changing their medical treatment practices and may be hesitant to select our products or TCAR for recommendation to patients for a variety of reasons, including:

- Long-standing relationships with competing companies and distributors that sell other products, such as stents and embolic protection devices for transfemoral carotid artery stenting, or CAS;
- Competitive response and negative selling efforts from providers of alternative carotid revascularization products;
- Perceived liability risk generally associated with the use of new products and procedures;
- Lack or perceived lack of sufficient clinical evidence, including long-term data, supporting clinical benefits;
- Reluctance to change to or use new products and procedures;

and

- Time commitment and skill development that may be required to gain familiarity and proficiency with TCAR and our products.

Physicians play a significant role in determining the course of a patient's treatment for carotid artery disease and, as a result, the type of treatment that will be recommended or provided to a patient. We focus our sales, marketing and education efforts primarily on vascular surgeons, and aim to educate referring physicians such as vascular surgeons, cardiologists, radiologists, neurologists, neurosurgeons and general practitioners regarding the patient population that would benefit from TCAR. However, we cannot assure you that we will achieve broad education or market acceptance among these practitioners. For example, if diagnosing physicians that serve as the primary point of contact for patients are not made aware of TCAR, they may not refer patients to physicians for treatment using our products, and those patients may instead not seek treatment at all or may be treated with alternative procedures. In addition, some physicians may choose to utilize TCAR on only a subset of their total patient population or may not adopt TCAR at all. If a physician experiences an adverse event in one or more of their TCAR patients or elects to convert TCAR to CEA mid-procedure, they may not continue offering and performing TCAR at the same rate or at all. Further, as TCAR is a new procedure, it may not fit into the workstreams of certain physicians. If we are not able to effectively demonstrate that TCAR is beneficial in a broad range of patients, adoption of TCAR will be limited and may not occur as rapidly as we anticipate or at all, which would have a material adverse effect on our business, financial condition and results of operations. We cannot assure you that TCAR or our products will achieve broad market acceptance among hospitals and physicians. Any failure of TCAR or our products to satisfy demand or to achieve meaningful market acceptance and penetration will harm our future prospects and have a material adverse effect on our business, financial condition and results of operations.

In addition, the medical device industry's relationship with physicians is under increasing scrutiny by the Health and Human Services Office of the Inspector General, or OIG, the Department of Justice, or DOJ, state attorneys general, and other foreign and domestic government agencies. Our failure to comply with laws, rules and regulations governing our relationships with physicians, or an investigation into our compliance by the OIG, DOJ, state attorneys general or other government agencies, could significantly harm our business.

In most cases, before physicians can use our products for the first time, our products must be approved for use by a hospital's new product or value analysis committee, or the staff of a hospital or health system. Following such approval, we may be required to enter into a purchase contract. Such approvals or requirements to enter into a purchase contract could deter or delay the use of our products by physicians. We cannot provide assurance that our efforts to obtain such approvals, enter into purchase contracts, or generate adoption will be successful or increase the use of our products, and if we are not successful, it could have a material adverse effect on our business, financial condition and results of operations.

Adoption of TCAR depends upon positive clinical data and medical society recommendations, and negative clinical data or medical society recommendations would adversely affect our business.

The rate of adoption of TCAR and sales of our products that facilitate the procedure is heavily influenced by clinical data. Although the Society for Vascular Surgery's TCAR Surveillance Project contains real world data comparing procedures, we have not conducted head-to-head clinical trials to compare TCAR to the procedures historically available to patients, such as CEA or CAS, which may limit the adoption of TCAR. Additionally, the Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis 2 clinical trial is currently funded by the National Institutes of Health, which compares the effectiveness of each of CEA and CAS with best medical management solutions. Although we estimate that enrollment will not be completed until sometime after 2026, interim results have been released from time to time. At the completion of the four-year follow-up, the trial could conclude that medical management alone achieves the same therapeutic results as CEA and/or CAS, which could have an adverse impact on the adoption of TCAR. Finally, our competitors and third parties may also conduct clinical trials of our products without our participation. Unfavorable or inconsistent clinical data from existing or future clinical trials conducted by us, our competitors or third parties, the interpretation of our or other clinical data or findings of new or more frequent adverse events, could have a material adverse effect on our business, financial condition and results of operations.

As physicians are influenced by guidelines issued by physician organizations, such as the Society for Vascular Surgery, the rate of adoption of TCAR and sales of our products that facilitate the procedure are also heavily influenced by medical society recommendations. We believe the Society for Vascular Surgery's Clinical Practice Guidelines, or SVS Guidelines, are of particular importance to the broader market acceptance of TCAR. The revised SVS Guidelines on the management of carotid artery disease were published in June 2021. Like previous versions of the guidelines, it generally discusses CAS and embolic protection methods, including flow reversal. The 2021 edition does state that TCAR is preferred over CEA and CAS in both symptomatic and asymptomatic, anatomically or physiologically high surgical risk patients. If subsequent versions of the SVS Guidelines do not recommend TCAR, or if the Society for Vascular Surgery issues a negative or limited statement regarding TCAR, physicians may not adopt or continue to use TCAR or our

products at the same rate or at all, which would have a material adverse effect on our business, financial condition and results of operations. Additionally, if key opinion leaders who currently support TCAR cease to recommend TCAR or our products, our business, financial condition and results of operations will be adversely affected.

Adoption of TCAR depends upon appropriate physician training, and inadequate training may lead to negative patient outcomes, affect adoption of TCAR and adversely affect our business.

The success of TCAR depends in part on the skill of the physician performing the procedure and on our customers' adherence to appropriate patient selection and proper techniques provided in training sessions conducted by our training faculty. For example, we train our customers to ensure correct use of our ENROUTE NPS and proper deployment of our ENROUTE stent. However, physicians rely on their previous medical training and experience when performing TCAR, and we cannot guarantee that all such physicians will have the necessary surgical and endovascular skills to perform the procedure. While we mandate physician attendance at our TCAR training program or training with proctors, we do not control which physicians perform TCAR or how much training they receive. Physicians who have not completed our training sessions may nonetheless attempt to perform TCAR. If physicians perform TCAR in a manner that is inconsistent with its labeled indications, with components that are not our products or without adhering to or completing our training sessions, their patient outcomes may not be consistent with the outcomes achieved in our and other clinical trials, studies or registries of TCAR. This result may negatively impact the perception of patient benefit and safety and limit adoption of TCAR and our products that facilitate the procedure, which would have a material adverse effect on our business, financial condition and results of operations. Additionally, physician organizations may adopt physician credentialing guidelines requiring TCAR training more extensive than our training program. If physicians conclude that we do not provide adequate TCAR training, they may be less likely to adopt TCAR and our products, which could have a material adverse effect on our business, financial condition and results of operations.

The COVID-19 pandemic and efforts to reduce its spread have impacted, and with the spread of new variants, continue to negatively impact, our business and operations.

The spread of COVID-19 and its variants, or COVID-19, in the United States has continued to result in travel restrictions impacting our sales professionals and therapy development specialists who support them. New virus variants, including the Delta variant, and increased infection rates during this period make the current COVID-related environment highly volatile and uncertain which creates uncertainty in the number of TCAR procedures and demand for our products as a result. Our field-based team continues to be available to support TCAR procedures, either in person or virtually. Members of our field team may, however, choose not to enter hospitals due to preexisting conditions, personal choice, or on doctors' orders or may be unable to enter hospitals due to hospital policy. In addition, hospitals may reduce staffing and postpone certain procedures in response to COVID-19 or divert resources to treat those patients with COVID-19. Some hospitals have also restricted or limited access for non-patients, including our sales professionals and therapy development specialists, which has negatively impacted our access to physicians and their patients. Our business and operations may be impacted by competition for operating room and hybrid operating rooms within hospitals that have dedicated certain resources only to COVID-19 patients. As hospitals cancel and defer elective surgeries, it reduces their revenue and impacts their financial results, which could result in pricing pressure on our products as they seek cost savings. Prolonged restrictions relating to COVID-19 could adversely affect our procedures and the revenue we derive as a result. Additionally, some hospitals may have cash flow problems or cease doing business due to the impact of COVID-19 on their operations, which could reduce the number of hospitals where TCAR is performed and adversely affect our ability to collect amounts due to us and our revenue as a result.

We expect these challenges to continue to impact the number of TCAR procedures in 2021, with procedure volumes impacted by increased COVID-19 hospitalizations and hospital capacity constraints due to the COVID-19 Delta variant. Patients may also be reluctant to visit their physicians at their offices or in hospitals due to fear of contracting COVID-19. Physicians may not be performing as many diagnostic tests for their patients and the labs where these tests are performed may not be open, staffed adequately or open the entire day. Even where physicians continue to treat symptomatic patients, treatment of asymptomatic patients is being deferred in many cases in areas where COVID-19 cases and hospitalizations are significant. The reduction in diagnostic testing and physician visits, the increase in deferred treatment, and patient behaviors are translating into fewer than expected TCAR procedures being performed in the current environment.

Governmental mandates related to COVID-19 or other infectious diseases have impacted, and we expect them to continue to impact, our personnel and personnel at third-party manufacturing facilities in the United States and other countries, and the availability or cost of materials, which would disrupt our supply chain and/or reduce our margins. While we have continued to operate with remote employees and essential employees on site, an extended implementation of governmental mandates could impact our ability to operate effectively and conduct ongoing manufacturing or research and development activities. However, we are considered an essential business under applicable state rules and our

manufacturing operations are ongoing. If key personnel or large groups of our employees contract the virus, that may also impact our business and operations. In the meantime, we have taken steps to provide for our employees, including providing the ability for employees to work remotely and implementing strategies to support appropriate social distancing techniques for onsite employees. In addition, we have required our employees to get the COVID-19 vaccine and believe we have achieved full compliance. We are also assessing our business continuity plans in the context of this pandemic. We have necessary components and raw materials on hand and appropriate distancing policies and protocols established to continue manufacturing and other operations.

The outbreak and persistence of COVID-19 in international markets that we have targeted for our international expansion has delayed preparation for and launch of such expansion efforts. Regulatory timelines for approval in some countries have been delayed. The spread of an infectious disease, including COVID-19, could also result in the inability of our suppliers to deliver components or raw materials to us on a timely basis. If there were a shortage of supply, the cost of these materials or components may increase and harm our ability to provide our products on a cost-effective basis. In connection with any supply shortages in the future, reliable and cost-effective replacement sources may not be available on short notice or at all, and this may force us to increase prices and face a corresponding decrease in demand for our products. In the event that any of our suppliers were to discontinue production of our key product components, developing alternate sources of supply for these components would be time consuming, difficult and costly. The extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including the duration and severity of the pandemic, the actions taken to reduce the transmission of COVID-19, and the speed with which normal economic and operating conditions resume, among others.

Finally, we anticipate that the COVID-19 pandemic may continue to impact clinical and regulatory matters. COVID-19 is delaying enrollment in clinical trials across the medical device industry and may affect any new trials we decide to pursue. Our ongoing diffusion weighted imaging trials in the US and Europe are experiencing patient enrollment delays. Additionally, we may experience regulatory delays in our effort to seek a label expansion for the ENROUTE stent in standard surgical risk patients, as the FDA has from time to time diverted resources to address the impact of COVID-19. COVID-19 may cause disruptions that could have a material adverse impact on our clinical trial plans and timelines, including:

- Delays in receiving authorizations from local regulatory authorities, ethics committees and institutional review boards to initiate planned clinical trials;
- Delays or difficulties in enrolling patients in our clinical trials;
- Delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- Delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruptions in global shipping that may affect the transport of clinical trial materials;
- Changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- Diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- Interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- Risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- Delays in necessary interactions with local regulators, ethics committees and other third parties and contractors due to limitations in employee resources or forced furlough of government employees;
- Limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- Refusal of the FDA to accept data from clinical trials in affected geographies.

Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the delay or denial of regulatory approvals or clearances of our product.

Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.

We seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions, but keep limited components, sub-assemblies, materials and finished products on hand. To ensure adequate inventory supply and manage our operations with our manufacturing partners and suppliers, we forecast anticipated materials requirements and demand for our products in order to predict inventory needs and then place orders with our suppliers based on these predictions. Our ability to accurately forecast demand for our products would be negatively affected by many factors, including our rapid growth, product recalls, pandemics, failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our products, our failure to accurately forecast customer acceptance of new products, changes to hospital capacity, staffing, procedure and protocol changes, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions.

