# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, DC 20549**

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended June 30, 2020**

**OR**

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

**For the transition period from _____to _____**

**Commission File Number: 001-39293**

# Inari Medical, Inc.

**(Exact Name of Registrant as Specified in its Charter)**

| **Delaware** | **45-2902923** |
|---|---|
| **( State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |
| **9 Parker, Suite 100 Irvine, California** | **92618** |
| **(Address of principal executive offices)** | **(Zip Code)** |

**Registrant's telephone number, including area code: (877) 923-4747**

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, $0.001 par value per share | NARI | The Nasdaq Global Select Market |

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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of August 7, 2020, the registrant had 48,522,958 shares of common stock, $0.001 par value per share, outstanding.

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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,”, “would”, “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. All statements other than statements of historical fact contained in this Quarterly Report, including without limitation statements regarding our business model and strategic plans for our products, technologies and business, including our implementation thereof, the impact on our business, financial condition and results of operation from the ongoing and global COVID-19 pandemic, or any other pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide, the timing of and our ability to obtain and maintain regulatory approvals, our commercialization, marketing and manufacturing capabilities and strategy, our expectations about the commercial success and market acceptance of our products, the sufficiency of our cash, cash equivalents and short-term investments, and the plans and objectives of management for future operations and capital expenditures are forward-looking statements.

The forward-looking statements in this Quarterly Report are only predictions and are based largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of known and unknown risks, uncertainties, and assumptions, including those described under the sections in this Quarterly Report entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Quarterly Report. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the future events and trends discussed in this Quarterly Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely upon these forward-looking statements as predictions of future events. The events and circumstances reflected in the forward-looking statements may not be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, performance, or achievements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. We intend the forward-looking statements contained in this Quarterly Report to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”).

## PART I—FINANCIAL INFORMATION

**Item 1. Condensed Consolidated Financial Statements (Unaudited).**

**INARI MEDICAL, INC.**
**Condensed Consolidated Balance Sheets**
**(in thousands, except share data)**
(unaudited)

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| **Assets** | | |
| **Current assets** | | |
| Cash and cash equivalents | $ 194,836 | $ 23,639 |
| Restricted cash | 50 | 50 |
| Accounts receivable, net | 15,392 | 11,302 |
| Inventories, net | 5,620 | 3,953 |
| Prepaid expenses and other current assets | 3,866 | 464 |
| Total current assets | 219,764 | 39,408 |
| Property and equipment, net | 4,176 | 3,331 |
| Restricted cash | 338 | 338 |
| Deposits and other assets | 76 | 1,469 |
| **Total assets** | $ 224,354 | $ 44,546 |
| **Liabilities, Mezzanine Equity and Stockholders' Equity (Deficit)** | | |
| **Current liabilities** | | |
| Accounts payable | $ 2,294 | $ 2,549 |
| Payroll-related accruals | 7,223 | 5,225 |
| Accrued expenses and other current liabilities | 1,385 | 1,096 |
| Total current liabilities | 10,902 | 8,870 |
| Notes payable, net | 29,582 | 19,481 |
| Warrant liabilities | — | 1,169 |
| **Total liabilities** | 40,484 | 29,520 |
| **Commitments and contingencies (Note 6)** | | |
| **Mezzanine equity** | | |
| Redeemable convertible preferred stock, par value $0.001, no shares authorized, issued, and outstanding as of June 30, 2020; 32,225,227 shares authorized, 31,968,570 shares issued and outstanding as of December 31, 2019; aggregate liquidation preference of zero as of June 30, 2020 and $54,415 as of December 31, 2019 | — | 54,170 |
| **Stockholders' equity (deficit)** | | |
| Preferred stock, $0.001 par value, 10,000,000 shares authorized, no shares issued and outstanding at June 30, 2020; no shares authorized, issued, and outstanding at December 31, 2019 | — | — |
| Common stock, $0.001 par value, 300,000,000 and 49,019,607 shares authorized as of June 30, 2020 and December 31, 2019, respectively; 48,360,081 and 6,720,767 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively | 48 | 7 |
| Additional paid in capital | 224,726 | 2,061 |
| Accumulated deficit | (40,904) | (41,212) |
| **Total stockholders' equity (deficit)** | 183,870 | (39,144) |
| **Total liabilities, mezzanine equity and stockholders' equity (deficit)** | $ 224,354 | $ 44,546 |

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

**INARI MEDICAL, INC.**
**Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)**
**(in thousands, except share and per share data)**
**(unaudited)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| Revenue | $ 25,392 | $ 10,072 | $ 52,345 | $ 17,017 |
| Cost of goods sold | 3,487 | 1,331 | 6,193 | 2,262 |
| Gross profit | 21,905 | 8,741 | 46,152 | 14,755 |
| Operating expenses | | | | |
| Research and development | 3,628 | 1,580 | 6,646 | 2,789 |
| Selling, general and administrative | 18,880 | 7,803 | 35,273 | 13,229 |
| Total operating expenses | 22,508 | 9,383 | 41,919 | 16,018 |
| Income (loss) from operations | (603) | (642) | 4,233 | (1,263) |
| Other income (expense) | | | | |
| Interest income | 146 | 24 | 201 | 48 |
| Interest expense | (463) | (229) | (809) | (456) |
| Change in fair value of warrant liabilities | (2,884) | (118) | (3,317) | (242) |
| Total other expenses | (3,201) | (323) | (3,925) | (650) |
| Net income (loss) and comprehensive income (loss) | $ (3,804) | $ (965) | $ 308 | $ (1,913) |
| Net income (loss) per share | | | | |
| Basic | $ (0.16) | $ (0.17) | $ 0.02 | $ (0.34) |
| Diluted | $ (0.16) | $ (0.17) | $ 0.01 | $ (0.34) |
| Weighted average common shares used to compute net income (loss) per share, | | | | |
| Basic | 24,295,900 | 5,753,332 | 15,339,755 | 5,676,995 |
| Diluted | 24,295,900 | 5,753,332 | 47,362,292 | 5,676,995 |

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

**INARI MEDICAL, INC.**
**Condensed Consolidated Statements of Mezzanine Equity and Stockholders' Equity (Deficit)**
**(in thousands, except share data)**
**(unaudited)**

| | Redeemable Convertible Preferred Stock | | Common Stock | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Subscription Receivable | Additional Paid In Capital | Accumulated Deficit | Total Stockholders' Equity (Deficit) |
| **Balance,** December 31, 2019 | 31,968,570 | $ 54,170 | 6,720,767 | $ 7 | $ — | $ 2,061 | $ (41,212) | $ (39,144) |
| Options exercised for common stock | — | — | 58,498 | — | — | 22 | — | 22 |
| Share based compensation expense | — | — | — | — | — | 495 | — | 495 |
| Net income | — | — | — | — | — | — | 4,112 | 4,112 |
| **Balance,** March 31, 2020 | 31,968,570 | 54,170 | 6,779,265 | 7 | — | 2,578 | (37,100) | (34,515) |
| Conversion of preferred stock to common stock upon initial public offering | (31,968,570) | (54,170) | 31,968,570 | 32 | — | 54,138 | — | 54,170 |
| Issuance of common stock in connection with initial public offering, net of issuance costs of $16.3 million | — | — | 9,432,949 | 9 | — | 162,970 | — | 162,979 |
| Conversion and reclassification of preferred stock warrants to common stock warrants upon initial public offering | — | — | — | — | — | 4,486 | — | 4,486 |
| Exercise of common stock warrants | — | — | 102,533 | — | — | 4 | — | 4 |
| Options exercised for common stock | — | — | 76,764 | — | — | 45 | — | 45 |
| Share based compensation expense | — | — | — | — | — | 505 | — | 505 |
| Net loss | — | — | — | — | — | — | (3,804) | (3,804) |
| **Balance,** June 30, 2020 | — | $ — | 48,360,081 | $ 48 | $ — | $ 224,726 | $ (40,904) | $ 183,870 |
| | | | | | | | | |
| **Balance,** December 31, 2018 | 31,968,570 | $ 54,170 | 6,310,865 | $ 6 | $ (758) | $ 1,430 | $ (40,124) | $ (39,446) |
| Adjustment to recognize new revenue recognition standard | — | — | — | — | — | — | 104 | 104 |
| Options exercised for common stock | — | — | 50,806 | — | — | 11 | — | 11 |
| Interest earned on subscription receivable | — | — | — | — | (4) | - | — | (4) |
| Share based compensation expense | — | — | — | — | — | 91 | — | 91 |
| Net loss | — | — | — | — | — | - | (948) | (948) |
| **Balance,** March 31, 2019 | 31,968,570 | 54,170 | 6,361,671 | 6 | (762) | 1,532 | (40,968) | (40,192) |
| Options exercised for common stock | — | — | 31,173 | — | — | 9 | — | 9 |
| Interest earned on subscription receivable | — | — | — | — | (4) | — | — | (4) |
| Share based compensation expense | — | — | — | — | — | 99 | — | 99 |
| Net loss | — | — | — | — | — | — | (965) | (965) |
| **Balance,** June 30, 2019 | 31,968,570 | $ 54,170 | 6,392,844 | $ 6 | $ (766) | $ 1,640 | $ (41,933) | $ (41,053) |

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

**INARI MEDICAL, INC.**
**Condensed Consolidated Statements of Cash Flows**
**(in thousands)**
**(unaudited)**

| | Six Months Ended June 30, | |
|---|---|---|
| | **2020** | **2019** |
| **Cash flows from operating activities** | | |
| Net income (loss) | $ 308 | $ (1,913) |
| Adjustments to reconcile net income (loss) to net cash used in operating activities: | | |
| Depreciation | 573 | 228 |
| Amortization of deferred financing costs | 113 | 46 |
| Share based compensation expense | 1,000 | 190 |
| Amortization of fair value of warrants issued with debt | — | 8 |
| Provision for doubtful accounts | 84 | — |
| Loss on change in fair value of warrant liabilities | 3,317 | 242 |
| Changes in: | | |
| Accounts receivable | (4,174) | (3,572) |
| Inventories | (1,667) | (1,082) |
| Prepaid expenses and other assets | (3,391) | 17 |
| Accounts payable | (255) | 147 |
| Payroll-related accruals, accrued liabilities and other liabilities | 2,287 | 1,914 |
| Net cash used in operating activities | (1,805) | (3,775) |
| **Cash flows from investing activities** | | |
| Purchase of property and equipment | (1,418) | (899) |
| Net cash used in investing activities | (1,418) | (899) |
| **Cash flows from financing activities** | | |
| Proceeds from issuance of common stock upon initial public offering, net of issuance costs paid | 164,361 | — |
| Proceeds from notes payable | 10,000 | — |
| Debt financing costs | (12) | — |
| Proceeds from exercise of stock options | 67 | 20 |
| Proceeds from warrants exercises | 4 | — |
| Net cash provided by financing activities | 174,420 | 20 |
| **Net increase (decrease) in cash** | 171,197 | (4,654) |
| **Cash, cash equivalents and restricted cash beginning of period** | 24,027 | 21,884 |
| **Cash, cash equivalents and restricted cash end of period** | $ 195,224 | $ 17,230 |
| | | |
| **Supplemental disclosures of cash flow information:** | | |
| Cash paid for income taxes | $ 81 | $ 10 |
| Cash paid for interest | $ 618 | $ 403 |
| | | |
| **Noncash investing and financing:** | | |
| Common stock issued on conversion of convertible preferred stock | $ 54,170 | $ — |
| Common stock warrants issued on conversion of preferred stock warrants and the reclassification of the warrant liability | $ 4,486 | $ — |
| Deferred initial public offering cost recorded to additional paid in capital | $ 1,382 | $ — |
| Accrual of deferred interest obligation associated with debt | $ 100 | $ — |

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

## 1. Organization

### *Description of Business*

Inari Medical, Inc. (the "Company") was incorporated in Delaware in July 2011 and is headquartered in Irvine, California. The Company develops, manufactures, markets and sells devices for the interventional treatment of venous diseases. The Company received initial 510(k) clearance from the U.S. Food and Drug Administration (the "FDA") in February 2015 for its FlowTriever system, used primarily to treat pulmonary emboli, and in February 2017 for its ClotTriever system, used for the treatment of deep vein thrombosis.

### *Initial Public Offering*

In May 2020, the Company completed an initial public offering ("IPO") of its common stock. As part of the IPO, the Company issued and sold 9,432,949 shares of its common stock, which included 1,230,384 shares sold pursuant to the exercise of the underwriters' over-allotment option, at a public offering price of $19.00 per share. The Company received net proceeds of approximately $163.0 million from the IPO, after deducting underwriters' discounts and commissions of $12.6 million and offering costs of $3.7 million, of which $1.4 million was incurred as of December 31, 2019. Upon the completion of the IPO, all shares of Series A, B, and C redeemable convertible preferred stock then outstanding were converted into 31,968,570 shares of common stock on a one-to-one basis.

In addition, on the completion of the IPO, all the Company's outstanding preferred stock warrants were converted into warrants to purchase an aggregate of 256,588 shares of common stock, which resulted in the reclassification of the convertible preferred stock warrant liability to additional paid-in capital.

In connection with the Company's IPO, in May 2020, the Company's certificate of incorporation was amended and restated to provide for 300,000,000 authorized shares of common stock with a par value of $0.001 per share and 10,000,000 authorized shares of preferred stock with a par value of $0.001 per share.

### *Reverse Stock Splits*

In March 2020, the Company's board of directors approved an amendment to the Company's certificate of incorporation to effect a reverse split of shares of the Company's common stock and redeemable convertible preferred stock on a 1-for-1.19 basis.

In May 2020, the Company's board of directors approved an amendment to the Company's certificate of incorporation to effect a second reverse split of shares of the Company's common stock and redeemable convertible preferred stock on a 1-for-1.20 basis. All common stock, redeemable convertible preferred stock, warrants, stock options, RSUs and per share information presented in the financial statements have been adjusted to reflect the effect of both reverse stock splits on a retroactive basis for all periods presented. Any fractional shares resulting from the reverse stock splits are rounded down to a whole share.

## 2. Summary of Significant Accounting Policies

### *COVID-19 and CARES Act*

The Company has been actively monitoring the novel coronavirus, or COVID-19, situation and its impact. In response to the pandemic, numerous state and local jurisdictions have imposed "shelter-in-place" orders, quarantines and other restrictions. In the United States, governmental authorities have recommended, and in certain cases required, that elective, specialty and other procedures and appointments, be suspended or canceled. Similarly, in March 2020, the governor of California, where the Company's headquarters are located, issued "stay at home" orders limiting non-essential activities, travel and business operations. Such orders or restrictions have resulted in reduced operations at the Company's headquarters, work stoppages, slowdowns and delays, travel restrictions and cancellation of events. These orders and restrictions have significantly decreased the number of procedures performed using the Company's products and otherwise negatively impacted operations.

In response to the impact of COVID-19, the Company implemented a variety of measures intended to help manage through the impact and position it to resume operations quickly and efficiently once these restrictions are lifted. Some of these measures include: adapting, expanding and improving various sales, physician outreach and training programs to address the current environment; producing approximately four months' worth of inventory before temporarily suspending production and executing a work from home strategy for administrative functions. The impact of COVID-19 is changing daily and cannot be predicted. As a result, the Company expects the pandemic to continue to negatively impact its business, financial condition and results of operations.

On March 27, 2020, the President signed into law the "Coronavirus Aid, Relief, and Economic Security (CARES) Act." The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations, increased limitations on qualified charitable contributions, and technical corrections to tax depreciation methods for qualified improvement property. The Company currently may be eligible but has not taken advantage of the payroll protection program, emergency grants and business loans under the CARES Act. The Company expects to monitor the impact that the CARES Act may have on its business, financial condition, results of operations, or liquidity.

***Basis of Presentation of Unaudited Interim Condensed Consolidated Financial Statements***

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Certain prior year reported amounts have been reclassified to conform with the 2020 presentation.

The interim condensed consolidated balance sheet as of June 30, 2020, the condensed consolidated statements of operations, mezzanine equity and stockholders' deficit, and cash flows for the three and six months ended June 30, 2020 and 2019 are unaudited. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair presentation of the Company's consolidated financial position as of June 30, 2020 and its consolidated results of operations and cash flows for the three and six months ended June 30, 2020 and 2019. The financial data and the other financial information disclosed in the notes to the condensed consolidated financial statements related to the three and six months periods are also unaudited. The condensed consolidated results of operations for any interim period are not necessarily indicative of the results to be expected for the full year or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2019 included herein was derived from the audited financial statements as of that date. These interim condensed consolidated financial statements should be read in conjunction with our audited financial statements included in the Company's prospectus dated May 21, 2020 filed pursuant to Rule 424(b)(4) with the U.S. Securities and Exchange Commission on May 26, 2020.

***Principles of Consolidation***

In May 2020, the Company formed Inari Medical International, Inc., a wholly-owned subsidiary incorporated in Delaware. All intercompany balances and transactions have been eliminated in consolidation.

***Management Estimates***

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Significant estimates and assumptions made in the accompanying financial statements include, but are not limited to the collectability of receivables, valuation of inventory, the fair value of common stock warrants, the fair value of preferred stock warrant liabilities, the fair value of stock options, recoverability of the Company's net deferred tax assets, and related valuation allowance and certain accruals. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could materially differ from those estimates.

***JOBS Act Accounting Election***

As an emerging growth company under the Jumpstart Our Business Startups Act of 2012 ("the JOBS Act"), the Company is eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. the Company has elected to take advantage of the extended transition period for adopting new or revised accounting standards that have different effective dates for public and private companies until such time as those standards apply to private companies.

***Cash, Cash Equivalents and Restricted Cash***

The Company considers cash on hand, cash in demand deposit accounts including money market funds, and instruments with a maturity date of 90 days or less at date of purchase to be cash and cash equivalents. The Company maintains its cash, cash equivalent and restricted cash balances with banks. Under the Dodd-Frank Wall Street Reform and Consumer Protection Act, deposits of up to

$250,000 at FDIC-insured institutions are covered by FDIC insurance. At times, deposits may be in excess of the FDIC insurance limit; however, management does not believe the Company is exposed to any significant related credit risk.

Restricted cash as of June 30, 2020 and December 31, 2019 consisted of a cash secured letter of credit in the amount of $338,000 representing collateral for the Company's facility lease. Restricted cash additionally included as of June 30, 2020 and December 31, 2019, a compensating balance of $50,000 to secure the Company's corporate purchasing cards.

***Accounts Receivable, net***

Trade accounts receivable are recorded at the invoiced amount, net of any allowance for doubtful accounts. Any allowance for doubtful accounts is developed based upon several factors including the customers' credit quality, historical write-off experience and any known specific issues or disputes which exist as of the balance sheet date. Account receivable balances are written off against the allowance after appropriate collection efforts are exhausted. The allowance for doubtful accounts was $146,000 and $62,000 as of June 30, 2020 and December 31, 2019, respectively, and no accounts receivable write offs were recognized during the three and six months ended June 30, 2020 and 2019. Despite the Company's efforts to minimize credit risk exposure, customers could be adversely affected if future economic and industry trends, including those related to COVID-19, change in such a manner as to negatively impact their cash flows. The full effects of COVID-19 on the Company's customers are highly uncertain and cannot be predicted. As a result, the Company's future collection experience can differ significantly from historical collection trends. If the Company's clients experience a negative impact on their cash flows, it could have a material adverse effect on the Company's results of operations and financial condition.

***Inventories, net***

The Company values inventory at the lower of the actual cost to purchase or manufacture the inventory or net realizable value for such inventory. Cost, which includes material, labor and overhead costs, is determined on the first-in, first out method, or FIFO. The Company regularly reviews inventory quantities in process and on hand, and when appropriate, records a provision for obsolete and excess inventory. The Company writes down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements based on future demand and as compared to remaining shelf life. The estimate of excess quantities is subjective and primarily dependent on the Company's estimates of future demand for a particular product. If the estimate of future demand is inaccurate based on actual sales, the Company may increase the write down for excess inventory for that component and record a charge to inventory impairment in the accompanying condensed consolidated statement of operations and comprehensive income (loss).

***Property and Equipment***

Property and equipment are stated at cost. Additions and improvements that extend the lives of the assets are capitalized while expenditures for repairs and maintenance are expensed as incurred. Depreciation is provided using the straight-line method over the estimated useful lives of the assets, ranging from three to seven years. Leasehold improvements are depreciated over the shorter of the useful life of the improvement or the lease term, including renewal periods that are reasonably assured.

Upon sale or disposition of property and equipment, any gain or loss is included in the accompanying statement of operations.

***Deferred Initial Public Offering Costs***

Specific incremental legal, accounting and other fees and costs directly attributable to a proposed or actual offering of securities may properly be deferred and charged against the gross proceeds of the offering. As of December 31, 2019, there were approximately $1,382,000 of offering costs, primarily consisting of legal, accounting and printing fees, which were capitalized in other non-current assets on the balance sheet. In May 2020, upon the closing of the IPO, total deferred costs of approximately $3,701,000 were offset against the Company's IPO proceeds.

***Impairment of Long-lived Assets***

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparing the carrying amount to the future net undiscounted cash flows which the assets are expected to generate. If such assets are considered impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset. The Company has not identified any such impairment losses to date.

***Fair Value of Financial Instruments***

The Company's cash, cash equivalents and restricted cash, accounts receivable, accounts payable and accrued liabilities approximate their fair value due to their liquidity or short maturities. Management believes that its long term debt bears interest at the prevailing market rates for instruments with similar characteristics; accordingly, the carrying value of this instrument approximates its fair value as of June 30, 2020 and December 31, 2019.

The Company measures and records certain financial assets and liabilities at fair value on a recurring basis. U.S. GAAP provides a fair value hierarchy that distinguishes between (i) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (ii) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three broad levels.

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of assets or liabilities.

See Note 3 for further information.

***Convertible Preferred Stock Warrant Liability***

The Company has accounted for its freestanding warrants to purchase shares of the Company's convertible preferred stock as liabilities at fair value upon issuance primarily because the preferred shares underlying the warrants contain contingent redemption features outside the control of the Company. The warrants are subject to remeasurement at each balance sheet date and any change in fair value is recognized as the change in fair value of warrant liability and recorded to other expense in the statements of operations. The carrying value of the warrants continued to be adjusted until the completion of the IPO, which occurred in May 2020. At that time, the preferred stock warrant liability was adjusted to fair value and reclassified to additional paid-in capital, a component of stockholders' equity (deficit) (see Note 3).

***Revenue Recognition***

On January 1, 2019, the Company adopted Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers*, using the modified retrospective method applied to contracts which were not completed as of that date.

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.

Product sales of the FlowTriever and ClotTriever systems are made to hospitals in the United States utilizing the Company's direct sales force. Revenue is comprised of product revenue net of returns, administration fees and sales rebates.

*Performance Obligation*—The Company has revenue arrangements that consist of a single performance obligation, delivery of the Company's products. The satisfaction of this performance obligation occurs with the transfer of control of the Company's product to its customers, either upon shipment or delivery of the product.

Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring goods. The amount of revenue that is recognized is based on the transaction price, which represents the invoiced amount and includes estimates of variable consideration such as rebate and administrative fees, where applicable. The Company provides a 30-day unconditional right of return period. The Company establishes estimated provisions for returns at the time of sale based on historical experience. Historically, the actual product returns have been immaterial to the Company's financial statements.

Assuming all other revenue recognition criteria have been met, the Company recognizes revenue for arrangements where the Company has satisfied its performance obligation of delivering the product. For sales where the Company's sales representatives hand

deliver products directly to the hospital, control of the products transfers to the customer upon such hand delivery. For sales where products are shipped, control of the products transfers either upon shipment or delivery of the products to the customer, depending on the shipping terms and conditions. As of June 30, 2020 and December 31, 2019, the Company recorded $302,000 and $330,000, respectively, of unbilled receivables, which are included in accounts receivable, net, in the accompanying balance sheet.

For both the three months ended June 30, 2020 and 2019, 40% of revenue was derived from the sale of ClotTriever products, and 60% of revenue was derived from the sale of FlowTriever products. For the six months ended June 30, 2020 and 2019, 38% and 39% of revenue was derived from the sale of ClotTriever products, respectively, and 62% and 61% of revenue was derived from the sale of FlowTriever products, respectively.

The Company offers payment terms to its customer of less than three months and these terms do not include a significant financing component. The Company excludes taxes assessed by governmental authorities on revenue-producing transactions from the measurement of the transaction price.

The Company offers its standard warranty to all customers and no warranties are available for sale on a standalone basis. The Company's warranty provides that its products are free of material defects and conform to specifications, and offer to repair, replace or refund the purchase price of defective products. This assurance does not constitute a service and is not considered a separate performance obligation. The Company estimates warranty liabilities at the time of revenue recognition and records it as a charge to cost of goods sold.

Costs associated with product sales include commissions and are recorded in selling, general and administrative expenses. The Company applies the practical expedient and recognizes commissions as expense when incurred because the amortization period is less than one year.

***Cost of Goods Sold***

Cost of goods sold consists primarily of the cost of raw materials, components, direct labor and manufacturing overhead. Overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management, including stock-based compensation. Cost of goods sold also includes depreciation expense for production equipment and certain direct costs such as shipping costs and royalty expense.

***Shipping Costs***

Shipping costs billed to customers are not included in revenue, and are reported as a reduction of costs of goods sold.

***Advertising Costs***

Advertising costs are charged to operations as incurred. Advertising costs were $74,000 and $6,000 for the three months ended June 30, 2020 and 2019, respectively and $111,000 and $34,000 for the six months ended June 30, 2020 and 2019, respectively. Advertising costs are included in selling, general and administrative expenses in the accompanying statements of operations.

***Research and Development***

Research and development costs are expensed as incurred and include the costs to design, develop, test, deploy and enhance new and existing products. Research and development costs also include expenses associated with clinical studies, registries and sponsored research. These costs include direct salary and employee benefit related costs for research and development personnel, costs for materials used and costs for outside services.

***Patent-related Expenditures***

Expenditures related to patent research and applications, which are primarily legal fees, are expensed as incurred and are included in selling, general and administrative expenses in the accompanying statements of operations.

***Stock-based Compensation***

The Company's employee and non-employee share-based awards result in a cost that is measured at fair value on the awards' grant date, based on the estimated number of awards that are expected to vest. Stock-based compensation is recognized over the service period.

***Income Taxes***

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Management assesses the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to the Company's historical operating performance and the recorded cumulative net losses in prior fiscal periods, the net deferred tax assets have been fully offset by a valuation allowance.

The Company recognizes uncertain income tax positions at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Changes in recognition or measurement are reflected in the period in which judgment occurs. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of provision for income taxes.

***Foreign Currency Transactions***

Certain vendors are paid in currencies other than the US dollar. Transaction gains and losses are included in selling, general and administrative expenses.

***Comprehensive Income (Loss)***

The Company's net income (loss) equaled comprehensive income (loss) for the three and six months ended June 30, 2020 and 2019.

***Net Income (Loss) per Share of Common Stock***

Basic net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, without consideration for potential dilutive common shares. Diluted net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net income (loss) per share calculation, redeemable convertible preferred stock and warrants, and common stock options are considered to be potentially dilutive securities. For the periods the Company is in a net loss position, 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.

The Company allocates no loss to participating securities because they have no contractual obligation to share in the losses of the Company. The shares of the Company's convertible preferred stock participate in any dividends declared by the Company and are therefore considered to be participating securities.