Inventory levels in excess of customer demand may result in a portion of our inventory becoming obsolete or expiring, as well as inventory write-downs or write-offs. Conversely, if we underestimate customer demand for our products or our own requirements for components, subassemblies and materials, our manufacturing partners and suppliers may not be able to deliver components, sub-assemblies and materials to meet our requirements and our manufacturing may be affected by the impact of COVID-19 on our suppliers, which could result in inadequate inventory levels or interruptions, delays or cancellations of deliveries to our customers, any of which would damage our reputation, customer relationships and business. In addition, several components, sub-assemblies and materials incorporated into our products require lengthy order lead times, and additional supplies or materials may not be available when required on terms that are acceptable to us or our manufacturing partners, or at all, and our manufacturing partners and suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, any of which could have an adverse effect on our ability to meet customer demand for our products and our results of operations.

We have limited long-term data regarding the safety and effectiveness of our products, including our ENROUTE stent and TCAR generally.

Our products enable TCAR, which is a relatively new procedure, and our success depends on acceptance of our products and TCAR by the medical industry, including physicians and hospitals. The FDA reviews our products for safety and effectiveness, prior to commercial launch of these products. Thereafter, physicians, through their own use of the products and evaluation of clinical data, make their own decisions as to whether our products are safe and effective for their patients and improve their clinical outcomes. Important factors upon which the effectiveness of our products, including our ENROUTE stent, will be measured include but are not limited to long-term data regarding the risk of stroke and death and the rates of restenosis and reintervention following TCAR. The long-term clinical benefits of procedures that use our products are not fully known. Any failure of our stent or in-stent restenosis of the carotid artery following deployment of the stent could deter physicians from adopting our products and could have a material adverse effect on our business, financial condition and results of operations.

The results of short-term clinical experience of our products do not necessarily predict long-term clinical benefit. We believe that physicians will compare the rates of long-term risk of stroke and death, as well as restenosis and reintervention for procedures using our products, against alternative procedures, such as CEA and CAS. If the long-term data do not meet physicians' expectations, or if long-term data indicate that our products are not as safe or effective as other treatment options or as current short-term data would suggest, our products may not become widely adopted, physicians may recommend alternative treatments for their patients and our business could be harmed.

If we are not able to maintain adequate levels of third-party coverage and reimbursement for the procedures using our products, if third parties rescind or modify their coverage, or if patients are left with significant out-of-pocket costs, it would have a material adverse effect on our business, financial condition and results of operations.

TCAR is currently covered under certain circumstances for certain patients by the Centers for Medicare and Medicaid Services, and has been covered by some commercial payers, independent networks and other entities not governed by the National Coverage Determination. In the United States, we derive our revenue from sales to hospitals and medical centers, which typically bill all or a portion of the costs and fees associated with our products to various third-party payers, including Medicare, Medicaid, Veterans' Administration, private commercial insurance companies, health maintenance organizations and other healthcare-related organizations, and then bill patients for any applicable deductibles or co-

payments. For example, our contracts are with the hospitals and medical centers that purchase our products for use with TCAR and not with the commercial payers. As a result, access to adequate coverage and reimbursement for our products by third-party payers is essential to the acceptance of our products by our customers.

However, in the United States, there is no uniform policy of coverage and reimbursement for medical device products and services among third-party payers, so coverage and reimbursement can differ significantly from payer to payer, and each coverage decision and level of reimbursement is independent. As a result, third-party reimbursement may not be available or adequate for our products, and there is no guarantee that we will be able to maintain our current levels of coverage or reimbursement or be able to expand coverage to other insurance carriers. Further, payers continually review new technologies for possible coverage and can, without notice, deny or limit coverage for products and procedures or delay coverage approval until further clinical data are available. As a result, the coverage determination process is often a time-consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate reimbursement will be obtained, or maintained if obtained. If third-party reimbursement is not available or adequate for TCAR procedures using our products, or if there is any decline in the amount that payers are willing to reimburse our customers for TCAR or our products, new customers may not adopt, or may reduce their rate of adoption of, our products and we could experience additional pricing pressure, any of which could have a material adverse effect on our business, financial condition and results of operations.

Our products are covered for Medicare beneficiaries under a National Coverage Determination, or NCD, for Percutaneous Transluminal Angioplasty and for non-Medicare beneficiaries based on prior authorizations and individual insurer medical polices. Based on reimbursement information regarding CEA and CAS, we estimate that approximately 79% of carotid procedures are reimbursed by the U.S. Centers for Medicare & Medicaid Services, or CMS, and the remaining approximately 21% are reimbursed by commercial and other payers. Medicare is managed by CMS, which make the final determination regarding Medicare hospital and physician coverage and payment. Any future reconsideration of the applicable Medicare NCD may result in expansion of coverage of CAS and TCAR procedures based on FDA-approved indications or continued coverage limitations to CMS approved CAS investigational studies. CMS reimburses hospital inpatient services based on Medicare Severity Diagnosis Related Groups, or MS-DRGs. All CAS and CEA procedures are currently paid only as Medicare inpatient procedures. CMS policy focus on hospital price transparency, site (e.g. inpatient, outpatient, ambulatory surgery center and office) neutral payments and MS-DRG refinements may place additional downward pressure on future hospital inpatient payments. Medicare payments to physicians are based on a Resource Based Relative Value System. CMS policy changes to increase reimbursement for physician primary care services may result in reductions to physician payments for specialty services and procedures. As a result of any reductions in payments to hospitals and physicians for TCAR procedures, TCAR utilization may decline, which would have a material adverse effect on our business, financial condition and results of operations. Additionally, patients may elect to reduce or defer out-of-pocket costs during times of economic uncertainty or periods of legislative change. If hospital, physician and/or patient demand for TCAR, and thus our products that facilitate the procedure, is adversely affected by third-party reimbursement policies and decisions, it will have a material adverse effect on our business, financial condition and results of operations.

Internationally, reimbursement systems in foreign markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In certain international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Additionally, many international markets have government-managed healthcare systems that control reimbursement for products and procedures. In most markets there are both private insurance systems and government-managed systems. If sufficient levels of coverage and reimbursement are not available for TCAR or our current or future products, in either the United States or internationally, the demand for our products and our revenues will be adversely affected.

Additionally, when payers combine their operations, the combined company may elect to reimburse for TCAR at the lowest rate paid by any of the participants in the consolidation or use its increased size to negotiate reduced rates. If one of the payers participating in the consolidation does not reimburse for TCAR at all, the combined company may elect not to reimburse for TCAR, which would adversely impact our business, financial condition and results of operations.

If we fail to comply with our obligations in our intellectual property license from Cordis, we could lose license rights that are important to our business.

We are a party to a license agreement with Cordis, under which Cordis has granted us a worldwide, non-exclusive, royalty-bearing license to certain of its intellectual property related to the PRECISE® carotid stent for transcervical treatment of carotid artery disease with an intravascular stent for certain applications for accessing blood vessels through the neck and cervical area. Cardinal Health recently sold Cordis to private equity firm Hellman & Friedman LLC.. This license agreement imposes, and we expect that any future license agreements will impose, certain diligence, royalty, and other obligations on us. If we fail to comply with these obligations, our licensors, including Cordis, may have the right to reduce the scope of our rights or terminate these agreements, in which event we may not be able to develop and market

any product that is covered by these agreements. Termination of this license for failure to comply with such obligations or for other reasons, or reduction, elimination or expiration of our licensed rights under it or any other license or agreement, may result in our having to negotiate new or reinstated licenses on less favorable terms or our not having sufficient intellectual property rights to operate our business or cause us to enter into new licenses for different stents. The occurrence of such events could materially harm our business and financial condition.

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we in-license, and any failure by us or our licensors, including Cordis, to obtain, maintain, defend and enforce these rights could have a material adverse effect on our business. In some cases we do not have control over the prosecution, maintenance or enforcement of the patents that we license, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain, defend and enforce the licensed patents.

We rely on Cordis to supply the ENROUTE stent, and if Cordis fails to supply the ENROUTE stent in sufficient quantities or at all, it will have a material adverse effect on our business, financial condition and results of operations.

We rely on Cordis to manufacture the ENROUTE stent pursuant to a supply agreement between us and Cordis Corporation. We strive to maintain an inventory of several months' worth of ENROUTE stents to guard against potential shortfalls in supply, and we estimate that it would take one to two years to find an alternative supplier for our ENROUTE stent and multiple years to identify and seek approval for another stent, and in each case qualify it for use with our other products. In addition, Cordis currently manufactures the ENROUTE stent at a facility in Juarez, Mexico. This facility has previously and in the future could become subject to a COVID-19 outbreak which would cause Cordis to temporarily shut down manufacturing operations, which would in turn present risk to the ongoing supply of our stents used in TCAR procedures. The current political and trade relationship between the United States and Mexico is strained due to the prior administration and could deteriorate further. If Cordis's ability to manufacture the ENROUTE stent is interrupted as a result, or if Cordis experiences a product recall or breaches its supply agreement with us, we may not have a sufficient number of stents for delivery to support TCAR procedures. Finally, we or Hellman & Friedman LLC may wish to re-evaluate certain aspects of the license and supply agreement which may lead to lengthy or costly negotiations. Any shortfall in the supply of ENROUTE stents may result in lower adoption rates for TCAR, fewer TCAR procedures being performed generally, and a material adverse effect on our business, financial condition and results of operations.

TCAR involves surgical risks and is contraindicated in certain patients, which may limit adoption.

Risks of TCAR using our products include the risks that are common to surgical and endovascular procedures, including perforation, dissection, embolization, bleeding, infection, nerve injury and restenosis. Endovascular procedures occurring in the carotid arteries also include the additional risks of stroke, heart attack and death. We are aware of certain characteristics and features of TCAR that may prevent widespread market adoption, including the fact that physicians would need to adopt a new procedure, and that training for physicians will be required to enable them to effectively operate our products.

Our current products are contraindicated, and therefore should not be used, in certain patients. Our ENROUTE NPS is contraindicated in patients in whom antiplatelet and/or anticoagulation therapy is contraindicated; patients with uncorrected bleeding disorders; patients with severe disease of the ipsilateral common carotid artery; and patients with uncontrollable intolerance to flow reversal. Our ENROUTE stent is contraindicated in patients in whom antiplatelet and/or anticoagulation therapy is contraindicated; patients in whom the ENROUTE NPS is unable to be placed; patients with uncorrected bleeding disorders; patients with known allergies to nitinol; and patients with lesions in the ostium of the common carotid artery. Our ENHANCE peripheral access kit is contraindicated in patients with a known or suspected obstruction in the vessel. Our ENROUTE guidewire is contraindicated in patients judged not acceptable for percutaneous intervention. Additionally, patients that lack at least five centimeters of common carotid artery free of significant disease are not indicated for our ENROUTE NPS.

We face manufacturing risks that could adversely affect our ability to manufacture products and could reduce our gross margins and negatively affect our business and operating results.

Our business strategy depends on our ability to manufacture our current and future products in sufficient quantities and on a timely basis to meet customer demand, while adhering to product quality standards, complying with regulatory quality system requirements and managing manufacturing costs. We have a facility located in Sunnyvale, California, where we assemble and package certain of our products, and inspect, release and ship all of our products, either directly to our customers, our facility in Minnesota or to our third-party logistics and warehousing service. We currently produce our ENROUTE NPS at our Sunnyvale facility, and we and the contract manufacturers of our other products do not have

redundant facilities. If our or our manufacturing partners' facilities suffers damage, or a force majeure event, this could materially impact our ability to operate.

We are also subject to numerous other risks relating to our manufacturing capabilities, including:

- Quality and reliability of components, sub-assemblies and materials that we source from third-party suppliers, who are required to meet our quality specifications, the majority of which are our single source suppliers for the products they supply;
- Our or our manufacturing partners' inability to secure components, sub-assemblies and materials in a timely manner, in sufficient quantities or on commercially reasonable terms;
- Our or our manufacturing partners' inability to maintain compliance with quality system requirements or pass regulatory quality inspections;
- Our or our manufacturing partners' failure to develop products in a timely manner or to required specifications or to increase production capacity or volumes to meet demand;
- Our or our manufacturing partners' inability to design or modify production processes to enable us to produce future products efficiently or implement changes in current products in response to design or regulatory requirements; and
- Difficulty identifying and qualifying, and obtaining new regulatory approvals, for alternative suppliers for components in a timely manner.