***Segment Reporting***

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its Chief Executive Officer. The Company has determined it operates in one segment - the development and commercialization of innovative and minimally invasive mechanical thrombectomy devices to treat thromboembolism in the venous system. Geographically, we sell to hospitals in the United States. Segment information is consistent with how management reviews the business, makes investing and resource allocation decisions and assesses operating performance.

***Recently Adopted Accounting Pronouncements***

In June 2018, the FASB issued ASU No. 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which expands guidance on accounting for share-based payment awards, which includes share-based payment transactions for acquiring goods and services from nonemployees and aligns the accounting for share-based payments for employees and non-employees. The Company adopted this guidance effective January 1, 2020. The adoption of this guidance did not have a material impact on the Company's financial statements.

***Recent Accounting Pronouncements***

In February 2017, the FASB issued ASU 2017-02, *Leases*, as amended, which requires lessees to recognize "right of use" assets and liabilities for all leases with terms of more than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2017-02 requires additional quantitative and qualitative financial statement note disclosures about the leases, significant judgments made in accounting for those leases and amounts recognized in the financial statements about those leases. The amended guidance will be effective for the Company on January 1, 2022 with early adoption permitted. Management is evaluating the impact that adopting this guidance will have on the financial statements, but anticipates an increase in assets and liabilities due to the recognition of the required right-of-use asset and corresponding liability for all significant lease obligations that are currently classified as operating leases. The income statement recognition of lease expense is not expected to materially change from the current methodology.

In June 2016, the FASB issued ASU 2016-13 "*Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*" which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model, which requires the use of forward-looking information to calculate credit loss estimates. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes will result in earlier recognition of credit losses. The guidance will be effective for the Company on January 1, 2023 with early adoption permitted. Management is evaluating the impact that adopting this guidance will have on the financial statements.

**3. Fair Value Measurements**

The following tables summarize the Company's financial assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy as of June 30, 2020 and December 31, 2019 (in thousands):

| | December 31, 2019 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| **Liabilities:** | | | | |
| Convertible preferred stock warrant liability | $ — | $ — | $ 1,169 | $ 1,169 |
| Total liabilities | $ — | $ — | $ 1,169 | $ 1,169 |

| | June 30, 2020 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| **Liabilities:** | | | | |
| Convertible preferred stock warrant liability | $ — | $ — | $ — | $ - |
| Total liabilities | $ — | $ — | $ - | $ - |

The change in the fair value of the warrant liability is summarized below (in thousands):

| | Six Months Ended June 30, | |
|---|---|---|
| | 2020 | 2019 |
| Beginning balance | $ 1,169 | $ 213 |
| Change in fair value of warrant liability | 3,317 | 242 |
| Conversion of preferred stock warrants to common stock warrants upon the closing of the IPO | (4,486) | — |
| Ending balance | $ — | $ 455 |

The valuation of the Company's convertible preferred stock warrant liability contains unobservable inputs that reflect the Company's own assumptions for which there was little, if any, market activity for at the measurement date. Accordingly, the Company's convertible preferred stock warrant liability was measured at fair value in a recurring basis using unobservable inputs and are classified as Level 3 inputs, and any change in fair value was recognized as other expense in the statements of operations (see Note 11).

**4. Inventories, net**

Inventories are net of reserves totaling $318,000 and $537,000 as of June 30, 2020 and December 31, 2019, respectively, and consist of the following (in thousands):

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| Raw materials | $ 1,817 | $ 1,067 |
| Work in process | 911 | 640 |
| Finished goods | 2,892 | 2,246 |
| | $ 5,620 | $ 3,953 |

**5. Property and Equipment. net**

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

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| Manufacturing equipment | $ 2,922 | $ 2,190 |
| Leasehold improvements | 1,012 | 932 |
| Computer software | 351 | 296 |
| Furniture and fixtures | 389 | 259 |
| Computer hardware | 711 | 527 |
| Assets in progress | 643 | 406 |
| | 6,028 | 4,610 |
| Accumulated depreciation | (1,852) | (1,279) |
| | $ 4,176 | $ 3,331 |

Depreciation expense of $218,000 and $95,000 was included in operating expenses and $81,000 and $22,000 was included in cost of goods sold for the three months ended June 30, 2020 and 2019, respectively. Depreciation expense of $418,000 and $185,000 was included in operating expenses and $155,000 and $43,000 was included in cost of goods sold for the six months ended June 30, 2020 and 2019, respectively.

***Capitalized Implementation Costs of a Hosting Arrangement***

The Company implemented a new enterprise resource planning, or ERP, system during 2019. The ERP system is a cloud-based hosting arrangement that is a service contract. The Company early and prospectively adopted ASU 2018-15, *Intangibles—Goodwill and Other-Internal Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract* in the classification of costs incurred in connection with the implementation of this hosted ERP system. Based on the guidance, the Company expensed all costs (internal and external) that were incurred in the planning and post-implementation operation stages and capitalized approximately $149,000 in implementation costs related to the application development stage. The capitalized costs are amortized on a straight-line basis over the non-cancelable contract term of three years. As of June 30, 2020 and December 31, 2019, approximately $41,000 and $46,000, respectively, of the capitalized costs were classified in current assets and $54,000 and $87,000, respectively, were classified in noncurrent assets, respectively. The Company began amortizing the capitalized implementation costs in October 2019, which was the date the ERP system was placed in production and ready for its intended use. Amortization expense for the three and six months ended June 30, 2020 was approximately $16,000 and $39,000, respectively, and is included in selling, general and administrative expenses.

**6. Commitments and Contingencies**

***Operating Leases***

In March 2019, the Company executed a five-year lease for a facility in Irvine, California, where all operations of the Company were moved when the Company obtained control of the facility in September 2019. The lease expires in September 2024 and contains two optional extension periods of five years each. In addition to the minimum future lease commitments presented below, the lease requires the Company to pay property taxes, insurance, maintenance, and repair costs. The lease includes a one-month rent holiday concession and escalation clauses for increased rent over the lease term. Rent expense is recognized using the straight-line method over the term of the lease. The Company records deferred rent calculated as the difference between rent expense and the cash rental payments.

Rent expense under the lease agreements for the three months ended June 30, 2020 and 2019 was $170,000 and $51,000, respectively, and $324,000 and $101,000 for the six months ended June 30, 2020 and 2019, respectively. The Company also leases certain equipment under operating leases expiring in 2024. Future minimum commitments under all lease agreements are as follows (in thousands):

| Year ending December 31: | Amount |
|---|---|
| Remainder of 2020 | $ 304 |
| 2021 | 628 |
| 2022 | 656 |
| 2023 | 707 |
| 2024 | 601 |
| | $ 2,896 |

***Indemnification***

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

The Company's amended and restated certificate of incorporation contains provisions limiting the liability of directors, and its amended and restated bylaws provide that the Company will indemnify each of its directors to the fullest extent permitted under Delaware law. The Company's amended and restated certificate of incorporation and amended and restated bylaws also provide its board of directors with discretion to indemnify its officers and employees when determined appropriate by the board. In addition, the Company has entered and expects to continue to enter into agreements to indemnify its directors and executive officers.

***Legal Proceedings***

From time to time, the Company may become involved in legal proceedings arising out of the ordinary course of its business. Management is currently not aware of any matters that will have a material adverse effect on the financial position, results of operations or cash flows of the Company.

**7. Concentrations**

All the Company's revenue is derived from the sale of catheter-based therapeutic devices in the United States. For the three and six months ended June 30, 2020 and 2019, there were no customers which accounted for more than 10% of the Company's revenue. There were no customers which accounted for more than 10% of the Company's accounts receivable as of June 30, 2020 and December 31, 2019.

No vendor accounted for more than 10% of the Company's purchases for the three and six months ended June 30, 2020 and 2019. There were no vendors which accounted for more than 10% of the Company's accounts payable as of June 30, 2020 and December 31, 2019.

**8. Related Party**

***Licensed Patents***

Certain stockholders of the Company are stockholders of Inceptus Medical, Inc. ("Inceptus"). Beginning in September 2011, the Company engaged Inceptus to develop the technology that has led to certain components used in the Company's products, the FlowTriever and the ClotTriever systems. In October 2014, the Company, through a license agreement with Inceptus, obtained an exclusive, perpetual, fully paid-up irrevocable, worldwide license to the patents, patent applications and technology, including the right to grant and authorize sublicenses, to make, have made, use, sell, offer for sale, import and otherwise exploit products in connection with the licensed technology. The licensed technology is any and all technology involving a high wire count braid, excluding the tubular braiding subject to the sublicense agreement described below.

Included in prepaid expenses and other current assets was a non-interest-bearing retainer paid by the Company to Inceptus. The retainer was applied to amounts owed by the Company to Inceptus at a time mutually agreed to by both parties. For three and six months ended June 30, 2019, the Company incurred development expenses with Inceptus of $3,000 and $6,000, respectively, which were applied against the balance of the retainer and included in research and development expense. In December 2019, Inceptus repaid in full to the Company the outstanding balance of the retainer. For the three and six months ended June 30, 2020, the Company incurred and paid development expenses with Inceptus of $9,000 and $13,000, respectively, which were included in research and development expense.

***Sublicense Agreement***

In August 2019, the Company entered into a sublicense agreement with Inceptus, pursuant to which Inceptus granted to the Company a non-transferable, worldwide, exclusive sublicense to its licensed intellectual property rights related to the tubular braiding for the non-surgical removal of clots and treatment of embolism and thrombosis in human vasculature other than carotid arteries, coronary vasculature and cerebral vasculature; such rights were originally granted to Inceptus pursuant to an intellectual property license agreement with Drexel University, or Drexel License, under which Drexel retained certain rights to use, and to permit other non-commercial entities to use, the sublicensed intellectual property for educational and non-commercial research purposes. The Company is obligated to comply with, and to avoid acts or omissions that would reasonably be likely to cause a breach of the Drexel License. The sublicense agreement will continue until the expiration of the sublicensed patent, unless terminated earlier pursuant to the terms of the agreement. The Company may terminate the sublicense agreement at any time by providing prior written notice.

In connection with the sublicense agreement, during the year ended 2019 the Company paid Inceptus $139,000 for the reimbursement of expenses, milestone and administration fees. The Company was required to pay an ongoing quarterly administration fee of $18,000, which increased to $29,000 per quarter upon the completion of the Company's IPO. Additionally, the Company is obligated to pay Inceptus an ongoing royalty ranging from 1% to 1.5% of the net sales of products utilizing the licensed intellectual property, subject to a minimum royalty quarterly fee of $1,000. For the three and six months ended June 30, 2020, the Company recorded royalty expense of $95,000 and $186,000, respectively, which is included in cost of goods sold.

***Other Services***

The Company utilizes MRI The Hoffman Group, a recruiting services company owned by the brother of the Chief Executive Officer and President and member of the board of directors of the Company. The Company paid for recruiting services provided by MRI The Hoffman Group amounting to $170,000 and $90,000 for the three months ended June 30, 2020 and 2019, respectively, and $249,000 and $170,000 for the six months ended June 30, 2020 and 2019, respectively. No amounts were due to MRI The Hoffman Group at June 30, 2020 and December 31, 2019.

**9. Debt**

The Company had the following outstanding debt, net of deferred financing costs and discounts, as of June 30, 2020 and December 31, 2019 (in thousands):

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| Revolving line of credit | $ 5,000 | $ 5,000 |
| Term loan | 25,000 | 15,000 |
| Final payment fee | 250 | 150 |
| Total notes payables | 30,250 | 20,150 |
| Unamortized discount and debt issuance costs | (668) | (669) |
| Notes payable, net | $ 29,582 | $ 19,481 |

***Credit Facility***

In December 2019, the Company entered into a $40 million credit facility with Signature Bank (the "SB Credit Facility") and concurrently repaid and extinguished its term loan with East West Bank. The SB Credit Facility consists of a term loan of up to $25 million and a revolving line of credit of $15 million. The term loan is available in two tranches: a $15 million tranche that was fully funded on the closing date, and a $10 million tranche to be available through December 2020 subject to the Company's achievement of at least $60 million of trailing 12-month revenue no later than August 2020. The Company used part of the proceeds from the first tranche to fully repay the $10 million term loan with East West Bank. In March 2020, the Company borrowed an additional $10 million which was available under the term loan.

The maturity date of the new term loan is in December 2024. Under the agreement, the Company is required to make monthly interest payments through December 2021, subject to two six-month extensions to the interest-only period, which are available following the achievement of specified revenue milestones. The first extension is available upon the achievement by the Company of $100 million of trailing 12-month revenue within the initial interest-only period, and the second extension is available upon the achievement of $113 million of trailing 12-month revenue no later than June 30, 2022. Together, these extensions provide for a potential interest only-period of 36 months, through December 2022. The term loan bears interest at an annual rate equal to the greater of 5.50% or the Prime Rate plus 0.50%. Following the expiration of the interest-only period or any extension thereof, the Company will be required to repay the term loan in equal monthly installments of principal plus interest through maturity.

Under the revolving line of credit, the Company may borrow, repay and re-borrow up to 80% of eligible accounts receivable up to a maximum of $15 million. The original maturity date of the revolving line of credit was in December 2022 and was extended to December 2024 when the Company completed its IPO. The Company is required to make monthly payments of interest only through maturity of the revolving line of credit, at which point the entire principal balance is due. The revolving line of credit bears interest at an annual rate equal to the greater of 5.00% or the prime rate.

The Company paid a facility fee of $50,000 at time of closing and a final payment fee of 1.0% of the funded term loan amount will be payable at maturity, for which the Company recorded $250,000 and $150,000 as a liability as of June 30, 2020 and December 31, 2019, respectively. During the year ended December 31, 2019, the Company also paid a placement fee of $363,000 to a broker and approximately $124,000 in legal and other fees directly attributable to the new facility. The SB Credit Facility is secured by substantially all the Company's assets, excluding intellectual property. The SB Credit Facility includes a double negative pledge on the Company's intellectual property. The Company may prepay the SB Credit Facility at any time without any penalty or premium. The SB Credit Facility agreement contains minimum revenue financial covenants, measured monthly, which require the Company to achieve trailing 12-month revenue of $40 million no later than December 31, 2019 with incremental monthly increases to $60 million no later than December 31, 2020. Minimum revenue covenant levels will be set annually during the term of the SB Credit Facility by mutual agreement based on the Company's annual forecast. The Company was in compliance with all debt covenants as of June 30, 2020.

Maturities of the SB Credit Facility, including the 1.0% final payment fee, are as follows (in thousands):

| Year ending December 31: | Amount |
|---|---|
| 2020 | $ — |
| 2021 | 694 |
| 2022 | 8,333 |
| 2023 | 8,333 |
| 2024 | 12,890 |
| Total future payments | 30,250 |
| Unamortized discount and debt issuance costs | (668) |
| Note payable | $ 29,582 |

***Deferred Financing Costs***

Costs incurred directly related to debt are presented as a reduction of the related debt instrument and amortized over the life of the related loan on an effective interest method as follows as of June 30, 2020 and December 31, 2019 (in thousands):

| | June 30, 2020 | December 31, 2019 |
|---|---|---|
| Deferred financing costs | $ 798 | $ 686 |
| Accumulated amortization | (130) | (17) |
| Unamortized deferred financing costs | $ 668 | $ 669 |

**10. Redeemable Convertible Preferred Stock**

Redeemable convertible preferred stock ("convertible preferred stock") consists of the following as of December 31, 2019 (in thousands, except share data):

| | Shares Authorized | Shares Issued and Outstanding | Net Carrying Value | Liquidation Value |
|---|---|---|---|---|
| Series A | 6,299,019 | 6,221,977 | $ 8,777 | $ 8,885 |
| Series B | 11,270,319 | 11,090,726 | 18,474 | 18,530 |
| Series C | 14,655,889 | 14,655,867 | 26,919 | 27,000 |
| Total | 32,225,227 | 31,968,570 | $ 54,170 | $ 54,415 |

In connection with the IPO in May 2020, the 31,968,570 shares of redeemable convertible preferred stock were converted into 31,968,570 shares of common stock, resulting in the reclassification of the related redeemable convertible preferred stock of $54.2 million to common stock and APIC. There are no redeemable convertible preferred stock outstanding as of June 30, 2020.

As of December 31, 2019, the Company classified its Series A, Series B, and Series C convertible preferred stock outside of stockholders' deficit as mezzanine equity because, the holders of redemption rights that were not within the Company's control and in the event of certain "liquidation events" that were not solely within the control of the Company (including liquidation, sale or transfer of control of the Company), the shares would become redeemable at the option of the holders. As of December 31, 2019, the Company had not adjusted the carrying values of the convertible preferred stock to their deemed liquidation values of such shares since a liquidation event was not probable at the balance sheet date.

**11. Stockholder's Equity**

***Authorized Stock***

As of December 31, 2019, the Company had authorized capital of 81,244,834 shares of stock, consisting of 49,019,607 shares of common stock, par value $0.001 per share, and 32,225,227 shares of Preferred Stock, par value $0.001 per share, 6,299,019 of which were designated Series A Preferred Stock, 11,270,319 of which were designated Series B Preferred Stock and 14,655,889 of which were designated Series C Preferred Stock.

Upon the closing of the IPO in May 2020, and as of June 30, 2020, the Company had authorized 310,000,000 shares of stock, of which 300,000,000 shares are designated as common stock and 10,000,000 shares are designated as preferred stock. All stock has a par value of $0.001 per share. There are no shares of preferred stock outstanding as of June 30, 2020.

***Warrants***

The Company previously issued common stock warrants and redeemable convertible preferred stock warrants.

Warrants issued and outstanding as of June 30, 2020 are as follows:

| | Warrants Outstanding | | |
|---|---|---|---|
| | Number of warrants | Exercise Price | Expiration |
| Common stock warrants | 179,558 | $ 1.67 | 4/28/2026 - 3/30/2027 |
| Total outstanding warrants | 179,558 | | |

Warrants issued and outstanding as of December 31, 2019 were as follows:

| | Warrants Outstanding | | |
|---|---|---|---|
| | Number of warrants | Exercise Price | Expiration |
| Common stock warrants | 27,810 | $ 0.14 | 10/19/2025 |
| Series A preferred stock warrants | 77,030 | $ 1.43 | 12/10/2021 |
| Series B preferred stock warrants | 179,558 | $ 1.67 | 4/28/2026 - 3/30/2027 |
| Total preferred stock warrants | 256,588 | | |
| Total outstanding warrants | 284,398 | | |

The Series A and Series B redeemable convertible preferred stock warrants (“Preferred Warrants”) allowed the holders to obtain shares of redeemable convertible preferred stock that contain a liquidation preference. Because this liquidation preference may have been payable in cash upon a change in control of the Company or upon exercise of redemption rights and because such a transaction was considered to be outside of the control of the Company, the Preferred Warrants were classified as liabilities on the accompanying balance sheets and were presented at their estimated fair values at each reporting date. On the completion of the IPO, all the outstanding Preferred Warrants were converted into warrants to purchase an aggregate of 256,588 shares of common stock, which resulted in the reclassification of the convertible preferred stock warrant liability to additional paid-in capital.

In June 2020, 27,810 common stock warrants were exercised for cash. In addition, 77,030 warrants were net exercised and the Company issued 74,723 shares of common stock.

The fair value of the Preferred Warrants was determined using the Black Scholes option pricing model with the following assumptions:

| | May 21, 2020 (1) | | December 31, 2019 | |
|---|---|---|---|---|
| | Series A | Series B | Series A | Series B |
| Expected volatility | 51.10% | 50.00% | 41.40% | 39.80% |
| Preferred stock fair value (per share) | $ 19.00 | $ 19.00 | $ 5.88 | $ 5.94 |
| Dividend yield | 0.00% | 0.00% | 0.00% | 0.00% |
| Risk free interest rates | 0.17% | 0.53% | 1.58% | 1.83% |
| Expected remaining term in years | 1.55 | 5.94-6.86 | 1.95 | 6.33-7.25 |

(1) Date the Company’s registration statement on Form S-1 was declared effective

## 12. Equity Incentive Plan

***2011 Equity Incentive Plan and 2020 Incentive Award Plan***

In 2011, the Company adopted the 2011 Equity Incentive Plan (the "2011 Plan") to permit the grant of share-based awards, such as stock grants and incentives and non-qualified stock options to employees, directors, consultants and advisors. The Board has the authority to determine to whom awards will be granted, the number of shares, the term and the exercise price.

In March 2020, the Company adopted the 2020 Incentive Award Plan (the "2020 Plan"), which became effective in connection with the IPO. As a result, the Company may not grant any additional awards under the 2011 Plan. The 2011 Plan will continue to govern outstanding equity awards granted thereunder. The Company has initially reserved 3,468,048 shares of common stock for the issuance of a variety of awards under the 2020 Plan, including stock options, stock appreciation rights, awards of restricted stock and awards of restricted stock units. In addition, the number of shares of common stock reserved for issuance under the 2020 Plan will automatically increase on the first day of January for a period of up to ten years, commencing on January 1, 2021, in an amount equal to 3% of the total number of shares of the Company's capital stock outstanding on the last day of the preceding year, or a lesser number of shares determined by the Company's board of directors. As of June 30, 2020, there were 3,658,683 shares available for issuance under the 2020 Plan, including 269,268 shares which remained available under the 2011 Plan at the time the 2020 Plan became effective.

*Stock Options*

A summary of stock option activity under the 2011 Plan for the six months ended June 30, 2020 is as follows (intrinsic value in thousands):

| | Number of Awards | Weighted Average Exercise Price | Weighted Average Fair Value | Weighted Average Remaining Contractual Life (in years) | Intrinsic Value |
|---|---|---|---|---|---|
| **Outstanding**, December 31, 2019 | 4,082,302 | $ 0.90 | $ 0.74 | 8.76 | $ 22,667 |
| Granted | 305,494 | 7.47 | 3.73 | | |
| Exercised | (135,263) | 0.50 | 0.38 | | 3,381 |
| Cancelled | (98,380) | 8.50 | 3.63 | | 1,007 |
| **Outstanding**, June 30, 2020 | 4,154,153 | $ 1.22 | $ 0.90 | 8.37 | $ 196,160 |
| Vested and exercisable at June 30, 2020 | 1,508,051 | $ 0.54 | $ 0.46 | 7.87 | $ 72,241 |
| Vested and expected to vest at June 30, 2020 | 4,154,153 | $ 1.22 | $ 0.90 | 8.37 | $ 196,160 |

The aggregate intrinsic values of options outstanding, vested and exercisable, and vested and expected to vest were calculated as the difference between the exercise price of the options and the estimated fair value of the Company's common stock, as determined by the Board, as of December 31, 2019 and June 30, 2020.

The fair value of each option grant was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions for the six months ended June 30, 2020 and 2019:

| | 2020 | 2019 |
|---|---|---|
| Expected volatility | 40.60% | 82.10% - 93.40% |
| Weighted-average volatility | 40.60% | 92.07% |
| Common stock fair value (per share) | $7.88 - $9.05 | $0.59 - $1.01 |
| Dividend yield | 0.00% | 0.00% |
| Risk free interest rates | 1.46% - 1.68% | 1.85% - 2.44% |
| Expected remaining term in years | 5.90 - 6.07 | 5.97 - 6.06 |

*Restricted Stock Units*

In March 2019, the Company granted under the 2011 Plan, 2,867,326 restricted stock unit awards ("RSUs") to certain employees that vest only upon the satisfaction of both a time-based service condition and a performance-based condition. The time-based service condition for these awards generally is satisfied over four years. The performance-based condition is a liquidity event requirement that was satisfied on the effective date of the IPO of the Company's common stock. The RSUs vest on the first date upon

which both the service-based and performance-based requirements are satisfied. If the RSUs vest, the actual number of RSUs that will vest will be dependent on the per share value of the Company's common stock, which is a market-based condition, determined based on the average closing price of the Company's common stock for the three-month period immediately preceding the satisfaction of the service condition.

The probabilities of the actual number of RSUs expected to vest are reflected in the grant date fair values, and the compensation expense for these awards will be recognized assuming the requisite service period is rendered, and only if the performance-based condition is considered probable to be satisfied.

Through May 21, 2020, no stock-based compensation expense had been recognized for these awards because the liquidity event performance condition described above for the RSUs was not considered probable of being satisfied. Upon the completion of the Company's IPO, the Company recognized $159,000 of stock-based compensation expense related to such awards.

*2020 Plan*

RSUs are share awards that entitle the holder to receive freely tradable shares of the Company's common stock upon vesting. The RSUs cannot be transferred and the awards are subject to forfeiture if the holder's employment terminates prior to the release of the vesting restrictions. The RSUs generally vest over a four-year period with straight-line vesting and a 25% one year cliff or over a three year period in equal amounts on a quarterly basis, provided the employee remains continuously employed with the Company. The fair value of the RSUs is equal to the closing price of the Company's common stock on the grant date.

RSU activity under the 2020 Plan is set forth below (intrinsic value in thousands):

| | Number of Awards | Weighted Average Fair Value | Intrinsic Value |
|---|---|---|---|
| **Outstanding**, December 31, 2019 | — | $ — | $ — |
| Granted | 104,538 | 49.25 | 5,128 |
| **Outstanding**, June 30, 2020 | 104,538 | $ 49.25 | $ 50,638 |
| Vested and exercisable at June 30, 2020 | — | $ — | $ — |
| Vested and expected to vest at June 30, 2020 | 104,538 | $ 49.25 | $ 50,638 |

Total compensation cost for all share-based payment arrangements recognized was as follows (in thousands):

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| Cost of goods sold | $ 42 | $ 9 | $ 72 | $ 12 |
| Research and development | 77 | 21 | 124 | 40 |
| Selling, general and administrative | 386 | 69 | 804 | 138 |
| | $ 505 | $ 99 | $ 1,000 | $ 190 |

Total compensation costs as of June 30, 2020 related to all non-vested awards to be recognized in future periods was $7,967,000 and is expected to be recognized over the weighted average period of 3.4 years.

***Employee Share Purchase Plan (ESPP)***

In May 2020, the Company adopted the 2020 Employee Stock Purchase Plan ("ESPP"), which became effective on the date the ESPP was adopted by the Company's board of directors. The Company has initially reserved 990,870 shares of common stock for purchase under the ESPP. Each offering to the employees to purchase stock under the ESPP will begin on each August 1 and February 1 and will end on the following January 31 and July 31, respectively. The first offering period is expected to begin on August 1, 2020 and end on January 31, 2021. On each purchase date, which falls on the last date of each offering period, ESPP participants will purchase shares of common stock at a price per share equal to 85% of the lesser of (1) the fair market value per share of the common stock on the offering date or (2) the fair market value of the common stock on the purchase date. The occurrence and duration of offering periods under the ESPP are subject to the determinations of the Company's Compensation Committee, in its sole discretion.

## 14. Income Taxes

The following table reflects the Company's provision (benefit) for income taxes for the periods indicated (in thousands):

| | Three Months Ended | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| Income (loss) before taxes | $ (3,804) | $ (965) | $ 308 | $ (1,913) |
| Income tax provision (benefit) | — | — | — | — |
| Net income (loss) | $ (3,804) | $ (965) | $ 308 | $ (1,913) |
| Income tax provision (benefit) as a percentage of income taxes | 0.00% | 0.00% | 0.00% | 0.00% |

The Company's effective tax rate is driven by pre-tax income (loss), business credits, net operating loss carryforwards, and the valuation allowance. No tax provision (benefit) was recorded for the three and six months ended June 30, 2020 and 2019.