As demand for our products increases, we will have to invest additional resources to purchase components, sub-assemblies and materials, hire and train employees and enhance our manufacturing processes. If we fail to increase our production capacity efficiently, we may not be able to fill customer orders on a timely basis, our sales may not increase in line with our expectations and our operating margins could fluctuate or decline. In addition, although we expect some of our products in development to share product features, components, sub-assemblies and materials with our existing products, the manufacture of these products may require modification of our or our manufacturing partners' current production processes or unique production processes, the hiring of specialized employees, the identification of new suppliers for specific components, sub-assemblies and materials or the development of new manufacturing technologies. It may not be possible for us or our manufacturing partners' to manufacture these products at a cost or in quantities sufficient to make these products commercially viable or to maintain current operating margins, all of which could have a material adverse effect on our business, financial condition and results of operations.

We depend on a limited number of single source suppliers to manufacture our components, sub-assemblies and materials, which makes us vulnerable to supply shortages and price fluctuations that could have a material adverse effect on our business, financial condition and results of operations.

We rely on single source suppliers for the components, sub-assemblies and materials for our products. These components, sub-assemblies and materials are critical and there are relatively few alternative sources of supply. We have not qualified or obtained necessary regulatory approvals for additional suppliers for most of these components, sub-assemblies and materials, and we do not carry a significant inventory of these items. While we believe that alternative sources of supply may be available, we cannot be certain whether they will be available if and when we need them, or that any alternative suppliers would be able to provide the quantity and quality of components and materials that we would need to manufacture our products if our existing suppliers were unable to satisfy our supply requirements. To utilize other supply sources, we would need to identify and qualify new suppliers to our quality standards and obtain any additional regulatory approvals required to change suppliers, which could result in manufacturing delays and increase our expenses. Our manufacturing partners rely on single source suppliers as well, and are subject to the foregoing risks.

Our and our manufacturing partners' dependence on third-party suppliers subjects us to a number of risks that could impact our ability to manufacture our products and harm our business, including:

- Interruption of supply resulting from modifications to, or discontinuation of, a supplier's operations;
- Delays in product shipments resulting from uncorrected defects, reliability issues or a supplier's failure to produce components that consistently meet our quality specifications;
- Price fluctuations due to a lack of long-term supply arrangements with our suppliers for key components;
- Inability to obtain adequate supply in a timely manner or on commercially reasonable terms;

- Difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- Inability of suppliers to comply with applicable provisions of the FDA's Quality System Regulation, or QSR or other applicable laws or regulations enforced by the FDA and other state and applicable regulatory authorities;
- Inability to adequately ensure the quality of products and components manufactured by third parties;
- Production delays related to the evaluation and testing of products and components from alternative suppliers and corresponding regulatory qualifications;
- Delays in delivery by our suppliers due to changes in demand from us or their other customers; and
- An outbreak of disease or similar public health threat, such as the existing threat of COVID-19, particularly as it may impact our supply chain.

Although we require our third-party suppliers to supply us with components that meet our specifications and comply with applicable provisions of the QSR and other applicable legal and regulatory requirements in our agreements and contracts, and we perform incoming inspection, testing or other acceptance activities to ensure the components meet our requirements, there is a risk that our suppliers will not always act consistent with our best interests, and may not always supply components that meet our requirements or supply components in a timely manner. For example, in the first quarter of 2021, we announced the voluntary recall of certain lots of our ENROUTE Transcarotid Stent System, manufactured by one of our third-party suppliers, Cordis. Our decision to recall these lots was based on complaints we received about tips detaching from the stent delivery system as well as internal testing that we conducted. We have determined the root cause of the detachment was a single operator at Cordis, who, over a specific timeframe, produced lots in which a small number of units were not reliably manufactured to specification. Recalls like this one could cause the supply of our TCAR products to customers to be interrupted, us to incur additional expenses, have to purchase replacement products, negative publicity or damage to our reputation, any of which could cause our results of operations to be adversely impacted.

Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.

We seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions, but keep limited components, sub-assemblies, materials and finished products on hand. To ensure adequate inventory supply and manage our operations with our manufacturing partners and suppliers, we forecast anticipated materials requirements and demand for our products in order to predict inventory needs and then place orders with our suppliers based on these predictions. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including our rapid growth, failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our products, our failure to accurately forecast customer acceptance of new products, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions.

Inventory levels in excess of customer demand may result in a portion of our inventory becoming obsolete or expiring, as well as inventory write-downs or write-offs. Conversely, if we underestimate customer demand for our products or our own requirements for components, subassemblies and materials, our manufacturing partners and suppliers may not be able to deliver components, sub-assemblies and materials to meet our requirements, which could result in inadequate inventory levels or interruptions, delays or cancellations of deliveries to our customers, any of which would damage our reputation, customer relationships and business. In addition, several components, sub-assemblies and materials incorporated into our products require lengthy order lead times, and additional supplies or materials may not be available when required on terms that are acceptable to us or our manufacturing partners, or at all, and our manufacturing partners and suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, any of which could have an adverse effect on our ability to meet customer demand for our products and our results of operations.

Our quarterly and annual results may fluctuate significantly and may not fully reflect the underlying performance of our business.

Our quarterly and annual results of operations, including our revenue, net income or net loss and cash flow, may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Fluctuations in quarterly and annual results may decrease the value of our common stock. Because our quarterly results may fluctuate, period-to-period comparisons

may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing.

We have a limited total addressable market based on our current labeling restrictions.

The total addressable market for TCAR is limited by a number of factors. Approximately 166,000 patients with carotid artery disease in the United States received treatment in the form of surgical or endovascular intervention in 2019. Of this group, we estimate that approximately one-third would be outside the scope of the FDA-approved labeling for the ENROUTE stent, as those patients are not deemed to be at high risk for adverse events from CEA, or high surgical risk. Although we have submitted a PMA supplement to the FDA to expand the labeling for the ENROUTE stent to treat patients at standard risk for adverse events from CEA, the current FDA-approved labeling for the ENROUTE stent is limited to patients at high risk for adverse events from CEA. Patients at high risk for adverse events from CEA are defined as having significant comorbidities and/or anatomic risk factors, and/or advanced age, that would make them riskier candidates for CEA. Furthermore, the safety and effectiveness of TCAR has not been established for certain patients. For example, the FDA-cleared labeling for the ENROUTE NPS states that patients should have at least five centimeters of common carotid artery free of significant disease for initial access to the artery and positioning of the ENROUTE sheath. In addition, per the FDA-approved labeling for the ENROUTE stent, TCAR is limited to asymptomatic patients with carotid artery stenosis of at least 80% and symptomatic patients with carotid artery stenosis of at least 50%, both of which must also be high surgical risk. In addition, physicians may choose to perform CEA in patients with certain anatomical characteristics, including heavily calcified carotid arteries, calcified lesions and severe vessel tortuosity. Finally, current labeling for our products includes contraindications for certain patients, thus further reducing our total addressable market.

Expanding the addressable market for TCAR is dependent upon labeling and reimbursement expansion initiatives.

The ENROUTE stent is not currently indicated for use in standard surgical risk patients. To access a larger portion of the market for carotid artery disease, we have filed for and will need to obtain approval by the FDA for a label expansion of the ENROUTE stent in standard surgical risk patients and obtain corresponding reimbursement coverage expansion for TCAR. FDA approval of an ENROUTE stent label expansion may require additional data from clinical studies or registries, which we are pursuing. However, there are no guarantees that we will be able to obtain such clinical study or registry data or FDA approval of a label expansion for the ENROUTE stent, or that any label expansion or additional reimbursement coverage will be sufficient to adequately access the standard risk portion of the market for carotid artery disease patients. If we are unable to obtain labeling and reimbursement coverage expansion, it may have a material adverse effect on our business, financial condition and results of operations.

Changes in public health insurance coverage and government reimbursement rates for the TCAR procedures using our products could affect the adoption of our products and our future revenue.

The federal government is considering ways to change, and has changed, the manner in which healthcare services are paid for in the United States. Individual states may also enact legislation that impacts Medicaid payments to hospitals and physicians. In addition, CMS establishes Medicare payment levels for hospitals and physicians on an annual basis, which can increase or decrease payment to such entities. Internationally, medical reimbursement systems vary significantly from country to country, with some countries limiting medical centers' spending through fixed budgets, regardless of levels of patient treatment, and other countries requiring application for, and approval of, government or third-party reimbursement. Even if we succeed in bringing our products to market in additional foreign countries, uncertainties regarding future healthcare policy, legislation and regulation, as well as private market practices, could affect our ability to sell our products in commercially acceptable quantities at acceptable prices.

Cost-containment efforts of our customers, purchasing groups and governmental organizations could have a material adverse effect on our sales and profitability.

In an effort to reduce costs, many hospitals in the United States have become members of Group Purchasing Organizations, or GPOs, and Integrated Delivery Networks, or IDNs. GPOs and IDNs negotiate pricing arrangements with medical device companies and distributors and then offer these negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. Bids are generally solicited from multiple providers with the intention of driving down pricing or reducing the number of vendors. Due to the highly competitive nature of the GPO and IDN contracting processes, we may not be able to obtain new, or maintain existing, contract positions with major GPOs and IDNs. Furthermore, the increasing leverage of organized buying groups reduces market prices for our products and/or require administrative fees, thereby reducing our revenue and/or margins.

While having a contract with a GPO or IDN for a given product category can facilitate sales to members of that GPO or IDN, such contract positions can offer no assurance that any level of sales will be achieved, as sales are typically made pursuant to individual purchase orders. Even when a provider is the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN are generally free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause by the GPO or IDN upon 60 to 90 days' notice. Accordingly, the members of such groups may choose to purchase alternative products due to the price or quality offered by other companies, which could result in a decline in our revenue.

We may not be able to achieve or maintain satisfactory pricing and margins for our products.

Manufacturers of medical devices have a history of price competition, and we can give no assurance that we will be able to achieve satisfactory prices for our products or maintain prices at the levels we have historically achieved. Any decline in the amount that payers reimburse our customers for TCAR could make it difficult for customers to continue using, or to adopt, our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, our gross margins will decrease, which will adversely affect our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode. We will continue to be subject to significant pricing pressure, which could harm our business and results of operations.

If our manufacturing facility becomes damaged or inoperable, or if we are required to vacate a facility, we may be unable to produce the products we manufacture or we may experience delays in production or an increase in costs, which could adversely affect our results of operations.

We currently maintain our manufacturing and much of our research and development and non-field-based sales, general and administrative operations in a building located in Sunnyvale, California, which is situated on or near earthquake fault lines, and we do not yet have redundant manufacturing. Should our building be significantly damaged or destroyed by natural or man-made disasters, such as earthquakes, fires or other events, it could take months to relocate or rebuild, during which time our employees may seek other positions, our research, development and manufacturing would cease or be delayed and our products may be unavailable. Moreover, the use of a new facility or new manufacturing, quality control, or environmental control equipment or systems generally requires FDA review and, with respect to certain products, approval of a PMA supplement. Because of the time required to authorize manufacturing in a new facility under FDA, the State of California and non-U.S. regulatory requirements, we may not be able to resume production on a timely basis even if we are able to replace production capacity in the event we lose manufacturing capacity. While we maintain property and business interruption insurance, such insurance has limits and would only cover the cost of rebuilding and relocating and lost revenue, but not general damage, losses caused by earthquakes, losses we may suffer due to our products being replaced by competitors' products or loss in value due to associated decreases in our stock price. The inability to perform our research, development and manufacturing activities, combined with our limited inventory of materials and components and manufactured products, may cause physicians to discontinue using our products or harm our reputation, and we may be unable to reestablish relationships with such physicians in the future. Consequently, a catastrophic event at our facility could have a material adverse effect on our business, financial condition and results of operations.

Furthermore, the current lease for our manufacturing facility expires in 2024, and our operations are growing at a pace that may require us to find a replacement or expansion facility in California sooner. We may be unable to renew our lease or find a new facility on commercially reasonable terms. If we were unable or unwilling to renew at the proposed rates, relocating our manufacturing facility would involve significant expense in connection with the movement and installation of key manufacturing equipment and any necessary recertification with regulatory bodies, and we cannot assure investors that such a move would not delay or otherwise adversely affect our manufacturing activities or operating results. If our manufacturing capabilities were impaired by our move, we may not be able to manufacture and ship our products in a timely manner, which would adversely impact our business.

In addition, we rely on our manufacturing partners to supply certain of our products, and our partners are subject to similar risks with respect to their facilities. If our manufacturing partners' facilities are damaged or destroyed and their ability to supply products to us is limited, it could negatively affect our reputation, physician relationships and TCAR adoption, all of which could have a material adverse effect on our business, financial condition and results of operations. Several of our products are sterilized at a particular third party facility, with limited alternate facilities. If an event occurs that results in damage to or closure of one or more of such facilities, we may be unable to sterilize such products at the previous levels or at all. Because of the time required to approve and license a sterilization facility, a third party may not be available on a timely basis to replace capacity in the event sterilization capacity is lost.

If we fail in our training initiatives, to increase our sales and marketing capabilities or to develop broad brand awareness, our growth will be impeded and our business will suffer.

We currently rely on our direct sales force to sell our products in targeted geographic regions in the U.S., and any failure to maintain and grow our direct sales force could harm our business. The members of our direct sales force are highly trained and possess substantial technical and clinical expertise, which we believe is critical in driving adoption of TCAR. The members of our U.S. sales force are at-will employees. The loss of these personnel to competitors, or otherwise, could materially harm our business. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical and clinical expertise and qualifications, or if we are unable to successfully instill such technical and clinical expertise in replacement personnel, our revenues and results of operations could be materially harmed.

In order to generate future growth, we plan to continue to expand and leverage our sales, marketing, and medical affairs infrastructure to increase our trained physician and hospital customer base and our business. Identifying and recruiting qualified sales, marketing and medical affairs personnel and training them on TCAR, on applicable federal and state laws and regulations, and on our internal policies and procedures requires significant time, expense and attention. It often takes several months or more before a sales representative is fully trained and productive. Our sales force may subject us to higher fixed costs than those of companies with competing products, such as stents, that utilize independent third parties, which could place us at a competitive disadvantage. Our business may be harmed if our efforts to expand and train our sales force do not generate a corresponding increase in revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our products. Any failure to hire, develop and retain talented sales personnel, to achieve desired productivity levels in a reasonable period of time or timely reduce fixed costs, could have a material adverse effect on our business, financial condition and results of operations. Our ability to increase our customer base and achieve broader market acceptance of our products will depend to a significant extent on our ability to expand our marketing efforts. We plan to dedicate significant resources to our marketing programs. Our business may be harmed if our marketing efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our brand is critical to achieving broad acceptance of our products and penetrating new accounts. Brand promotion activities may not generate patient or physician awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. Our medical affairs department may not train physicians at a rate sufficient to expand our physician base in a manner consistent with our business plan. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the physician acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad adoption of our products.

The market for our products is highly competitive. If our competitors are able to develop or market carotid artery disease treatments that are safer, more effective or gain greater acceptance in the marketplace, than any products we develop, our commercial opportunities will be reduced or eliminated.

Our industry is highly competitive, subject to change and significantly affected by new product introductions and other activities of industry participants. We are initially positioning TCAR as an alternative to CEA and CAS in high surgical risk patients. CEA has historically been performed by vascular surgeons as the primary surgical solution for carotid artery disease. The major manufacturers of products, such as patches and shunts, used in connection with CEA include LeMaitre Vascular, Getinge / Maquet, Baxter, Terumo, Gore and Edwards. Some competitors market products for use in CAS, such as peripheral access kits, stents, distal and proximal embolic protection devices, guidewires, balloons and sheaths. Such companies include Abbott, Boston Scientific, Cordis, Medtronic, Terumo, Gore, Contego Medical and InspireMD. These technologies, other products that are in current clinical trials, new drugs or additional indications for existing drugs could demonstrate better safety, effectiveness, clinical results, lower costs or greater physician and patient acceptance.

We compete, or may compete in the future, against other companies which have longer operating histories, more established products and greater resources, which may prevent us from achieving significant market penetration or improved operating results. These companies enjoy several competitive advantages, including:

- Greater financial and human capital resources;
- Significantly greater name recognition;
- Established relationships with vascular surgeons and other treating specialties, referring physicians, customers and third-party payers;
- Additional lines of products, and the ability to offer rebates or bundle products to offer greater discounts or incentives to gain a competitive advantage; and
- Established sales, marketing and worldwide distribution networks.

Because of the size of the market opportunity for the treatment of carotid artery disease, we believe potential competitors have historically dedicated and will continue to dedicate significant resources to aggressively promote their products or develop new products. New treatment options may be developed that could compete more effectively with our products due to the prevalence of carotid artery disease and the extensive research efforts and technological progress that exist within the market.

Our ability to compete depends on our ability to innovate successfully and deliver any new products in a timely manner.

The market for our products is competitive, dynamic, and marked by rapid and substantial technological development and product innovation. New entrants or existing competitors could attempt to develop products that compete directly with ours. Demand for our products and future related products could be diminished by equivalent or superior products and technologies offered by competitors. If we are unable to innovate successfully, our products could become obsolete and our revenue would decline as our customers purchase our competitors' products.

We are currently focused on development of existing products for TCAR and other indications, new products for TCAR and new products for other indications. If we are unable to develop new products, applications or features due to constraints, such as insufficient cash resources, high employee turnover, inability to hire personnel with sufficient technical skills or a lack of other research and development resources, we may not be able to maintain our competitive position compared to other companies. Furthermore, many of our competitors devote a considerably greater amount of funds to their research and development programs than we do, and those that do not may be acquired by larger companies that would allocate greater resources to research and development programs. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our competitors could harm our business.

Any significant delays in our product launches may significantly impede our ability to enter or compete in a given market and may reduce the sales that we are able to generate from these products. We may experience delays in any phase of a product development, including during research and development, clinical trials, regulatory review, manufacturing and marketing. Delays in product introductions could have a material adverse effect on our business, financial condition and results of operations.

Defects or failures associated with our products could lead to additional recalls, safety alerts or litigation, as well as significant costs and negative publicity.

Our business is subject to significant risks associated with manufacture, distribution and use of medical devices that are placed inside the human body, including the risk that patients may be severely injured by or even die from the misuse or malfunction of our products caused by design flaws or manufacturing defects. In addition, component failures, design defects, off-label uses or inadequate disclosure of product-related information could also result in an unsafe condition or the injury or death of a patient. These problems could lead to a recall or market withdrawal of, or issuance of a safety alert relating to, our products and could result in significant costs, negative publicity and adverse competitive pressure. For example, in the first quarter of 2021, we announced the voluntary recall of certain lots of our ENROUTE Transcarotid Stent System, manufactured by one of our third-party suppliers, Cordis. Our decision to recall these lots was based on complaints we received about tips detaching from the stent delivery system as well as internal testing that we conducted. We believe the root cause of the detachment was a single operator at Cordis, who, over a specific timeframe, produced lots in which a small number of units were not reliably manufactured to specification. The circumstances giving rise to recalls are unpredictable, and any recalls of existing or future products increase the probability of inspection by, or additional scrutiny from, the FDA and could have a material adverse effect on our business, financial condition and results of operations.

We provide a limited warranty that our products are free of material defects and conform to specifications, and offer to repair, replace or refund the purchase price of defective products. As a result, we bear the risk of potential warranty claims on our products. In the event that we attempt to recover some or all of the expenses associated with a warranty claim against us from our suppliers or vendors, we may not be successful in claiming recovery under any warranty or indemnity provided to us by such suppliers or vendors and any recovery from such vendor or supplier may not be adequate.

The medical device industry has historically been subject to extensive litigation over product liability claims. Operating in the area of the neck with the brain as the end organ is dangerous and presents risks of adverse events such as bleeding, arterial dissection, cranial nerve injury, myocardial infarction, stroke and death, which subject us to a greater risk of being involved in litigation than companies with products used in less critical areas of the body. We may be subject to product liability claims if our products cause, or merely appear to have caused, an injury or death, even if due to physician error. In addition, an injury or death that is caused by the activities of our suppliers, such as those that provide us with

components and raw materials, or by an aspect of a treatment used in combination with our products, such as a complementary drug or anesthesia, may be the basis for a claim against us by patients, hospitals, physicians or others purchasing or using our products, even if our products were not the actual cause of such injury or death. We may choose to settle any claims to avoid fault and complication not due to failure of our products. An adverse outcome involving one of our products could result in reduced market acceptance and demand for all of our products, and could harm our reputation and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture or marketing of our products could result in the suspension or delay of regulatory reviews of our premarket notifications or applications for marketing. Any of the foregoing problems could disrupt our business and have a material adverse effect on our business, financial condition and results of operations.

Although we carry product liability insurance in the United States and in other countries in which we conduct business, including for clinical trials and product marketing, we can give no assurance that such coverage will be available or adequate to satisfy any claims. Product liability insurance is expensive, subject to significant deductibles and exclusions, and may not be available on acceptable terms, if at all. If we are unable to obtain or maintain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. Defending a suit, regardless of its merit or eventual outcome, could be costly, could divert management's attention from our business and might result in adverse publicity, which could result in reduced acceptance of our products in the market, product recalls or market withdrawals.

We are required to file adverse event reports under Medical Device Reporting, or MDR, regulations with the FDA, which reports are publicly available on the FDA's website. 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.

The failure of TCAR to meet patient expectations or the occurrence of adverse events from TCAR could impair our financial performance.

Our future success depends upon patients having an experience with TCAR that meets their expectations in order to increase physician demand for our products as a result of positive feedback, social media and word-of-mouth. Patients may be dissatisfied if their expectations of the procedure and results, among other things, are not met. Despite what we believe to be the safety profile of our products, patients may experience adverse events such as arterial restenosis or dissection, cranial nerve injury, wound complications, transient ischemic attacks, stroke, heart attack, and death. If the results of TCAR do not meet the expectations of the patients, or patients experience adverse events, it could discourage patients from referring TCAR to others. For example, although we have not received any reports of strokes, deaths or other long-term patient sequelae from the tip detachments that triggered our recent recall, if there were to be patient injury, dissatisfied patients may express negative opinions through social media or we may otherwise suffer reputational damage or become subject to product liability lawsuits. Any failure to meet patient expectations and any resulting negative publicity or lawsuits could harm our reputation and future sales.

We depend on our senior management team and the loss of one or more key employees or an inability to attract and retain highly skilled employees could harm our business.

Our success depends largely on the continued services of key members of our executive management team and others in key management positions. For example, the services of Erica Rogers, our Chief Executive Officer, and Lucas Buchanan, our Chief Financial and Chief Operating Officer, are essential to driving adoption of our products, executing on our corporate strategy and ensuring the continued operations and integrity of financial reporting within our company. In addition, the services of Andrew Davis, our Chief Commercial Officer, are critical to driving the growth in sales of our products. Any of our employees may terminate their employment with us at any time. We do not currently maintain key person life insurance policies on any of our employees. If we lose one or more key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy.

In addition, our research and development programs, and sales efforts depend on our ability to attract and retain highly skilled engineers and sales professionals. We may not be able to attract or retain qualified engineers and sales professionals in the future due to the competition for qualified personnel. We have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than we do. When we hire employees from competitors or other companies, their former employers have previously and may in the future attempt to assert that these employees or we have breached legal obligations, which may result in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees, particularly in the San Francisco

Bay Area, often consider the value of the stock awards they receive in connection with their employment along with salary, benefits and other factors. If the perceived benefits of our stock awards decline, either because we are a public company or for other reasons, it may harm our ability to recruit and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed.

The use, misuse or off-label use of our products may result in injuries that lead to product liability suits, which could be costly to our business.