*Valuation Allowance*

ASC 740 requires that the tax benefit of net operating losses, or NOLs, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryback or carryforward periods. Management believes that recognition of the deferred tax assets arising from the above-mentioned tax benefits from NOLs and credit carryforwards is currently not likely to be realized and, accordingly, has provided a valuation allowance against its deferred tax assets.

*Uncertain Tax Positions*

The Company has recorded uncertain tax positions related to its federal and California research and development credit carryforwards. No interest or penalties have been recorded related to the uncertain tax positions due to other available NOLs to offset the uncertain tax positions. It is not expected that there will be a significant change in uncertain tax position in the next 12 months. The Company is subject to U.S. federal and state income tax as well as to income tax in multiple state jurisdictions, and various foreign jurisdictions. In the normal course of business, the Company is subject to examination by tax authorities. As of the date of the financial statements, there are no tax examinations in progress. The statute of limitations for tax years ended after December 31, 2015 and December 31, 2016 are open for state and federal tax purposes, respectively.

*CARES Act*

The Coronavirus Aid, Relief, and Economic Security, or CARES, Act became effective on March 27, 2020. It was a response to the market volatility and instability resulting from the coronavirus pandemic and includes provisions to support businesses in the form of loans, grants, and tax changes, among other types of relief. The Company has reviewed the income tax changes included in the CARES Act, which primarily includes the expansion of the carryback period for NOLs, changes to the deduction and limitation on interest, and acceleration of depreciation for Qualified Improvement Property. The Company has analyzed these changes and does not believe there will be a material effect on the Company's income tax provision. The Company currently does not expect to apply for loans or grants under the CARES Act.

## 15. Retirement Plan

In December 2017, the Company adopted the Inari Medical, Inc. 401(k) Plan which allows eligible employees after one month of service to contribute pre-tax and Roth contributions to the plan, as allowed by law. The plan assets are held by Vanguard and the plan administrator is Ascensus. The Company does not currently make fund-matching contributions.

## 16. Net Loss Per Share

The following outstanding potentially dilutive common stock equivalents have been excluded from the calculation of diluted net loss per share for the periods presented due to their anti-dilutive effect:

| | For the Three Months Ended June 30, | | For the Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| Convertible preferred stock | 18,267,754 | 31,968,570 | — | 31,968,570 |
| Common stock options | 4,154,153 | 3,949,631 | — | 3,949,631 |
| RSUs | 2,971,864 | 2,867,326 | — | 2,867,326 |
| Restricted stock subject to future vesting | 239,861 | 566,259 | — | 566,259 |
| Convertible preferred stock warrants | — | 256,588 | — | 256,588 |
| Common stock warrants | 179,558 | 27,810 | — | 27,810 |
| | 25,813,190 | 39,636,184 | — | 39,636,184 |

**Item 2. Management's 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 our unaudited condensed consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q and our audited financial statements and related notes thereto for the year ended December 31, 2019, included in our prospectus dated May 21, 2020 filed with the U.S. Securities and Exchange Commission, pursuant to Rule 424(b)(4) under the Securities Act.*

**Overview**

We are a commercial-stage medical device company focused on developing products to treat and transform the lives of patients suffering from venous diseases. Our initial product offering consists of two minimally-invasive, novel catheter-based mechanical thrombectomy devices. We purpose-built our products for the specific characteristics of the venous system and the treatment of the two distinct manifestations of venous thromboembolism, or VTE – deep vein thrombosis and pulmonary embolism. Our ClotTriever product is FDA-cleared for the removal of clot from peripheral blood vessels and is used to treat patients suffering from deep vein thrombosis, or DVT. Our FlowTriever product is the first thrombectomy system FDA-cleared for the treatment of pulmonary embolism, or PE.

We believe the best way to treat VTE and improve the quality of life of patients suffering from this disease is to safely and effectively remove the blood clot. With that in mind, we designed and purpose-built our ClotTriever and FlowTriever products to remove large clots from large vessels and eliminate the need for thrombolytic drugs. We believe our products are transformational and could be the catalyst to drive an evolution of treatment for venous diseases, establishing our products as the standard of care for DVT and PE.

We believe our venous-focused commercial organization provides a significant competitive advantage. Our most important relationships are between our sales representatives and our target physicians, which include interventional cardiologists, interventional radiologists and vascular surgeons. We have developed systems and processes to harness the information gained from these relationships and we leverage this information to rapidly iterate products, introduce and execute physician education and training programs and scale our sales organization. We market and sell our products to hospitals, which are reimbursed by various third-party payors. We have dedicated meaningful resources to building a direct sales force in the United States, and we are actively expanding our sales organization through additional sales representatives and territories.

On May 27, 2020, we completed our IPO, which resulted in the issuance and sale of 9,432,949 shares of common stock, including 1,230,384 shares sold pursuant to the exercise of the underwriters' over-allotment option, at the IPO price of $19.00 per share. We received net proceeds of approximately $163.0 million from the IPO, after deducting underwriters' discounts and commissions of $12.6 million and offering costs of $3.7 million.

Prior to our IPO, our primary sources of capital were private placements of preferred stock, debt financing arrangements and revenue from sales of our products. Since inception, we have raised a total of approximately $54.2 million in net proceeds from private placements of preferred stock. As of June 30, 2020, we had cash and cash equivalents of $194.8 million, long-term debt of $30.0 million and an accumulated deficit of $40.9 million.

For the three months ended June 30, 2020, we generated revenue of $25.4 million, with a gross margin of 86.3% and net loss of $3.8 million, compared to revenue of $10.1 million, with a gross margin of 86.8% and net loss of $1.0 million for the three months ended June 30, 2019.

For the six months ended June 30, 2020, we generated revenue of $52.3 million, with a gross margin of 88.2% and net income of $0.3 million, compared to revenue of $17.0 million, with a gross margin of 86.7% and net loss of $1.9 million for the six months ended June 30, 2019.

**COVID-19**

In December 2019, a novel strain of coronavirus, SARS-CoV-2, was identified in Wuhan, China. Since then, SARS-CoV-2, and the resulting disease, COVID-19, has spread to most countries, including all 50 states in the United States. In response to the pandemic, 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. For example, in the United States, governmental authorities have recommended, and in certain cases required, that elective, specialty and other procedures and appointments be suspended or canceled to avoid non-essential patient exposure to medical environments and potential infection with COVID-19 and to focus limited resources and personnel capacity toward the treatment of COVID-19 patients. Similarly, on March 19, 2020, the governor of California, where our headquarters are located, issued "stay at home" orders limiting non-essential activities, travel and business operations. Such orders or restrictions have resulted in reduced operations at our headquarters (including our manufacturing facility), work stoppages, slowdowns and delays, travel restrictions and cancellation of events. These orders and restrictions have significantly decreased the number of procedures performed using our products and otherwise negatively impacted our operations, including new customer procurement and onboarding.

In response to the impact of COVID-19, we have implemented a variety of measures intended to help us manage through its impact and position us to resume operations quickly and efficiently once these restrictions are lifted. These measures exist across several operational areas and include:

- Continuing to build our team, including identifying and recruiting our next group of new sales representatives;
- Enhancing our physician outreach and training with the launch of our Clot Warrior Academy consisting of a series of live webinars and an online education portal;
- Continuing to support procedures using our products both in-person and virtually;
- Adapting, expanding and improving our sales training programs and customer engagement to address the current environment;
- Continuing to expand our engineering infrastructure and focusing on organic opportunities;
- Producing approximately four months' worth of inventory before temporarily suspending production in April 2020;
- Continuing to protect and support our employees, including no layoffs, furloughs or compensation reductions to date;
- Executing a successful work-from-home strategy for administrative functions that includes launching various efficiency projects in information technology, accounting and operations;
- Monitoring and reviewing recent case studies of VTE patients suffering from COVID-19;
- Initiating market assessment and commercial entry planning for our international expansion; and
- Accessing the remaining $10.0 million on our term loan on March 23, 2020.

Despite the negative impacts from COVID-19, for the six months ended June 30, 2020, approximately 4,900 procedures were performed using our products, compared to approximately 1,500 procedures in the six months ended June 30, 2019. However, the economic disruptions associated with COVID-19 began to negatively impact our procedure volume beginning in mid-March, and weekly procedure volumes declined by approximately 40% by mid-April when compared to weekly procedure volumes in early March. The decrease in procedure volume impacted DVT procedures and PE procedures relatively equally, with both types of procedures declining during this period. We saw a recovery in procedure volume in June that was higher than our pre COVID-19 peak. During July, we saw continued sequential growth beyond June.

While procedure volumes overall have decreased, most recently, weekly procedure volumes for both DVT and PE are showing early signs of stabilization. The numbers of remotely supported procedures and unassisted procedures are starting to increase. We expect that as hospitals recover from the impacts of COVID-19 and return to operations, they will prioritize procedures based on their acuity, safety and efficiency, as well as economic impact to the hospital, and that procedures using our products will be well-positioned to treat this anticipated backlog of patients. For example, DVT and PE prognoses can warrant clinical priority at hospitals, and our products facilitate short, single-session treatments that have the potential to reduce hospital burden and drive hospital and physician efficiency. Moreover, we recognize that while physicians may have used conservative care, postponed or been required to postpone procedures to treat VTE, there are increased risks associated with delayed treatment for these patients. As a result, we believe the decrease in procedures represents a backlog of patients that could receive treatment using our products.

While we are encouraged by our recent results and the potential backlog of patients, we are aware that the actual and perceived impact of COVID-19 is changing daily and cannot be predicted. As a result, we cannot assure you that our recent weekly procedure volumes are indicative of future results or that we will not experience additional negative impacts associated with COVID-19, which could be significant. The COVID-19 pandemic has negatively impacted our business, financial condition and results of operations by significantly decreasing and delaying the number of procedures performed using our products, and we expect the pandemic to continue to negatively impact our business, financial condition and results of operations. We are aware of recent publications regarding incidence rates of VTE in COVID-19 patients, and continue to monitor research and developments involving VTE and COVID-19. See "Risk Factors—Risks Related to Our Business—A pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide, including the outbreak of the novel strain of coronavirus disease, COVID-19, could adversely affect our business" for more information regarding the potential impact of COVID-19 on our business and operations.

***Procedure Volume***

We regularly review a number of operating and financial metrics to evaluate our business, measure our performance, identify trends affecting our business, formulate our business plan and make strategic decisions. We believe the number of procedures performed to treat DVT and PE using our products is an indicator of our ability to drive adoption and generate revenue. We believe this is an important metric for our business; however, we anticipate that additional metrics may become important as our business grows. The following table lists the number of procedures performed in each of the three month periods as indicated:

| | Three Months Ended | | | | | |
|---|---|---|---|---|---|---|
| **Procedures(1)** | **March 31, 2019** | **June 30, 2019** | **Sept 30, 2019** | **Dec. 31, 2019** | **March 31, 2020** | **June 30, 2020** |
| DVT | 300 | 500 | 700 | 1,000 | 1,300 | 1,400 |
| PE | 300 | 400 | 600 | 800 | 1,100 | 1,100 |
| | 600 | 900 | 1,300 | 1,800 | 2,400 | 2,500 |

(1) We define a procedure as any instance in which a physician treats DVT or PE using our products. We estimate the number of procedures performed based on records created by our sales representatives. This metric has limitations as we only have records for the procedures where our sales representatives have notice that a procedure has been performed. Revenue is recognized based on hospital purchase orders, not based on the procedure records created by our sales representatives. Numbers are rounded to the nearest hundred.

**Components of our Results of Operations**

***Revenue***

We currently derive all our revenue from the sale of our ClotTriever and FlowTriever products to hospitals in the United States. Our customers typically purchase an initial stocking order of our products and then reorder replenishment product as procedures are performed. No single customer accounted for 10% or more of our revenue during the three and six months ended June 30, 2020 and 2019. For the three and six months ended June 30, 2020, approximately 56% of our customers used both of our products, 32% used ClotTriever only and 12% used FlowTriever only. We expect revenue to increase in absolute dollars as we expand our sales organization and sales territories, add customers, expand the base of physicians that are trained to use our products, expand awareness of our products with new and existing customers and as physicians perform more procedures using our products. For both the three months ended June 30, 2020 and 2019, 40% of revenue was derived from the sale of ClotTriever products and 60% of revenue was derived from the sale of FlowTriever products. For the six months ended June 30, 2020 and 2019, 38% and 39% of revenue was derived from the sale of ClotTriever products, respectively, and 62% and 61% of revenue was derived from the sale of FlowTriever products, respectively. For the six months ended June 30, 2020, our blended revenue per procedure was approximately $9,100. Blended revenue per procedure represents the average of the average selling price per ClotTriever and the average price per FlowTriever procedure.

***Cost of Goods Sold and Gross Margin***

We manufacture and/or assemble all of our products at our facility in Irvine, California. Cost of goods sold consists primarily of the cost of raw materials, components, direct labor and manufacturing overhead. Overhead costs include the cost of quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management, including stock-based compensation. Cost of goods sold also includes depreciation expense for production equipment and certain direct costs such as shipping costs and royalty expense. Shipping costs billed to customers are reported as a reduction of cost of goods sold. We expect cost of goods sold to increase in absolute dollars as our revenue grows and 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, including average selling prices, product sales mix, production and ordering volumes, manufacturing costs, product yields, headcount and cost-reduction strategies. Our gross margin could fluctuate from quarter to quarter as we introduce new products, and as we adopt new manufacturing processes and technologies.

Treatments using the FlowTriever may involve one or more Triever aspiration catheters and one or more FlowTriever catheters. We charge customers the same price for each FlowTriever procedure, regardless of the number of components used. As a result, changes in the number of components used, the cost of these components and the introduction of additional components can impact our gross margin.