The ENROUTE stent has been approved by the FDA for the treatment of high surgical risk patients who require carotid revascularization and meet certain treatment parameters. If physicians expand the patient population in which they elect to use our products that is outside of the intended use approved by the FDA, then the use, misuse, or off-label use of our products may result in outcomes and adverse events including stroke, myocardial infarction and death, potentially leading to product liability claims. Our products are not indicated for use in all patients with carotid artery disease, and therefore cannot be marketed or advertised in the United States for certain uses without additional approvals or clearances from the FDA. However, we cannot prevent a physician from using our products for off-label applications or using components or products that are not our products when performing TCAR. In addition, we cannot guarantee that physicians are trained by us or their peers prior to utilizing our products. Complications resulting from the use of our products off-label or use by physicians who have not been trained appropriately, or at all, may expose us to product liability claims and harm our reputation. Moreover, if the FDA determines that our promotional materials or physician training, including our paid consultants' educational materials, constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to enforcement action, including warning letters, untitled letters, fines, penalties, or seizures. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines and/or other penalties against companies for alleged improper promotion and has investigated, prosecuted, and/or enjoined several companies from engaging in off-label promotion.

In addition, if our products are defectively designed, manufactured or labeled, contain defective components or are misused, we may become subject to costly litigation initiated by physicians, hospitals or patients. Product liability claims are especially prevalent in the medical device industry and could harm our reputation, divert management's attention from our core business, be expensive to defend and may result in sizable damage awards against us. Although we maintain product liability insurance, we may not have sufficient insurance coverage for future product liability claims. We may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation, significantly increase our expenses, and reduce product sales. Product liability claims could cause us to incur significant legal fees and deductibles and claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and operating results.

If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be harmed.

Any growth that we experience in the future will require us to expand our sales, general and administrative personnel, manufacturing and distribution operations, and facilities and information technology infrastructure. In addition to the need to scale our organization, future growth will impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. Rapid expansion in personnel could mean that less experienced people manufacture, market and sell our products, which could result in inefficiencies and unanticipated costs, reduced quality and disruptions to our operations. In addition, rapid and significant growth may strain our administrative and operational infrastructure. Our ability to manage our business and growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

As demand for our products or any of our future products increases, we will need to continue to scale our capacity, expand customer service, billing and systems processes and enhance our internal quality assurance program. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available to facilitate the growth of our business. Failure to implement necessary procedures, transition to new processes or hire the necessary personnel could result in higher costs or inability to meet increased demand. If we encounter difficulty meeting market demand, quality standards or physician expectations, our reputation could be harmed and our business could suffer.

Due to our recent growth in our business, we are actively searching for additional space to provide offices and facilities for the employees we expect to hire. We have supplemented our distribution operations with third-party logistics

and warehousing services in another part of the country and have leased additional facilities in the Minneapolis, Minnesota area and are also considering additional leased facilities in the San Francisco Bay Area. There is competition for office, shipping and warehousing space in the San Francisco Bay area and elsewhere and we can provide no assurance that we will find additional space or that such space will be on reasonable terms. If we are unable to obtain additional space or support on commercially reasonable terms our costs may go up or our business operations may be adversely affected.

We may need substantial additional funding and may not be able to raise capital when needed, which could force us to delay, reduce or eliminate our product development programs and commercialization efforts.

We believe that our cash and cash equivalents and investments and expected revenue will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months. However, we have based these estimates on assumptions that may prove to be incorrect, and we could spend our available financial resources much faster than we currently expect. Our future funding requirements will depend on many factors, including:

- The degree and rate of market acceptance of TCAR and our products;
- Whether we acquire third-party companies, products or technologies;
- Restructuring, refinancing or repayment of debt;
- The scope and timing of investment in our sales force and physician training;
- The scope, rate of progress and cost of our research and development activities, current or future clinical studies and additional regulatory clearances or approvals;
- The scope and timing of investment in acute ischemic stroke and other neurovascular and cardiac products we develop;
- The costs associated with any future product recall that may occur;
- The costs of attaining, defending and enforcing our intellectual property rights;
- The impact of COVID-19, including new variants, on our business and operations;
- The emergence of competing technologies or other adverse market developments; and
- The rate at which we expand internationally.

We may seek to raise additional capital through equity offerings or debt financings and such additional financing may not be available to us on acceptable terms, or at all. In addition, any additional equity or debt financing that we raise may contain terms that are not favorable to us or our stockholders. For example, if we raise funds by issuing equity or equity-linked securities, the issuance of such securities could result in dilution to our stockholders. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline.

In addition, the terms of debt securities issued or borrowings could impose significant restrictions on our operations including restrictive covenants, such as limitations on our ability to, among other things, dispose of assets, effect certain mergers, incur debt, grant liens, pay dividends and distributions on capital stock, make investments and acquisitions, and enter into transactions with affiliates, and other operating restrictions that could adversely affect our ability to conduct our business.

In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms, such as relinquishment or licensing of certain technologies or products that we otherwise would seek to develop or commercialize ourselves, or reserve for future potential arrangements when we might otherwise be able to achieve more favorable terms. In addition, we may be forced to work with a partner on one or more of our products or market development programs, which could lower the economic value of those programs to us.

If we are unable to obtain adequate financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, delay clinical trials necessary to market our products, or delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products. If this were to occur, our ability to grow and support our business and to respond to market challenges could be significantly limited, which could have a material adverse effect on our business, financial condition and results of operations.

We have a significant amount of debt, which may affect our ability to operate our business and secure additional financing in the future.

As of September 30, 2021, we had an aggregate of approximately $49.0 million in principal outstanding under our Loan Agreement with Stifel Bank. We must make significant interest-only monthly payments under the Loan Agreement, which has diverted and will continue to divert resources from other activities. Our obligations under the Loan Agreement are collateralized by substantially all of our assets, excluding intellectual property, and we are subject to customary affirmative and negative covenants, including covenants limiting our ability and the ability of our subsidiaries to, among other things, dispose of assets, effect certain mergers, incur debt, grant liens, pay dividends and distributions on capital stock, make investments and acquisitions, and enter into transactions with affiliates, in each case subject to customary exceptions for a loan facility of this size and type. The covenants related to the Loan Agreement, as well as any future financing agreements into which we may enter, may restrict our ability to finance our operations and engage in, expand or otherwise pursue our business activities and strategies. While we have not previously breached and are not currently in breach of these or any other covenants contained in our Loan Agreement, there can be no guarantee that we will not breach these covenants in the future. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in a default under the Loan Agreement. If not waived, future defaults could cause all of the outstanding indebtedness under the Loan Agreement to become immediately due and payable, termination of commitments to extend further credit, a 5% increase in the applicable rate of interest and the exercise by the lender of other rights and remedies provided for under the Loan Agreement. If we do not have or are unable to generate sufficient cash available to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, our assets could be foreclosed upon and we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern.

We may acquire other companies or technologies, or enter into license agreements, distribution arrangements or strategic partnerships, which could fail to result in a commercial product or generate sales, divert our management's attention, result in additional dilution to our stockholders and otherwise disrupt our operations and harm our operating results.

Although we currently have no agreements or commitments to complete any such transactions, we may in the future seek to acquire, license or invest in businesses, products or technologies that we believe could complement or expand our portfolio, enhance our technical capabilities or otherwise offer growth opportunities. We could also seek to enter into distribution arrangements or strategic partnerships with third parties that we believe could increase our revenue or offer other commercial benefits. However, we cannot assure you that we would be able to successfully complete any acquisition, license agreement or distribution agreement we choose to pursue, or that we would be able to successfully integrate any business or product or technology in a cost-effective and non-disruptive manner. Similarly, we cannot guarantee that we would derive benefits from any distribution arrangement or other strategic partnership. The pursuit of potential acquisition, license or partnering opportunities may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable transactions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or strategic partners, or be successful in entering into an agreement with any particular target or partner, or obtain the expected benefits of any acquisition, license, investment or other strategic partnership arrangement.

To date, the growth of our operations has been largely organic, and we have limited experience in acquiring other businesses or technologies. We may not be able to successfully integrate any acquired personnel, operations and technologies, or effectively manage the combined business following an acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our operating results. In addition, if an acquired business, product or technology fails to meet our expectations, our operating results, business and financial condition may suffer.

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

As of December 31, 2020, we had U.S. federal and state net operating loss carryforwards, or NOLs, of $241.9 million and $209.8 million, respectively. Our U.S. federal NOLs arising in tax years ending on or before December 31, 2017 are subject to expiration and will begin to expire in 2027 (U.S. federal NOLs arising in tax years ending after December 31, 2017 are not subject to expiration) and our state NOLs will begin to expire in 2028. We may use these NOLs to offset taxable income for U.S. federal and state income tax purposes. However, Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, may limit the NOLs we may use in any year for U.S. federal income tax purposes in the event of certain changes in ownership of our company. An "ownership change" pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. Although we have not performed a formal study under Section

382 of the Code, we believe we may have experienced at least one "ownership change" in the past and may have experienced others. In addition, future issuances or sales of our stock, including certain transactions involving our stock that are outside of our control, could result in future "ownership changes." "Ownership changes" that have occurred in the past or that may occur in the future could result in the imposition of an annual limit on the amount of pre-ownership change NOLs and other tax attributes we can use to reduce our taxable income or income tax liability, potentially increasing and accelerating our liability for income taxes, and also potentially causing those tax attributes to expire unused. Any limitation on using NOLs could, depending on the extent of such limitation and the NOLs previously used, result in our retaining less cash after payment of U.S. federal and state income taxes during any year in which we have taxable income, rather than losses, than we would be entitled to retain if such NOLs were available as an offset against such income for U.S. federal and state income tax reporting purposes, which could adversely impact our operating results. Furthermore, under the Tax Cuts and Jobs Act of 2017, although the treatment of U.S. federal NOLs arising in tax years beginning on or before December 31, 2017 has generally not changed, U.S. federal NOLs arising in tax years beginning after December 31, 2017 may only be used to offset 80% of our taxable income. This change may require us to pay U.S. federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

As international expansion of our business occurs, it will expose us to market, regulatory, political, operational, financial, legal and economic risks associated with doing business outside of the United States.

Our long-term strategy is to increase our international presence, including but not limited to securing regulatory approvals in Japan and China. We currently have the right to affix the CE Mark to our products, allowing us to commercialize in Europe in the future if we choose to do so. This strategy may include establishing and maintaining physician outreach and education capabilities outside of the United States and expanding our relationships with international distributors, providers and payers. Doing business internationally involves a number of risks, including:

- Difficulties in staffing and managing our international operations;
- Multiple, conflicting and changing laws and regulations such as tax laws, privacy laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- Reduced or varied protection for intellectual property rights in some countries;
- Obtaining regulatory clearance where required for our products in various countries;
- Requirements to maintain data and the processing of that data on servers located within such countries;
- Complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- Difficulties in adequately training and managing international distributors;
- Limits on our ability to penetrate international markets if we are required to manufacture our products locally;
- Financial risks, such as longer payment cycles, difficulty collecting accounts receivable, foreign tax laws and complexities of foreign value-added tax systems, the effect of local and regional financial pressures on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- Restrictions on the site-of-service for use of our products and the economics related thereto for physicians, providers and payers;
- Natural disasters, political and economic instability, including wars, terrorism, political unrest, outbreak of disease, boycotts, curtailment of trade and other market restrictions; and
- Regulatory and compliance risks that relate to maintaining accurate information and control over activities subject to regulation under the United States Foreign Corrupt Practices Act of 1977, or FCPA, U.K. Bribery Act of 2010 and comparable laws and regulations in other countries.

Any of these factors could significantly harm our future international expansion and operations and, consequently, have a material adverse effect on our business, financial condition and results of operations.

Additionally, pursuant to the terms of our existing intellectual property license and supply agreement with Cordis, there are certain restrictions on our ability to sell the ENROUTE stent through select direct competitors of Cordis Corporation. If we are unable to locate international distributors that are not select direct competitors to Cordis Corporation, to market and sell our ENROUTE stent, our ability to expand our business internationally may be harmed, which could 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 our customers or patients, 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 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.

We could be adversely affected by violations of the FCPA and similar worldwide anti-bribery laws and any investigation, and the outcome of any investigation, by government agencies of possible violations by us of the FCPA could have a material adverse effect on our business.

The FCPA and similar worldwide anti-bribery laws prohibit companies and their intermediaries from corruptly providing any benefits to government officials for the purpose of obtaining or retaining business. We are in the process of further enhancing policies and procedures intended to help ensure compliance with these laws. In the future, we may operate in parts of the world that have experienced governmental corruption to some degree. Moreover, because of the significant role government entities play in the regulation of many foreign healthcare markets, we may be exposed to heightened FCPA and similar risks arising from our efforts to seek regulatory approval of and reimbursement for our products in such countries. We cannot assure you that our internal control policies and procedures will protect us from improper acts committed by our employees or agents. Violations of these laws, or allegations of such violations, would significantly disrupt our business and have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

We may become a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell and market our products.

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Additionally, our products include components that we purchase from vendors, and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell and/or export our products or to use product names. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. The defense of these matters can be time consuming, costly to defend in litigation, divert management's attention and resources, damage our reputation and brand and cause us to incur significant expenses or make substantial payments.

Vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third-party's patent or trademark or of misappropriating a third-party's trade secret.

Since patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our products. Competitors may also contest our patents, if issued, by showing the patent examiner that the invention was not original, was not novel or was obvious. In litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons. If a court agrees, we would lose our rights to those challenged patents.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees and consultants and any other partners or collaborators who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

Further, if such patents, trademarks, or trade secrets are successfully asserted against us, this may harm our business and result in injunctions preventing us from selling our products, license fees, damages and the payment of attorney fees and court costs. In addition, if we are found to willfully infringe third-party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties. Although patent, trademark, trade secret, and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign our products to avoid infringement.

Similarly, interference or derivation proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office, or USPTO, may be necessary to determine priority with respect to our patents, patent applications, trademarks or trademark applications. We may also become involved in other proceedings, such as reexamination, inter parties review, derivation or opposition proceedings before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing our products or using product names, which would have a significant adverse impact on our business, financial condition and results of operations.

Additionally, we may file lawsuits or initiate other proceedings to protect or enforce our patents, trademarks or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors may infringe our issued patents, trademarks or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or 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. Furthermore, even if our patents are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business position, financial condition and results of operations.

Our success will depend on our ability to obtain, maintain and protect our intellectual property rights.

In order to remain competitive, we must develop, maintain and protect the proprietary aspects of our brands, technologies and data. We rely on a combination of contractual provisions, confidentiality procedures and patent, copyright, trademark, trade secret and other intellectual property laws to protect the proprietary aspects of our brands, technologies and data. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Our success will depend, in part, on preserving our trade secrets, maintaining the security of our data and know-how and obtaining and maintaining other intellectual property rights. We may not be able to obtain or maintain intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage. In addition, our trade secrets, data and know-how could be subject to unauthorized use, misappropriation, or disclosure to unauthorized parties, despite our efforts to enter into confidentiality agreements with our employees, consultants, clients and other vendors who have access to such information, and could otherwise become known or be independently discovered by third parties. Our intellectual

property, including trademarks, could be challenged, invalidated, infringed, and circumvented by third parties, and our trademarks could also be diluted, declared generic or found to be infringing on other marks. If any of the foregoing occurs, we could be forced to re-brand our products, resulting in loss of brand recognition and requiring us to devote resources to advertising and marketing new brands, and suffer other competitive harm. Third parties may also adopt trademarks similar to ours, which could harm our brand identity and lead to market confusion. Failure to obtain and maintain intellectual property rights necessary to our business and failure to protect, monitor and control the use of our intellectual property rights could negatively impact our ability to compete and cause us to incur significant expenses. The intellectual property laws and other statutory and contractual arrangements in the United States and other jurisdictions we depend upon may not provide sufficient protection in the future to prevent the infringement, use, violation or misappropriation of our trademarks, data, technology and other intellectual property and services, and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated or otherwise violated.

We rely, in part, on our ability to obtain, maintain, expand, enforce, and defend the scope of our intellectual property portfolio or other proprietary rights, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights. The process of applying for and obtaining a patent 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, in a timely manner, or in all jurisdictions where protection may be commercially advantageous, or we may not be able to protect our proprietary rights at all. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. In addition, the issuance of a patent does not ensure that it is valid or enforceable, so even if we obtain patents, they may not be valid or enforceable against third parties. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. Issued patents may be challenged, narrowed, invalidated or circumvented. Decisions by courts and governmental patent agencies may introduce uncertainty in the enforceability or scope of patents owned by or licensed to us. Furthermore, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own products and practicing our own technology. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid, unenforceable or not infringed; competitors may then be able to market products and use manufacturing and analytical processes that are substantially similar to ours. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

If we are unable to protect the confidentiality of our other proprietary information, our business and competitive position may be harmed.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect and some courts are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, collaborators and others upon the commencement of their relationship with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection for our trade secrets, know-how, or other proprietary information in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how, or other proprietary information. There can be no assurance that such third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. Despite the protections we do place on our intellectual property or other proprietary rights, monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology.

To the extent our intellectual property or other proprietary information protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or otherwise obtain and use our products or technology, or develop similar technology. Our competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology.

Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our products, brand and business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of our products and harm our business, the value of our investment in research and development or acquisitions could be reduced and third parties might make claims against us related to losses of their confidential or proprietary information. Any of the foregoing could materially and adversely affect our business, financial condition and results of operations.

Further, it is possible that others will independently develop the same or similar technology or otherwise obtain access to our unpatented technology, and in such cases we could not assert any trade secret rights against such parties. Costly and time consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain trade secret protection, or if our competitors obtain our trade secrets or independently develop technology similar to ours or competing technologies, our competitive market position could be materially and adversely affected. In addition, some courts are less willing or unwilling to protect trade secrets and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases.

We also seek to preserve the integrity and confidentiality of our data and other confidential information 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 detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products, we may not be able to stop a competitor from marketing products that are the same as or similar to our products, which would have a material adverse effect on our business.

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

A company may attempt to commercialize competing products utilizing our proprietary design, trademarks or tradenames in foreign countries where we do not have sufficient patent protection and where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations.

Filing, prosecuting and defending patents or trademarks on our current and future products in all countries throughout the world would be prohibitively expensive. The requirements for patentability and trademarking may differ in certain countries, particularly developing countries. The laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from utilizing our inventions and trademarks in all countries outside the United States. Competitors may use our technologies or trademarks in jurisdictions where we have not obtained patent or trademark protection to develop or market their own products and further, may export otherwise infringing products to territories where we have patent and trademark protection, but enforcement on infringing activities is inadequate. These products or trademarks may compete with our products or trademarks, and our patents, trademarks 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, trademarks and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents and trademarks or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent and trademarks 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 and trademarks at risk of

being invalidated or interpreted narrowly and our patent or trademark applications at risk, 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. In addition, certain countries in Europe and certain developing countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

We may be subject to claims that we or our employees have misappropriated the intellectual property of a third party, including trade secrets or know-how, or are in breach of non-competition or non-solicitation agreements with our competitors and third parties may claim an ownership interest in intellectual property we regard as our own.

Many of our employees and consultants were previously employed at or engaged by other medical device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property or disclosed the alleged trade secrets or other proprietary information, of these former employers or competitors.

Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property we regard as our own, based on claims that our employees or consultants have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against any other claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers.

An inability to incorporate technologies or features that are important or essential to our products could have a material adverse effect on our business, financial condition and results of operations, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have an adverse effect on our business, financial condition and results of operations.

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

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also may affect patent litigation. These also include provisions that switched the United States from a “first-to-invent” system to a “first-to-file” system, allow third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith 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.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U.S.

Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

The failure of third parties to meet their contractual, regulatory, and other obligations could adversely affect our business.

We rely on suppliers, vendors, outsourcing partners, consultants, alliance partners and other third parties to research, develop, manufacture and commercialize our products and manage certain parts of our business. Using these third parties poses a number of risks, such as: (i) they may not perform to our standards or legal requirements; (ii) they may not produce reliable results; (iii) they may not perform in a timely manner; (iv) they may not maintain confidentiality of our proprietary information; (v) disputes may arise with respect to ownership of rights to technology developed with our partners; and (vi) disagreements could cause delays in, or termination of, the research, development or commercialization of our products or result in litigation or arbitration. Moreover, some third parties are located in markets subject to political and social risk, corruption, infrastructure problems and natural disasters, in addition to country-specific privacy and data security risk given current legal and regulatory environments. Failure of third parties to meet their contractual, regulatory, and other obligations may materially affect our business.

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

We rely on trademarks, service marks, tradenames and brand names to distinguish our products from the products of our competitors, and have registered or applied to register these trademarks. We cannot assure you that our trademark applications will be approved. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources towards advertising and marketing new brands and managing through regulatory implications such as relabeling. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Certain of our current or future trademarks may become so well known by the public that their use becomes generic and they lose trademark protection. 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, financial condition and results of operations may be adversely affected.

Risks Related to Government Regulation

Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, could harm our business, financial condition and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. In March 2010, the Affordable Care Act was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may affect our business, the Affordable Care Act:

- Established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;
- Implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- Expanded the eligibility criteria for Medicaid programs.

We do not yet know the full impact that the Affordable Care Act will have on our business. The taxes imposed by the Affordable Care Act and the expansion in the government's role in the U.S. healthcare industry may result in decreased sale of our products and, lower reimbursement by payers for our products, all of which may have a material adverse effect on our business, financial condition and results of operations. The Biden Administration and the U.S. Congress may take

further action regarding the Affordable Care Act, including, but not limited to, repeal or replacement. Most recently, the Tax Cuts and Jobs Act of 2017 was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. Additionally, all or a portion of the Affordable Care Act and related subsequent legislation may be modified, repealed or otherwise invalidated through judicial challenge, which could result in lower numbers of insured individuals, reduced coverage for insured individuals and adversely affect our business, financial condition and results of operations.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2029 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments which began in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. It is unclear what effect new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations or cash flows.

We expect additional state and federal healthcare policies and reform measures to be adopted in the future. Any of these could make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products after clearance or approval is obtained. They could result in reduced demand for our products or result in additional pricing pressure. Any such reforms could have a material adverse effect on our industry generally and on our customers. Any changes of, or uncertainty with respect to, future coverage or reimbursement rates could affect demand for our products, which in turn could impact our ability to successfully commercialize our products and could have an adverse material effect on our business, financial condition and results of operations. Changes and reforms in the European Union and other countries where we may decide to commercialize could have similar effects.

Changes in the CMS fee schedules may harm our revenue and operating results.

Government payers, such as Centers for Medicare and Medicaid Services, or CMS, as well as insurers, have increased their efforts to control the cost, utilization and delivery of healthcare services. From time to time, the U.S. Congress has considered and implemented changes in the CMS fee schedules in conjunction with budgetary legislation. Reductions of reimbursement by Medicare or Medicaid for procedures that use our products or changes in policy regarding coverage of these procedures, such as adding requirements for payment, or prior authorizations, may be implemented from time to time. Reductions in the reimbursement rates and changes in payment policies of other third-party payers may occur as well. Similar changes in the past have resulted in reduced payments for procedures that use medical device products as well as added costs and have added more complex regulatory and administrative requirements. Further changes in federal, state, local and third-party payer regulations or policies may have a material adverse impact on the demand for our products and on our business. Actions by agencies regulating insurance or changes in other laws, regulations, or policies may also have a material adverse effect on our business, financial condition and results of operations.

If we fail to comply with broad based healthcare and other governmental regulations, we could face substantial fines and penalties and our business, results of operations and financial condition could be adversely affected.