***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 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 facility overhead expenses. Additionally, R&D expenses include costs associated with our clinical trials and registries, including clinical study design, clinical study site initiation and study costs, data management, and internal and external costs associated with our regulatory compliance, including the costs of outside consultants and contractors that assist in the process of submitting and maintaining regulatory filings. We expense R&D costs as incurred. 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 trials and registries and other related activities.

***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, finance, information technology and human resource functions. Other SG&A expenses include sales commissions, travel expenses, promotional activities, marketing initiatives, market research and analysis, conferences and trade shows, physician training, professional services fees (including legal, audit and tax fees), insurance costs, general corporate expenses and facilities-related expenses. We expect SG&A expenses to continue to increase in absolute dollars as we expand our sales and marketing organization and infrastructure to both drive and support the anticipated growth in revenue and due to additional legal, accounting, insurance and other expenses associated with being a public company.

***Interest Income***

Interest income consists primarily of interest income earned on our cash and cash equivalents.

***Interest Expense***

Interest expense consists primarily of interest incurred on our outstanding indebtedness and non-cash interest related to the amortization of debt discount and issuance costs associated with our indebtedness.

***Change in Fair Value of Warrant Liabilities***

Change in fair value of warrant liabilities consists of gains and losses resulting from the remeasurement of the fair value of our preferred stock warrant liabilities at each balance sheet date. Upon the closing of our IPO, our outstanding preferred stock warrants automatically converted into warrants to purchase shares of our common stock. At such time, the final fair value of the warrant liability was reclassified to stockholders' equity (deficit). We will no longer record any related periodic fair value adjustments.

**Results of Operations**

***Comparison of the three months ended June 30, 2020 and 2019***

The following table sets forth the components of our unaudited statements of operations in dollars and as percentage of revenue for the periods presented (dollars in thousands):

| | Three Months Ended June 30, | | | | |
|---|---|---|---|---|---|
| | 2020 | % | 2019 | % | Change $ |
| Revenue | $ 25,392 | 100.0% | $ 10,072 | 100.0% | $ 15,320 |
| Cost of goods sold | 3,487 | 13.7% | 1,331 | 13.2% | 2,156 |
| Gross profit | 21,905 | 86.3% | 8,741 | 86.8% | 13,164 |
| Operating expenses: | | | | | |
| Research and development | 3,628 | 14.3% | 1,580 | 15.7% | 2,048 |
| Selling, general and administrative | 18,880 | 74.4% | 7,803 | 77.5% | 11,077 |
| Total operating expenses | 22,508 | 88.7% | 9,383 | 93.2% | 13,125 |
| Loss from operations | (603) | (2.4%) | (642) | (6.4%) | 39 |
| Other income (expense) | | | | | |
| Interest income | 146 | 0.6% | 24 | 0.3% | 122 |
| Interest expense | (463) | (1.8%) | (229) | (2.3%) | (234) |
| Change in fair value of warrant liabilities | (2,884) | (11.4%) | (118) | (1.2%) | (2,766) |
| Total other expenses, net | (3,201) | (12.6%) | (323) | (3.2%) | (2,878) |
| Net loss and comprehensive loss | $ (3,804) | (15.0%) | $ (965) | (9.6%) | $ (2,839) |

*Revenue*. Revenue increased $15.3 million, or 152.1%, to $25.4 million during the three months ended June 30, 2020, compared to $10.1 million during the three months ended June 30, 2019. The increase in revenue was due primarily to an increase in the number of products sold and an increase in the average selling prices of our products. The increase in revenue was offset in part by the negative impact of the COVID-19 pandemic on procedure volume and new orders during the three months ended June 30, 2020.

*Cost of Goods Sold and Gross Margin*. Cost of goods sold increased $2.2 million, or 162.0%, to $3.5 million during the three months ended June 30, 2020, compared to $1.3 million during the three months ended June 30, 2019. This increase was due to the increase in the number of products sold and additional manufacturing overhead costs incurred as we invested significantly in our operational infrastructure to support anticipated future growth. Gross margin for the three months ended June 30, 2020 decreased to 86.3%, compared to 86.8% for the three months ended June 30, 2019, due to $1.1 million in idle production capacity costs associated with the COVID-19 pandemic, partially offset by an increase in the average selling prices of our products and improved operating leverage.

*Research and Development Expenses*. R&D expenses increased $2.0 million, or 129.6%, to $3.6 million during the three months ended June 30, 2020, compared to $1.6 million during the three months ended June 30, 2019. The increase in R&D expenses was primarily due to an increase of $1.0 million of personnel-related expenses, $0.6 million in materials and supplies, and $0.4 million of clinical study and registry expenses.

*Selling, General and Administrative Expenses*. SG&A expenses increased $11.1 million, or 142.0%, to $18.9 million during the three months ended June 30, 2020, compared to $7.8 million during the three months ended June 30, 2019. The increase in SG&A costs was primarily due to an increase of $9.1 million in personnel-related expenses as a result of increased headcount across our organization and increased commissions due to higher revenue, an increase of $0.9 million in professional fees, and an increase of $0.4 million in insurance costs.

*Interest Income.* Interest income increased by $122,000 to $146,000 during the three months ended June 30, 2020, compared to $24,000 during the three months ended June 30, 2019. The increase in interest income was primarily due to an increase in average cash and cash equivalents during the three months ended June 30, 2020, compared to the three months ended June 30, 2019.

*Interest Expense.* Interest expense increased by $0.2 million or 102.2% during the three months ended June 30, 2020, compared to the three months ended June 30, 2019. This increase was primarily due to increased interest associated with $10.0 million of additional borrowings drawn under the credit facility with Signature Bank in December 2019, as well as $10.0 million of additional borrowings drawn in March 2020 in response to the COVID-19 pandemic. As of June 30, 2019, the aggregate outstanding principal balance under the amended and restated loan and security agreement with East West Bank was $10.0 million, which was subsequently prepaid in full and terminated. As of June 30, 2020, the aggregate outstanding principal balance under the credit facility with Signature Bank was $30.0 million.

*Change in Fair Value of Warrant Liabilities*. Change in fair value of warrant liabilities increased $2.8 million to $2.9 million for the three months ended June 30, 2020, compared to $0.1 million for three months ended June 30, 2019. This increase was due to the fair value remeasurement of our convertible preferred stock warrant liabilities.

***Comparison of the six months ended June 30, 2020 and 2019***

The following table sets forth the components of our unaudited statements of operations in dollars and as percentage of revenue for the periods presented (dollars in thousands):

| | Six Months Ended June 30, | | | | |
|---|---|---|---|---|---|
| | 2020 | % | 2019 | % | Change $ |
| Revenue | $ 52,345 | 100.0% | $ 17,017 | 100.0% | $ 35,328 |
| Cost of goods sold | 6,193 | 11.8% | 2,262 | 13.3% | 3,931 |
| Gross profit | 46,152 | 88.2% | 14,755 | 86.7% | 31,397 |
| Operating expenses: | | | | | |
| Research and development | 6,646 | 12.7% | 2,789 | 16.4% | 3,857 |
| Selling, general and administrative | 35,273 | 67.4% | 13,229 | 77.7% | 22,044 |
| Total operating expenses | 41,919 | 80.1% | 16,018 | 94.1% | 25,901 |
| Income (loss) from operations | 4,233 | 8.1% | (1,263) | (7.4%) | 5,496 |
| Other income (expense) | | | | | |
| Interest income | 201 | 0.4% | 48 | 0.3% | 153 |
| Interest expense | (809) | (1.5%) | (456) | (2.7%) | (353) |
| Change in fair value of warrant liabilities | (3,317) | (6.3%) | (242) | (1.4%) | (3,075) |
| Total other expenses, net | (3,925) | (7.4%) | (650) | (3.8%) | (3,275) |
| Net income (loss) and comprehensive income (loss) | $ 308 | 0.7% | $ (1,913) | (11.2%) | $ 2,221 |

*Revenue*. Revenue increased $35.3 million, or 207.6%, to $52.3 million during the six months ended June 30, 2020, compared to $17.0 million during the six months ended June 30, 2019. The increase in revenue was due primarily to an increase in the number of products sold and an increase in the average selling prices of our products. The increase in revenue was offset in part by the negative impact of the COVID-19 pandemic on procedure volume and new orders during the six months ended June 30, 2020.

*Cost of Goods Sold and Gross Margin*. Cost of goods sold increased $3.9 million, or 173.8%, to $6.2 million during the six months ended June 30, 2020, compared to $2.3 million during the six months ended June 30, 2019. This increase was due to the increase in the number of products sold and additional manufacturing overhead costs incurred as we invested significantly in our operational infrastructure to support anticipated future growth. Cost of goods sold for the six months ended June 30, 2020 was also impacted by $1.1 million in idle production capacity costs associated with the COVID-19 pandemic. Gross margin for the six months ended June 30, 2020 increased to 88.2%, compared to 86.7% for the six months ended June 30, 2019 due to an increase in the average selling prices of our products and improved operating leverage.

*Research and Development Expenses*. R&D expenses increased $3.9 million, or 138.3%, to $6.6 million during the six months ended June 30, 2020, compared to $2.8 million during the six months ended June 30, 2019. The increase in R&D expenses was primarily due to an increase of $1.5 million of personnel-related expenses, $1.1 million of clinical study and registry expenses and $1.0 million in materials and supplies.

*Selling, General and Administrative Expenses*. SG&A expenses increased $22.1 million, or 166.6%, to $35.3 million during the six months ended June 30, 2020, compared to $13.2 million during the six months ended June 30, 2019. The increase in SG&A costs was primarily due to an increase of $17.4 million in personnel-related expenses as a result of increased headcount across our organization and increased commissions due to higher revenue, an increase of $2.2 million in professional fees, an increase of $0.4 million in travel costs, an increase of $0.4 million in insurance costs, and an increase of $0.4 million in facility costs.

*Interest Income.* Interest income increased by $153,000 to $201,000 during the six months ended June 30, 2020, compared to $48,000 during the six months ended June 30, 2019. The increase in interest income was primarily due to an increase in average cash and cash equivalents during the six months ended June 30, 2020, compared to the six months ended June 30, 2019.

*Interest Expense.* Interest expense increased by $0.4 million or 77.4% during the six months ended June 30, 2020, compared to the six months ended June 30, 2019. This increase was primarily due to increased interest associated with $10.0 million of additional borrowings drawn under the credit facility with Signature Bank in December 2019, as well as $10.0 million of additional borrowings drawn in March 2020 in response to the COVID-19 pandemic. As of June 30, 2019, the aggregate outstanding principal balance under the amended and restated loan and security agreement with East West Bank was $10.0 million, which was subsequently prepaid in full and terminated. As of June 30, 2020, the aggregate outstanding principal balance under the credit facility with Signature Bank was $30.0 million.

*Change in Fair Value of Warrant Liabilities*. Change in fair value of warrant liabilities increased $3.1 million to $3.3 million for the six months ended June 30, 2020, compared to $0.2 million for six months ended June 30, 2019. This increase was due to the fair value remeasurement of our convertible preferred stock warrant liabilities.

**Liquidity and Capital Resources**

To date, our primary sources of capital have been the net proceeds we received through private placements of preferred stock, debt financing agreements, the sale of common stock in our IPO, and revenue from the sale of our products. On May 27, 2020, we completed our IPO, including the underwriters full exercise of their over-allotment option, selling 9,432,949 shares of our common stock at $19.00 per share. Upon completion of our IPO, we received net proceeds of approximately $163.0 million, after deducting underwriting discounts and commissions and offering expenses. As of June 30, 2020, we had cash and cash equivalents of $194.8 million, $30.0 million of principal outstanding under the credit facility with Signature Bank and an accumulated deficit of $40.9 million.

Based on our current planned operations, we expect that our cash and cash equivalents and available borrowings will enable us to fund our operating expenses for at least 12 months from the date hereof.

If our available cash balances and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements including because of lower demand for our products as a result of the risks described in this Quarterly Report, we may seek to sell additional common or preferred equity or convertible debt securities, enter into an additional credit facility or another form of third-party funding or seek other debt financing. The sale of equity and convertible debt securities may result in dilution to our stockholders and, in the case of preferred equity securities or convertible debt, those securities could provide for rights, preferences or privileges senior to those of our common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our platform technologies or products or grant licenses on terms that are not favorable to us. Additional capital may not be available on reasonable terms, or at all.

**Cash Flows**

The following table summarizes our cash flows for each of the six-month periods indicated (in thousands):

| | Six Months Ended June 30, | |
|---|---|---|
| | 2020 | 2019 |
| Net Cash (used in) provided by: | | |
| Operating activities | $ (1,805) | $ (3,775) |
| Investing activities | (1,418) | (899) |
| Financing activities | 174,420 | 20 |
| Net increase (decrease) in cash and cash equivalent | $ 171,197 | $ (4,654) |

***Net Cash Used in Operating Activities***

Net cash used in operating activities for the six months ended June 30, 2020 was $1.8 million, consisting primarily of net income of $0.3 million and non-cash charges of $5.0 million, offset by an increase in net operating assets of $7.1 million. The increase in net operating assets was primarily due to increases in accounts receivable of $4.1 million and inventories of $1.7 million to support the growth of our operations, an increase in prepaid and other assets of $3.4 million primarily from prepaid insurance, and a decrease in accounts payable of $0.3 million which were partially offset by increases in accrued liabilities of $2.3 million due to timing of payments and growth of our operations. The non-cash charges primarily consisted of $3.3 million in change in fair value of the preferred stock warrant liabilities, stock-based compensation of $1.0 million, and $0.6 million in depreciation.