The products we offer are highly regulated, and there can be no assurance that the regulatory environment in which we operate will not change significantly and adversely in the future. Our arrangements with physicians, hospitals and medical centers will expose us to broadly applicable fraud and abuse and other laws and regulations that may restrict the financial arrangements and relationships through which we market, sell and distribute our products. Our employees, consultants, and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements. Federal and state healthcare laws and regulations that may affect our ability to conduct business, include, without limitation:

- Federal and state laws and regulations regarding billing and claims payment applicable to TCAR and regulatory agencies enforcing those laws and regulations;
- FDA prohibitions against the advertisement, promotion and labeling of our products for off-label uses, or uses outside the specific indications approved by the FDA;

- The federal Anti-Kickback Statute, which broadly prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce 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 the CMS programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. Moreover, 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 civil False Claims Act. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $176,495 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines of up to $100,000 and imprisonment of up to 10 years. Similarly, violations can result in mandatory exclusion from participation in government healthcare programs, including Medicare and Medicaid;
- The federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government. These laws can apply to manufacturers who provide inaccurate information on coverage, coding, and reimbursement of their products to persons who bill third-party payers. Private individuals can bring False Claims Act "qui tam" actions, on behalf of the government and such individuals, commonly known as "whistleblowers," may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties ranging from $11,655 to $23,331 for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- Federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making, or causing to be made, false statements relating to healthcare matters;
- The federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- The FCPA, the U.K. Bribery Act of 2010, and other local anti-corruption laws that apply to our international activities;
- The federal Physician Payment Sunshine Act, or Open Payments, created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or Affordable Care Act, and its implementing regulations, which requires manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to licensed physicians, certain other healthcare professionals, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations, to report annually ownership and investment interests held by physicians and their immediate family members. Additionally, on October 24, 2018, President Trump signed into law the "Substance Use-Disorder Prevention that Promoted Opioid Recovery and Treatment for Patients and Communities Act" which in part (under a provision entitled "Fighting the Opioid Epidemic with Sunshine") extends the reporting and transparency requirements for physicians in the Physician Payments Sunshine Act to physician assistants, nurse practitioners, and other mid-level practitioners (with reporting requirements going into effect in 2022 for payments made in 2021). Applicable manufacturers are required to submit annual reports to CMS. Our failure to submit required information on time may result in civil monetary penalties of $11,766 per failure up to an aggregate of $176,495 per year (or up to an aggregate of $1.177 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information; HIPAA also created criminal liability for knowingly and willfully falsifying or concealing a material fact or making a materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Failure to comply with the HIPAA privacy and security standards when applicable can result in civil monetary penalties up to $59,522 per violation, not to exceed $1.79 million per calendar year for non-compliance of an identical provision, and, in certain circumstances, criminal penalties with fines up to $250,000 per violation and/or imprisonment. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages on behalf of residents of his or her state; and

- Analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers or patients; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers, foreign and state laws, including the E.U. General Data Protection Regulation, or GDPR, governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions or safe harbors, it is possible that some of our activities, such as stock-option compensation paid to physicians, could be subject to challenge under one or more of such laws. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments.

The growth of our business and sales organization and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to penalties, including significant criminal, civil, and administrative penalties, damages, fines, imprisonment, for individuals, exclusion from participation in government programs, such as Medicare and Medicaid, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

If we fail to obtain and maintain necessary regulatory clearances or approvals for our products, or if clearances or approvals for future products and indications are delayed or not issued, our commercial operations would be harmed.

Our products are subject to extensive regulation by the FDA in the United States and by regulatory agencies in other countries where we do business. Government regulations specific to medical devices are wide ranging and govern, among other things:

- Product design, development and manufacture;
- Laboratory, preclinical and clinical testing, labeling, packaging, storage and distribution;
- Premarketing clearance or approval;
- Record keeping;
- Product marketing, promotion and advertising, sales and distribution; and
- Post marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals.

Before a new medical device, including our recently FDA approved IDE for our feasibility study in acute ischemic stroke, Neuroprotection in Transcarotid Embolectomy (NITE-1), or a new intended use for an existing product, can be marketed in the United States, a company must first submit and receive either 510(k) clearance pursuant to Section 510(k) of the Food, Drug and Cosmetic Act, or the FDCA, or approval of a premarket approval, or PMA, application from the FDA, unless an exemption applies.

In many cases, the process of obtaining PMA approval, which was required for the ENROUTE stent, is much more rigorous, costly, lengthy and uncertain than the 510(k) clearance process. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, in order to clear the proposed device for marketing. To be "substantially equivalent," the proposed device must

have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based on extensive data, including technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices for which the 510(k) process cannot be used and that are deemed to pose the greatest risk. Modifications to products that are approved through a PMA application generally need prior FDA approval of a PMA supplement. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k), or such modification may put the device into class III and require PMA approval. The FDA's 510(k) clearance process usually takes from three to 12 months, but may last longer. The process of obtaining a PMA generally takes from one to three years, or even longer, from the time the PMA is submitted to the FDA until an approval is obtained. Any delay or failure to obtain necessary regulatory approvals or clearances would have a material adverse effect on our business, financial condition and results of operations.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- Our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;
- The disagreement of the FDA or the applicable foreign regulatory body with the design, conduct or implementation of our clinical trials or the analyses or interpretation of data from pre-clinical studies or clinical trials;
- Serious and unexpected adverse device effects experienced by participants in our clinical trials;
- The data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required;
- Our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- An advisory committee, if convened by the applicable regulatory authority, may recommend against approval of our application or may recommend that the applicable regulatory authority require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions, or even if an advisory committee, if convened, makes a favorable recommendation, the respective regulatory authority may still not approve the product;
- The applicable regulatory authority may identify significant deficiencies in our manufacturing processes, facilities or analytical methods or those of our third party contract manufacturers;
- The potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval; and
- The FDA or foreign regulatory authorities may audit our clinical trial data and conclude that the data is not sufficiently reliable to support approval or clearance.

Similarly, regulators may determine that our financial relationships with our principal investigators resulted in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial site or the utility of the clinical trial itself. Even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Moreover, the FDA and European Union regulatory authorities strictly regulate the labeling, promotion and advertising of our products, including comparative and superiority claims vis a vis competitors' products, that may be made about products.

As a condition of approving a PMA application, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device. As a part of our PMA approval, we agreed with the FDA to conduct a post-approval study at a minimum of 30 sites in the United States to evaluate the safety and effectiveness of our products in at least 600 subjects. We completed enrollment in this study and submitted our final report to the FDA. In February 2020 we received notice from the FDA of their review and that we have fulfilled the post-approval study requirement. A PMA supplement with the updated labeling was submitted to FDA in December 2019 and subsequently approved by FDA in June 2020. The updated labeling included outcomes and adverse event data from the ROADSTER 2 Post-Approval Study. Failure to have conducted the post-approval study in compliance with applicable

regulations or to have timely completed required post-approval studies or comply with other post-approval requirements could result in withdrawal of approval of the PMA, which would harm our business.

In addition, we are required to investigate all product complaints we receive, and timely file reports with the FDA, including MDRs that require that we report to regulatory authorities if our products may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. If these reports are not submitted in a timely manner, regulators may impose sanctions and we may be subject to product liability or regulatory enforcement actions, including warning letters, untitled letters, fines, civil penalties, recalls, seizures, operating restrictions, denial of requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products, withdrawal of current 510(k) clearances or premarket approvals and narrowing of approved or cleared product labeling, all of which could harm our business. In addition, the FDA may provide notice of and conduct additional inspections, such as “for cause” inspections, of our business, sites and facilities as part of its review process. As of October 31, 2021, we had filed 420 MDR reports with the FDA for adverse events and device malfunctions including, but not limited to, stroke, arterial dissection, tip detachment, stent thrombosis and wound complications.

If we initiate a correction or removal action for our products to reduce a significant risk to health posed by our products, we would be required to submit a publicly available correction and removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to an additional inspection by, or increased scrutiny from, the FDA, other international regulatory agencies and our customers regarding the quality and safety of our products. Furthermore, the submission of these reports could be used by competitors against us and cause physicians to delay or cancel prescriptions, which could harm our reputation. For example, in the first quarter of 2021, we announced the voluntary recall of certain lots of our ENROUTE Transcarotid Stent System, manufactured by one of our third-party suppliers, Cordis. Our decision to recall these lots was based on complaints we received about tips detaching from the stent delivery system as well as internal testing that we conducted. We have determined that the root cause of the detachment was a single operator at Cordis, who, over a specific timeframe, produced lots in which a small number of units were not reliably manufactured to specification. Recalls like this one could cause the supply of our TCAR products to customers to be interrupted, us to incur additional expenses, negative publicity or damage to our reputation, any of which could cause our results of operations to be adversely impacted.

The FDA and the Federal Trade Commission, or FTC, also regulate the advertising, promotion and labeling of our products to ensure that the claims we make are consistent with our regulatory clearances and approvals, that there is adequate and reasonable scientific data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including adverse publicity, warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

The FDA and state authorities have broad investigation and enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- Adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;
- Repair, replacement, refunds, recalls, termination of distribution, administrative detention or seizure of our products;
- Operating restrictions, partial suspension or total shutdown of production;
- Denial of our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products;
- Withdrawal of 510(k) clearance or premarket approvals that have already been granted; and
- Criminal prosecution.

If any of these events were to occur, our business and financial condition could be harmed. In addition, the FDA’s and other regulatory authorities’ policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our products. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, financial condition and results of operations.

Our clinical trials may fail to demonstrate competent and reliable evidence of the safety and effectiveness of our products, which would prevent or delay commercialization of our products in development.

We may be required to conduct clinical studies that demonstrate competent and reliable evidence that our products are safe and effective before we can commercialize our products. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot be certain that our planned clinical trials or any other future clinical trials will be successful. In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our products for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our products. Even if regulatory approval is secured for any of our products, the terms of such approval may limit the scope and use of our products, which may also limit their commercial potential.

Material modifications to our products may require new 510(k) clearances, premarket approval, or CE Marks, or may require us to recall or cease marketing our products until new clearances or approvals are obtained.

Material modifications to the intended use or technological characteristics of our products will require new 510(k) clearances, premarket approvals or CE Marks prior to implementing the modifications, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Furthermore, changes to our manufacturing facility or supplier of components used in our products require prior FDA approval of a PMA supplement. 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 effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or approval of a PMA supplement. We may not be able to obtain additional 510(k) clearances or premarket approvals for new products or for modifications to, or additional indications for, our products in a timely fashion, or at all. Delays in obtaining required future clearances would harm our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth. We have made modifications to our products in the past that we believe do not require additional clearances or approvals, and we may make additional modifications in the future. If the FDA or an EU Notified Body disagrees and requires new clearances or approvals for any of these modifications, we may be required to recall and to stop selling or marketing our products as modified, which could harm our operating results and require us to redesign our products. In these circumstances, we may be subject to significant enforcement actions.

If we, or our suppliers, fail to comply with the FDA's QSR or the European Union's Medical Device Directive, our manufacturing or distribution operations could be delayed or shut down and our revenue could suffer.

Our manufacturing and design processes and those of our third-party component suppliers are required to comply with the QSR and the European Union's Medical Device Directive, or MDD, both of which cover procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. We are also subject to similar state requirements and licenses, and to ongoing ISO 13485 compliance in our operations, including design, manufacturing, and service, to maintain our CE Mark. In addition, we must engage in extensive recordkeeping and reporting and must make available our facilities and records for periodic unannounced inspections by governmental agencies, including the FDA, state authorities, EU Notified Bodies and comparable agencies in other countries. If we fail a regulatory inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take timely and adequate corrective action in response to an adverse regulatory inspection could result in, among other things, a shutdown of our manufacturing or product distribution operations, significant fines, suspension of marketing clearances and approvals, seizures or recalls of our device, operating restrictions and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our products and cause our revenue to decline.

We are registered with the FDA as a medical device specifications developer and manufacturer. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Public Health, or CDPH, and our Notified Body to determine our compliance with the QSR and other regulations at both our design and manufacturing facilities, and these inspections may include the manufacturing facilities of our suppliers. These inspections may be initiated as a result of concerns regarding the safety of our products or the components thereof.

We can provide no assurance that we will continue to remain in material compliance with the QSR or MDD. If the FDA, CDPH or our notified body in the European Union, BSI, inspect any of our facilities and discover compliance problems, we may have to cease manufacturing and product distribution until we can take the appropriate remedial steps

to correct the audit findings. Taking corrective action may be expensive, time consuming and a distraction for management and if we experience a delay at our manufacturing facility we may be unable to produce our products, which would harm our business.

With the transition from the MDD to the new European Union Medical Device Regulation, or MDR, notified bodies are required to seek designation to operate as conformity assessment authorities under the new law, which was effective in May 2021. BSI, our notified body, successfully obtained designation to operate as conformity assessment authorities under the new law.

The impact of the new EU Medical Device Regulation may be costly and disruptive to our business.

The European Union has released regulations to ensure patient safety with the use of pharmaceuticals, medical devices and in-vitro diagnostics. The new regulations replace predecessor directives and emphasize a global convergence of regulations. Major changes include:

- Reclassification of some products;
- Greater emphasis on clinical data;
- Data transparency, including publication of clinical trial data and safety summaries;
- Defined content and structure for technical files to support registration;
- Unique device identification system;
- Greater burden on post-market surveillance and clinical follow-up;
- Reduction of adverse event reporting time from 30 to 15 days after the event; and
- More power to notified bodies.