Net cash used in operating activities for the six months ended June 30, 2019 was $3.8 million, consisting primarily of a net loss of $1.9 million and an increase in net operating assets of $2.6 million, partially offset by non-cash charges of $0.7 million. The increase in net operating assets was primarily due to an increase in accounts receivable of $3.6 million due to increase in sales and inventories of $1.1 million to support the growth of our operations, partially offset by increases in accrued liabilities of $1.9 million due to timing of payments and growth of our operations. Non-cash charges consisted primarily of $0.2 million in depreciation, stock-based compensation of $0.2 million, and the change in fair value of the convertible preferred stock warrants of $0.2 million.

***Net Cash Used in Investing Activities***

Net cash used in investing activities in the six months ended June 30, 2020 and 2019 was $1.4 million and $0.9 million, respectively, consisting of purchases of property and equipment.

***Net Cash Provided by Financing Activities***

Net cash provided by financing activities in the six months ended June 30, 2020 was $174.4 million primarily consisting of net IPO proceeds of $164.4 million and net proceeds of $10.0 million received from additional borrowings under the credit facility with Signature Bank.

There were no significant cash flow financing activities in the six months ended June 30, 2019.

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements, as defined by applicable regulations of the U.S. Securities and Exchange Commission, that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

**Contractual Obligations and Commitments**

There have been no material changes outside the ordinary course of business to the Company's contractual obligations from those disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in the prospectus dated May 21, 2020 filed with the U.S. Securities and Exchange Commission pursuant to Rule 424(b)(4) under the Securities Act.

**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. GAAP. 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 were no material changes to our critical accounting policies or in the methodology used for estimates from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in the Prospectus.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

***Interest Rate Risk***

The risk associated with fluctuating interest rates is primarily limited to our debt. As of June 30, 2020, we had $30.0 million outstanding under the SB Credit Facility. Under our SB Credit Facility, we are required to repay the term loan in monthly installments from December 2021 through December 2024, while the revolving line of credit is due in December 2022. The term loan accrues interest at an annual rate equal to the greater of 5.50% or the prime rate plus 0.50% and the revolving line of credit accrues interest at an annual rate equal to the greater of 5.0% or the prime rate. A hypothetical 10% relative change in interest rates during any of the years presented would not have had a material impact on our financial statements. We do not currently engage in hedging transactions to manage our exposure to interest rate risk.

***Credit Risk***

As of June 30, 2020, our cash and cash equivalents were maintained with three financial institutions in the United States, and our current deposits are likely in excess of insured limits. We do not believe we are exposed to any significant credit risk. Our cash equivalents are invested in highly rated money market funds.

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 June 30, 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 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 Exchange Act prior to the filing of this Quarterly Report. Based on that evaluation, our 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 not effective as described below.

However, our management, including our Chief Executive Officer and our Chief Financial Officer, has concluded that, notwithstanding the identified material weaknesses in our internal control over financial reporting, the condensed consolidated financial statements in this Quarterly Report fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with U.S. GAAP.

***Material Weakness in Internal Control Over Financial Reporting***

In connection with the preparation of our financial statements for the year ended December 31, 2019, we concluded there were material weaknesses in our internal controls over financial reporting. A “material weakness” is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The material weaknesses that were identified related to the segregation of duties throughout various financial processes and our documentation of internal controls.

***Management’s Plan to Remediate the Material Weaknesses***

With the oversight of senior management and our audit committee, we began the implementation of remediation steps in late 2019 and these measures were ongoing during the first and second quarter of 2020. These efforts focus on (i) the hiring of personnel with technical accounting and financial reporting experience and (ii) the implementation of improved accounting and financial reporting procedures and systems to improve the completeness, timeliness and accuracy of our financial reporting and disclosures including the assessment of more judgmental areas of accounting. We believe these measures will remediate the material weaknesses identified and strengthen our internal control over financial reporting. We are committed to continuing to improve our internal control processes and we will continue to diligently and vigorously review our financial reporting controls and procedures.

***Changes in Internal Control Over Financial Reporting***

There were no other changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period 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 our 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.**

We are not subject to any material legal proceedings.

**Item 1A. Risk Factors.**

### RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should consider and read carefully all of the risks and uncertainties described below, as well as other information included in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and related notes, before making an investment decision. The risks described below are not the only ones facing us. 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 or results of operations. In such case, the trading price of our common stock could decline, and you may lose all or part of your original investment. This Quarterly Report on Form 10-Q also contains forward-looking statements and estimates that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of specific factors, including the risks and uncertainties described below.*

### A Risks Related to Our Business

***We are an early-stage company with a history of significant 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 annual net losses since our original formation as Inceptus Newco1 Inc. in July 2011. For the years ended December 31, 2018 and 2019, we had a net loss of $10.2 million and $1.2 million, respectively. For the six months ended June 30, 2019 and 2020, we had a net loss of $1.9 million and a net income of $0.3 million, respectively. We expect to continue to incur additional losses in the future. As of June 30, 2020, we had an accumulated deficit of $40.9 million. To date, we have financed our operations primarily through equity and debt financings and from sales of our two products, the ClotTriever, for treatment of deep vein thrombosis, or DVT, and the FlowTriever, for treatment of pulmonary embolism, or PE. The losses and accumulated deficit have primarily been due to the substantial investments we have made to develop our products, costs related to our sales and marketing efforts, general research and development expenses, including costs related to clinical and regulatory initiatives to obtain marketing approval, and infrastructure improvements.

In addition, as a public company, we incur significant legal, accounting and other expenses. 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.

***Our revenue is generated from the sales of our two products and we are therefore highly dependent on the success of those products. We have limited commercial sales experience regarding our products, which makes it difficult to evaluate our current business, predict our future prospects and forecast our financial performance and growth.***

We began commercializing our products in the United States in 2017 and therefore do not have a long history operating as a commercial company. Over the next several years, we expect to continue to devote a substantial amount of resources to expand our commercialization efforts, drive increased adoption of our products and continue to develop new and improved products. Our limited commercialization experience and limited number of approved or cleared products make it difficult to evaluate our current business and predict our future prospects. These factors also make it difficult for us to forecast our future financial performance and growth, and such forecasts are subject to a number of uncertainties, including our ability to successfully complete preclinical studies and clinical trials and obtain FDA pre-market approval for future planned products or changes to existing products.

To date, all of our revenue has been derived, and we expect it to continue to be substantially derived, from sales of our ClotTriever and FlowTriever. Our products provide new catheter-based treatment options that we believe have the potential to become the standard of care for the two diseases that comprise venous thromboembolism, or VTE, namely DVT and PE. Physician awareness of, and experience with, our products is currently limited. As a result, our products have limited product and brand recognition within the medical industry for the treatment of VTE. The novelty of our products, together with our limited commercialization experience,

makes it difficult to evaluate our current business and predict our future prospects. A number of factors, including some outside of our control, may contribute to fluctuations in our financial results, including:

- Physician and hospital demand for our products and adoption of our products and catheter-based thrombectomy procedures;
- Changes in reimbursement rates by government or commercial payors;
- Positive or negative media coverage, or public, patient and/or physician perception, of our products or competing products and treatments;
- Any safety or effectiveness concerns that arise regarding our products or other catheter-based thrombectomy procedures;
- The effectiveness of our marketing and sales efforts, including our ability to have a sufficient number of talented sales representatives to sell our products;
- Unanticipated delays in product development or product launches;
- Our ability to raise additional capital on acceptable terms, or at all, if needed to support the commercialization of our products;
- Our ability to achieve and maintain compliance with all regulatory requirements applicable to our products;
- Our ability to obtain, maintain and enforce our intellectual property rights;
- Our third-party suppliers' ability to supply the components of our products in a timely manner, in accordance with our specifications, and in compliance with applicable regulatory requirements; and
- Introduction of new products or alternative treatments for VTE that compete with our products.

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 and rely on our products as our sole source of revenue, any factors that negatively impact our products 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 our products and catheter-based thrombectomy procedures by hospitals, physicians and patients.***

To date, a substantial majority of our product sales and revenue have been derived from a limited number of hospitals. Our future growth and profitability largely depend on our ability to increase physician and patient awareness of our products and on the willingness of physicians and hospitals to adopt our products and conduct catheter-based thrombectomy procedures for treatment of VTE. Physicians may not adopt 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 VTE. Even if we are able to raise awareness among physicians, they may be slow in changing their medical treatment practices and may be hesitant to select our products or conduct catheter-based thrombectomy procedures for a variety of reasons, including:

- Lack of experience with our products and concerns that we are relatively new to market;
- Perceived liability risk generally associated with the use of new products and treatment options;
- Lack or perceived lack of sufficient clinical evidence, including long-term data, supporting clinical benefits or the cost-effectiveness of our products over existing treatments;

- The failure of key opinion leaders to provide recommendations regarding our products, or to assure physicians, patients and healthcare payors of the benefits of our products as an attractive alternative to other treatment options;
- Perception that our products are unproven;
- Long-standing relationships with companies and distributors that sell other products or treatment options for VTE, such as repurposed arterial devices and thrombolytic drugs;
- Lack of availability of adequate third-party payor coverage or reimbursement;
- Competitive response and negative selling efforts from providers of alternative treatments; and
- Perception regarding the time commitment and skill development that may be required to gain familiarity and proficiency with our products.

To effectively market and sell our products, we will need to educate the medical community about the safety, efficacy, necessity and efficiency of our products and about the patient population that would potentially benefit from a catheter-based thrombectomy procedure using one of our products. We focus our sales, marketing and education efforts primarily on our target physicians, including interventional cardiologists, interventional radiologists and vascular surgeons, and also aim to educate and inform referring physicians, such as vascular surgeons, pulmonologists, radiologists, general practitioners and administrators regarding our products and the potential patient population. However, we cannot assure you that we will achieve broad education or market acceptance among these physicians. For example, if diagnosing physicians that serve as the primary point of contact for patients are not made aware of our products or catheter-based thrombectomy procedures, they may not refer patients to physicians for treatment using our products, and those patients may be treated with alternative procedures or treatments, such as anticoagulants alone or thrombolytic drugs. In addition, some physicians may choose to utilize our products on only a subset of their total patient population or may not adopt our products at all. If we are not able to effectively demonstrate that our products and catheter-based thrombectomy procedures are beneficial for a broad range of patients, adoption of our products 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 our products will achieve broad market acceptance among hospitals, physicians and patients. Any failure of 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.

***Adoption of our ClotTriever and FlowTriever products requires approval by hospital value analysis committees, group purchasing organizations and integrated delivery networks, or the staff of hospitals or health systems.***

In most cases, before physicians can use our products for the first time, our products must be approved for use by hospital value analysis committees, group purchasing organizations and integrated delivery networks, or the staff of hospitals or health systems. 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 our ClotTriever and FlowTriever products depends upon appropriate physician training, practice and patient selection.***

The success of our products depends in part on the skill of the physician performing the catheter-based thrombectomy procedures and on their adherence to our stated patient selection criteria and proper techniques that we provide in training sessions. For example, we train physicians to ensure correct use of our products; however, physicians rely on their previous medical training and experience when performing catheter-based thrombectomy procedures, and we cannot guarantee that all such physicians will have the necessary skills or experience to safely and effectively perform these procedures. We do not control which physicians perform these procedures or how much training they receive, and physicians who have not completed our training sessions may nonetheless attempt to perform catheter-based thrombectomy procedures with our products. In addition, a perception by physicians that our products are difficult to use may negatively impact adoption. If physicians perform these procedures in a manner that is inconsistent with our labeled indications, with components that are not our products, with patients who are not indicated for treatment with our products or without adhering to or completing our training sessions, the patient outcomes may be negative or inconsistent with the outcomes achieved in our clinical trials. This could negatively impact the perception of patient benefits and safety associated with our products and limit adoption of our products and catheter-based thrombectomy procedures generally, which would have a material adverse effect on our business, financial condition and results of operations.

***Adoption of our ClotTriever and FlowTriever products depends upon positive clinical data, and the safety and efficacy of our products are not yet supported by long-term clinical data, which could limit sales, and our products might therefore prove to be less safe or effective than initially thought.***

The rate of adoption and sales of our products is heavily influenced by clinical data. Currently, the primary clinical data regarding the safety and effectiveness of our products is limited to our FlowTriever Pulmonary Embolectomy Clinical Study, or FLARE study, which was a prospective, multicenter, single-arm study to evaluate the safety and effectiveness of our first-generation FlowTriever for use in the removal of clot from the pulmonary arteries in the treatment of 106 patients with acute intermediate-risk PE. Other studies, including a retrospective, single-center study conducted by St. Luke's Hospital in Kansas City, Missouri in 46 patients with intermediate- and high-risk PE and a retrospective, multicenter study in 27 patients with high-risk PE have been conducted examining the safety, efficacy and feasibility of treatment using the FlowTriever. No clinical trials or studies have been completed using the ClotTriever. To augment this data, we are currently enrolling our ClotTriever Outcomes, or CLOUT, and FlowTriever All-Comer Registry for Patient Safety and Hemodynamics, or FLASH, registries, each of which is intended to evaluate and assess real-world patient outcomes in up to 500 patients. We plan to conduct additional clinical trials to help drive increased awareness and adoption of our products with existing and new customers. Historical clinical results are not necessarily predictive of future clinical results, and we cannot assure you that the results reported in these registries will be consistent with, or better than, currently available clinical data. Moreover, the outcomes and updates resulting from these registries, including interim results, may be compared to the results of other products and treatments for DVT or PE, and if the comparisons are not favorable, it may limit the adoption of our products. In addition, our competitors and other 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 other third parties, the interpretation of our clinical data or findings of new or more frequent adverse events, could subject us to mandatory or voluntary product recalls, suspension or withdrawal of FDA or other governmental clearance or approval, significant legal liability or harm to our business reputation and could have a material adverse effect on our business, financial condition and results of operations.