Compliance with these new regulations may result in Europe being less attractive as a “first market” destination. Marketing authorization timelines will become more protracted and the costs of operating in Europe will increase. A significantly more costly path to regulatory compliance is anticipated. Adjusting to the new Medical Device Regulation may prove to be costly and disruptive to our business.

Our products have and may in the future be subject to product recalls that could harm our reputation.

The FDA and similar governmental authorities in other countries have the authority to require the recall of commercialized products in the event of material regulatory deficiencies or defects in design or manufacture. A government mandated or voluntary recall by us has occurred, and could occur again in the future, as a result of component failures, manufacturing errors or design or labeling defects. In January 2021, we announced the voluntary recall of certain lots of our ENROUTE Transcarotid Stent System. Additional recalls of our products would divert managerial attention, be expensive, harm our reputation with customers and harm our financial condition and results of operations. Additional recall announcements could also negatively affect our stock price.

Compliance with environmental laws and regulations could be expensive, and failure to comply with these laws and regulations could subject us to significant liability.

Our research and development and manufacturing operations involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment and disposal of products containing hazardous substances. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive and noncompliance could result in substantial liabilities, fines and penalties, personal injury and third-party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could harm our financial condition and operating results.

Risks Related to Ownership of Our Common Stock

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

- The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including:
- Changes in analysts' estimates, investors' perceptions, recommendations by securities analysts, the loss of analyst coverage or our failure to achieve analysts' estimates;
- Quarterly variations in our or our competitors' results of operations;
- Periodic fluctuations in our revenue, which could be due in part to the way in which we recognize revenue;
- The financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- General market conditions and other factors unrelated to our operating performance or the operating performance of our competitors;
- Changes in reimbursement by current or potential payers;
- Changes in operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular;
- Actual or anticipated changes in regulatory oversight of our products;
- The results of our clinical trials;
- The loss of key personnel, including changes in our board of directors and management;
- Product recalls or other problems associated with our products;
- Legislation or regulation of our market;
- Lawsuits threatened or filed against us, including litigation by current or former employees alleging wrongful termination, sexual harassment, whistleblower or other claims;
- The announcement of new products, product enhancements or new product trials by us or our competitors;
- Announced or completed acquisitions of businesses or technologies by us or our competitors;
- Announcements related to patents issued to us or our competitors and related litigation; and
- Developments in our industry.

In recent years, the stock markets generally have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of listed companies. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance.

In addition, in the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and harm our business, results of operations, financial condition and reputation. These factors may materially and adversely affect the market price of our common stock.

We are obligated to maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, to furnish a report by management on the effectiveness of our internal control over financial reporting. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. We are required to comply with, among other requirements, the auditor attestation requirements of Section 404. If we have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered accounting firm.

Our compliance with Section 404 requires that we incur substantial accounting expense and expend significant management efforts. We have engaged outside consultants who function in the capacity of an internal audit group, and we will continue to hire additional consultants, accounting and financial staff with appropriate public company experience and technical accounting knowledge as we maintain the system and process documentation necessary to perform the evaluation needed to comply with Section 404.

We cannot assure you that there will not be material weaknesses in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our ordinary shares could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy our current and any future material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Anti-takeover provisions in our amended and restated certificate of incorporation and bylaws, and Delaware law, could discourage a change in control of our company or a change in our management.

Our amended and restated certificate of incorporation and bylaws contain provisions that might enable our management to resist a takeover. These provisions include:

- A classified board of directors;
- Advance notice requirements applicable to stockholders for matters to be brought before a meeting of stockholders and requirements as to the form and content of a stockholders' notice;
- A supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation and bylaws;
- The right to issue preferred stock without stockholder approval, which could be used to dilute the stock ownership of a potential hostile acquirer;
- Allowing stockholders to remove directors only for cause;
- A requirement that the authorized number of directors may be changed only by resolution of the board of directors;
- Allowing all vacancies, including newly created directorships, to be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum, except as otherwise required by law;
- A requirement that our stockholders may only take action at annual or special meetings of our stockholders and not by written consent;
- Limiting the forum to Delaware for certain litigation against us; and
- Limiting the persons that can call special meetings of our stockholders to our board of directors, the chairperson of our board of directors, the chief executive officer or the president, in the absence of a chief executive officer.

These provisions might discourage, delay or prevent a change in control of our company or a change in our management. The existence of these provisions could adversely affect the voting power of holders of common stock and limit the price that investors might be willing to pay in the future for shares of our common stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder. See "Description of Capital Stock."

Our amended and restated certificate of incorporation and bylaws provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' abilities to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and bylaws provide that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum, to the fullest extent permitted by law, for (1) any derivative

action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against the company or any director or officer of the company arising pursuant to any provision of the Delaware General Corporation Law, (4) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or bylaws, or (5) any other action asserting a claim that is governed by the internal affairs doctrine shall be the Court of Chancery of the State of Delaware or federal court located within the State of Delaware if the Court of Chancery does not have jurisdiction, in all cases subject to the court's having jurisdiction over indispensable parties named as defendants. A complaint asserting a cause of action under the Securities Act may be brought in state or federal court. With respect to the Securities Exchange Act of 1934, or Exchange Act, only claims brought derivatively under the Exchange Act would be subject to the forum selection clause described above. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation and bylaws has been challenged in legal proceedings, and it is possible that, in connection with any action, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation and bylaws to be inapplicable or unenforceable in such action. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors and officers. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation and bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition and operating results. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

We have not paid dividends in the past and do not expect to pay dividends in the future, and, as a result, any return on investment may be limited to the value of our stock.

We have never paid cash dividends and do not anticipate paying cash dividends in the foreseeable future. The payment of dividends will depend on our earnings, capital requirements, financial condition, prospects for future earnings and other factors our board of directors may deem relevant. In addition, our loan agreement limits our ability to, among other things, pay dividends or make other distributions or payments on account of our common stock, in each case subject to certain exceptions. If we do not pay dividends, our stock may be less valuable because a return on your investment will only occur if our stock price appreciates and you then sell our common stock.

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

Unregistered Sales of Equity Securities

Not applicable.

Use of Proceeds from Public Offering of Common Stock

In May 2020, we completed an underwritten public offering of 6,808,154 shares of common stock through a registration statement on Form S-3/ASR (File No. 333-238007), which was automatically effective upon filing on May 5, 2020. Pursuant to this registration statement we sold an aggregate 1,923,076 shares of our common stock at a public offering price of $39.00 per share for an aggregate offering price of $75.0 million, and certain selling stockholders sold an additional 4,885,078 shares of common stock. We received cash proceeds of approximately $70.5 million, net of underwriting discounts and commissions of approximately $3.8 million and offering costs of approximately $0.7 million. On May 20, 2020, the underwriters fully exercised their option to purchase 1,021,223 additional shares of common stock from the selling stockholders pursuant to the underwriting agreement. We did not receive any of the proceeds from the sale of the shares of common stock by the selling stockholders.

J.P. Morgan Securities LLC and BofA Securities, Inc. acted as representatives of the underwriters for the offering. There has been no material change in the planned use of proceeds from the public offering as described in our final prospectus supplement filed with the SEC on May 7, 2020 pursuant to Rule 424(b) of the Securities Act.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibit Index

The exhibits listed in the accompanying index to exhibits are filed as part of, or incorporated by reference into, this Quarterly Report on Form 10-Q.

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1**	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the registrant as currently in effect.	S-1	333-230045	3.3	3/4/2019
3.2**	Bylaws of the registrant as currently in effect.	S-1	333-230045	3.5	3/4/2019
4.1**	Specimen Common Stock Certificate of the registrant.	S-1/A	333-230045	4.1	3/25/2019
4.2**	Amended and Restated Registration Rights Agreement by and among the registrant and certain stockholders, dated July 7, 2017.	S-1	333-230045	4.2	3/4/2019
4.3**	Amended and Restated Stockholders Agreement by and among the registrant and certain stockholders, dated July 7, 2017.	S-1	333-230045	4.3	3/4/2019
4.4**	Amendment to the Amended and Restated Registration Rights Agreement, dated March 21, 2019.	S-1/A	333-230045	4.8	3/25/2019
10.1**	Form of Indemnification Agreement for directors and executive officers.	S-1	333-230045	10.1	3/4/2019
10.2+**	2007 Stock Plan, as amended, and related form agreement.	S-1	333-230045	10.2	3/4/2019
10.3+**	2019 Employee Stock Purchase Plan and related form agreements.	S-1/A	333-230045	10.4	3/25/2019
10.4+**	Executive Incentive Compensation Plan.	S-1/A	333-230045	10.5	3/25/2019
10.5+**	2019 Equity Incentive Plan and related form agreements.	S-1/A	333-230045	10.6	3/25/2019
10.6#**	Supply Agreement by and between the registrant and Cordis Corporation, dated October 21, 2011, as amended by the Amendment dated March 12, 2012, the Second Amendment to Supply Agreement dated July 12, 2012, the Third Amendment to Supply Agreement dated April 19, 2013 and the Fourth Amendment to Supply Agreement dated April 9, 2018.	S-1	333-230045	10.6	3/4/2019
10.7#**	License Agreement by and between the registrant and Cordis Corporation, dated December 17, 2010.	S-1	333-230045	10.7	3/4/2019
10.8**	Quality Assurance Agreement by and among the registrant and Lake Region Medical and affiliates, dated May 4, 2015.	S-1	333-230045	10.8	3/4/2019
10.9#**	Amended and Restated Manufacturing and Supply Agreement by and between the registrant and Galt Medical Corporation, dated January 10, 2018.	S-1	333-230045	10.9	3/4/2019
10.10**	Loan and Security Agreement, dated October 29, 2020, by and between the registrant and Stifel Bank.	8-K/A	001-38847	10.1	11/4/2020
10.11**†	First Amendment to Loan and Security Agreement, dated January 15, 2021, by and between the registrant and Stifel Bank.	10-Q	001-38847	10.22	5/10/2021
10.12**	Lease Agreement by and between the registrant and ARHC UHPTHMN01 LLC, dated May 12, 2021.	10-Q	001-38847	10.23	8/6/2021
31.1*	Certification of Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*	Certification of Chief Executive Officer and Chief 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	XBRL Instance Document. The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH	XBRL Taxonomy Extension Schema Document.				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				

* Filed herewith.

** Previously filed.

\+ Indicates management contract or compensatory plan.

† Portions of this exhibit have been omitted pursuant to Rule 601(b)(10) of Regulation S-K.

\# Portions of the exhibit have been omitted pursuant to a request for confidential treatment. The omitted information has been filed separately with the SEC.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Quarterly Report on Form 10-Q to be signed on its behalf by the undersigned thereunto duly authorized.

SILK ROAD MEDICAL, INC.

November 9, 2021

By: /s/ Erica J. Rogers
Erica J. Rogers
President, Chief Executive Officer and Director (principal executive officer)

November 9, 2021

By: /s/ Lucas W. Buchanan
Lucas W. Buchanan
Chief Financial Officer and Chief Operating Officer (principal financial officer and principal accounting officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
Pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a),
As Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Erica J. Rogers, certify that:

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

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

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

4. The registrant's other certifying officer 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 we 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 quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

/s/ Erica J. Rogers
Erica J. Rogers
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 9, 2021

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
Pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a),
As Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Lucas W. Buchanan, certify that:

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

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

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

4. The registrant's other certifying officer 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 we 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 quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

/s/ Lucas W. Buchanan
Lucas W. Buchanan
Chief Financial Officer and Chief Operating Officer
(Principal Financial and Accounting Officer)

Date: November 9, 2021

Exhibit 32.1

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

In connection with the Quarterly Report of Silk Road Medical, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2021, as filed with the Securities and Exchange Commission (the "Report"), Erica J. Rogers, as Chief Executive Officer of the Company, and Lucas W. Buchanan, as Chief Financial Officer and Chief Operating Officer of the Company, each hereby certifies, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350), to his knowledge:

1. The Report, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act of 1934, as amended; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Erica J. Rogers
Erica J. Rogers
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 9, 2021

/s/ Lucas W. Buchanan
Lucas W. Buchanan
Chief Financial Officer and Chief Operating Officer
(Principal Financial and Accounting Officer)

Date: November 9, 2021

This certification accompanies the 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 Silk Road Medical, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.