Our products will be adopted and compete, in part, based on long-term data regarding patient outcomes and the risk of our products relative to other treatment options. The long-term clinical outcomes of catheter-based thrombectomy procedures with our products are not known and, due to the novelty of our products, there is no long-term data regarding patient outcomes beyond our current clinical trials. The results of short-term clinical experience of our products do not necessarily predict long-term clinical outcomes. We believe that physicians will compare the rates of long-term clinical outcomes for procedures using our products against alternative procedures and treatment options. 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, which will negatively affect our business, financial condition and results of operations.

***We have limited experience in training and marketing and selling our products and we may provide inadequate training, fail to increase our sales and marketing capabilities or fail to develop broad brand awareness in a cost effective manner.***

We have limited experience marketing and selling our products. We currently rely on our direct sales force to sell our products in targeted geographic regions and territories, and any failure to maintain and grow our direct sales force could harm our business. The members of our direct sales force are trained and possess technical expertise, which we believe is critical in driving the awareness and adoption of our products. 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 expertise and qualifications, or if we are unable to successfully instill such expertise in replacement personnel, our product sales, revenue and results of operations could be materially harmed.

In order to generate future growth, we plan to continue to significantly expand and leverage our commercial infrastructure to increase our customer base and increase awareness and adoption by existing customers to drive our growth. Identifying and recruiting qualified sales and marketing professionals and training them on our products and catheter-based thrombectomy procedures in the venous system, on applicable federal and state laws and regulations and on our internal policies and procedures requires significant time, expense and attention. It can take 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 or treatments, such as thrombolytic drugs, that can utilize independent third parties, placing 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 product sales and 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 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 sales and marketing and educational efforts. We plan to dedicate significant resources to our sales and marketing and educational programs. Our business may be harmed if these efforts and expenditures do not generate a

corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our brand in a cost effective manner is critical to achieving broad acceptance of our products and reaching new physicians, hospitals and patients. Brand promotion activities may not generate hospital 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. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the market 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.

***We manufacture and sell products that are used in a limited number of procedures and there is a limited total addressable market for our products. The sizes of the markets for our current products have not been established with precision, and may be smaller than we estimate.***

In the United States, approximately 668,000 patients are diagnosed with DVT and approximately 400,000 patients are diagnosed with PE each year. Of these, we estimate that approximately 242,000 patients present with DVT in the iliofemoral region and 200,000 patients have PE severe enough to cause right heart strain. Historically, we estimate that only 32% of such DVT patients and 10% of such PE patients have received treatment for these conditions beyond conservative medical management using anticoagulants. However, based on FDA clearance and indications of use for our products, we believe that the approximately 242,000 DVT patients and 200,000 PE patients per year are potential candidates for treatment using our products. The total addressable market for our products is subject to change from year to year and may be further limited by FDA restrictions or more narrowly defined indications, any of which could have a material adverse effect on our business, financial condition and results of operations.

Our estimates of the annual total addressable markets for our current products are based on a number of internal and third-party estimates, including, without limitation, the number of patients with DVT and PE treatable by our products and the assumed prices at which we can sell our products in markets that have not yet been fully established. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual total addressable market for our current products may prove to be incorrect. If the actual number of patients who would benefit from our solution, the price at which we can sell our products, or the annual total addressable market for our products is smaller than we have estimated, it may impair our sales growth and negatively affect our business, financial condition and results of operations.

***A pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide, including the outbreak of the novel strain of coronavirus disease, COVID-19, could adversely affect our business.***

If a pandemic, epidemic or outbreak of an infectious disease occurs in the United States or worldwide, our business may be adversely affected. In December 2019, a novel strain of coronavirus, SARS-CoV-2, was identified in Wuhan, China. Since then, SARS-CoV-2, and the resulting disease, COVID-19, has spread to most countries and all 50 states within the United States. The COVID-19 pandemic has negatively impacted our business, financial condition and results of operations by significantly decreasing and delaying the number of procedures performed using our products, and we expect the pandemic to continue to negatively impact our business, financial condition and results of operations. Similar to the general trend in elective and other surgical procedures, the number of procedures performed using our products has decreased significantly as healthcare organizations in the United States have prioritized the treatment of patients with COVID-19 or have altered their operations to prepare for and respond to the pandemic. For example, in the United States, governmental authorities have recommended, and in certain cases required, that elective, specialty and other procedures and appointments be suspended or canceled to avoid non-essential patient exposure to medical environments and potential infection with COVID-19 and to focus limited resources and personnel capacity toward the treatment of COVID-19 patients. We believe the COVID-19 pandemic has also negatively impacted the number of DVT and PE diagnoses as hospitals focus on COVID-19 and as patients postpone healthcare visits and treatments. Specifically, a significant number of procedures using our products were postponed or cancelled beginning in March 2020. In particular, the number of procedures using our ClotTriever and FlowTriever decreased significantly in and since March 2020. Decreases in procedures have been most prevalent in regions experiencing significant outbreaks, such as the northeast United States, while healthcare organizations in other regions have continued to undertake procedures using our products at reduced levels as compared to before the pandemic. These measures and challenges will likely continue for the duration of the pandemic, which is uncertain, and will continue to significantly reduce our revenue and negatively impact our business, financial condition and results of operations while the pandemic continues. Further, once the pandemic subsides, we anticipate there will be a substantial backlog of patients seeking appointments with physicians and surgeries to be performed at hospitals and ambulatory surgery centers relating to a variety of medical conditions, and as a result, patients seeking procedures performed using our products, particularly the ClotTriever, will have to navigate limited provider capacity. We believe this limited provider, hospital and ambulatory surgery center capacity could have a significant adverse effect on our business, financial condition and results of operations following the end of the pandemic.

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. On March 19, 2020, the governor of California, where our headquarters are located, issued “stay at home” orders limiting non-

essential activities, travel and business operations. Such orders or restrictions have resulted in reduced operations at our headquarters (including our manufacturing facility), work stoppages, slowdowns and delays, travel restrictions and cancellation of events and have restricted the ability of our front-line sales representatives to attend procedures in which our products are used, among other effects, thereby significantly and negatively impacting our operations. Other disruptions or potential disruptions include restrictions on the ability of our sales representatives and other personnel to travel and access customers for training and case support; inability of our suppliers to manufacture components and parts and to deliver these to us on a timely basis, or at all; disruptions in our production schedule and ability to manufacture and assemble products; inventory shortages or obsolescence; delays in actions of regulatory bodies; delays in clinical trials and studies; diversion of or limitations on employee resources that would otherwise be focused on the operations of our business, including because of sickness of employees or their families or the desire of employees to avoid contact with groups of people; delays in growing or reductions in our sales organization, including through delays in hiring, lay-offs, furloughs or other losses of sales representatives; restrictions in our ability to ship our products to customers; business adjustments or disruptions of certain third parties, including suppliers, medical institutions and clinical investigators with whom we conduct business; negative impact on our customers' credit profiles, which may adversely impact our future collection experience; and additional government requirements or other incremental mitigation efforts that may further impact our or our suppliers' capacity to manufacture our products. The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity and spread of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

While the potential economic impact brought by and the duration of any pandemic, epidemic or outbreak of an infectious disease, including COVID-19, may be difficult to assess or predict, the widespread COVID-19 pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of an infectious disease, including COVID-19, could materially affect our business. Such economic recession could have a material adverse effect on our long-term business as hospitals curtail and reduce capital and overall spending. In addition, the current economic downturn is resulting in significant job losses and reductions in disposable income and if patients are unable to obtain or maintain health insurance policies, this may significantly impact their ability to pay for the procedures utilizing our products, further negatively impacting our business, financial condition and results of operations. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

***Catheter-based treatment for PE is subject to a Medicare National Coverage Determination that may restrict Medicare coverage for procedures using our FlowTriever product for the treatment of PE.***

In 1983, the Centers for Medicare and Medicaid Services, or CMS, adopted a National Coverage Determination, or NCD, for Transvenous Pulmonary Embolectomy, NCD 240.6. At that time, NCD 240.6 deemed catheter-based pulmonary embolectomy to be experimental and non-covered by Medicare. There is currently uncertainty as to whether NCD 240.6 may apply to procedures using our FlowTriever product to treat PE. If NCD 240.6 is determined to exclude from Medicare coverage procedures that use our FlowTriever for the treatment of PE, there would be a material adverse effect on our business.

We understand that various medical societies, including the Society for Cardiovascular Angiography and Interventions, the Society for Interventional Radiology, and the Society for Vascular Medicine, as well as the American College of Cardiology, have requested that CMS remove NCD 240.6 through an expedited administrative removal process available for NCDs that have not been updated in at least ten years. We can give no assurance that NCD 240.6 will be removed. Further, CMS may elect to retain NCD 240.6 and begin enforcing NCD 240.6 with respect to procedures using our FlowTriever product for the treatment of PE, which could result in claim denials and overpayments for our customers and significantly impact demand for the FlowTriever, which would have a material adverse effect on our business, financial condition and results of operations.

***We may not be able to maintain adequate levels of third-party coverage and reimbursement, and third parties may rescind or modify their coverage or delay payments related to our products.***

We derive our revenue from sales of our ClotTriever and FlowTriever products to hospitals and other medical centers, which typically bill all or a portion of the costs and fees associated with our products to various third-party payors, including Medicare, Medicaid, 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, we sell our products to hospitals that purchase our products for use in catheter-based thrombectomy procedures and do not sell our products to commercial payors. As a result, access to adequate coverage and reimbursement for our products by third-party payors is essential to the acceptance and adoption of our products.

Coverage and reimbursement by governmental and third-party payors may depend upon a number of factors, including the determination that the product or service and its use or administration for a particular patient is:

- a covered benefit;

- safe, effective and medically necessary;
- appropriate for the specific patient;
- supported by guidelines established by the relevant professional societies;
- cost-effective; and
- neither experimental nor investigational.

Our customers typically bill third-party payors for the costs and fees associated with the procedures in which our products are used. Because there is often no separate reimbursement for supplies used in surgical procedures, the additional cost associated with the use of our products can affect the profit margin of the hospital or surgery center where the procedure is performed. Some of our target customers may be unwilling to adopt our products in light of potential additional associated cost. In addition, customers that perform the procedure may be subject to reimbursement claim denials upon submission of the claim. Customers may also be subject to recovery of overpayments if a payor makes payment for the claim and subsequently determines that the payor's coding, billing or coverage policies were not followed. These events, or any other decline in the amount payors are willing to reimburse our customers, could make it difficult for existing 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 could have a material adverse effect on our business, financial condition and results of operations and impair our ability to grow our business.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, no uniform policy of coverage and reimbursement for procedures using our products exists among third-party payors. Therefore, coverage and reimbursement for procedures using our products can differ significantly from payor to payor. Obtaining coverage and reimbursement can be a time-consuming process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products. We may not be able to provide data sufficient to satisfy governmental and third-party payors that procedures using our products should be covered and reimbursed.

Payors continually review new and existing technologies for possible coverage and can, without notice, deny or reverse coverage for new or existing products and procedures. There can be no assurance that third-party payor policies will provide coverage for procedures in which our products are used. For instance, if NCD 240.6 is determined to exclude Medicare coverage for procedures using FlowTriever for the treatment of PE, there would be a material adverse effect on our business, financial condition and results of operations. If we are not successful in reversing existing non-coverage policies, or if third-party payors that currently cover or reimburse our products and related procedures reverse or limit their coverage in the future, or if other third-party payors issue similar policies, this could have a material adverse effect on our business.

Further, we believe that future coverage and reimbursement may be subject to increased restrictions, such as additional prior authorization requirements, both in the United States and in international markets. If Medicare no longer covers any of our products, there would be a material adverse effect on our business, financial condition and results of operations. In addition, Medicare Administrative Contractors could issue a local coverage determination decision that could restrict the patients eligible for the treatment with our products or in another manner unfavorable to our business. Third-party coverage and reimbursement for procedures using our products or any of our products in development for which we may receive regulatory clearance or approval may not be available or adequate in either the United States or international markets. Further, other VTE treatments, such as thrombolytic drugs, may be more widely covered or subject to different co-pay policies and requirements, which could impact demand for our products. If hospital, physician and/or patient demand for our products is adversely affected by third-party reimbursement policies and decisions, it could have a material adverse effect on our business, financial condition and results of operations.

***The market for our products is highly competitive. Our competitors may have longer operating histories, more established products and greater resources than we do, and may be able to develop or market treatments that are safer, more effective or gain greater acceptance in the marketplace than our products.***

The medical device industry is highly competitive, subject to rapid change and significantly affected by the introduction of new products and technologies and other activities of industry participants. We compete with manufacturers of thrombolytic drugs, such as Roche, and with medical device companies that manufacture thrombectomy devices and systems used to treat vascular blockages. These systems include water jets, ultrasonic acoustic field generators, aspirators, catheters and others. Our primary medical device competitors are Boston Scientific Corporation, Penumbra, AngioDynamics, Teleflex, Shandong Weigao and smaller companies that have single products or a limited range of products. Some competitors offer products for mechanical and catheter-based thrombectomy procedures, many of which are existing products for the arterial system that have been retrofitted or adjusted for the venous system. These competing 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 market acceptance than our products.

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

- Established treatment patterns pursuant to which drugs are generally first-line or concurrent therapies for the treatment of VTE;
- Established relationships with hospitals and physicians who prescribe their drugs or are familiar with existing interventional procedures for the treatment of VTE;
- Established relationships with key stakeholders, including interventional cardiologists, interventional radiologists and vascular surgeons, referring physicians, vascular surgeons, pulmonologists, radiologists, general practitioners and administrators;
- Greater financial and human capital resources;
- Significantly greater name recognition;
- 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.

One of the major hurdles to adoption of our products will be overcoming established treatment patterns, which will require education of physicians and supportive clinical data. However, because of the size of the market opportunity for the treatment of DVT and PE, we believe current and potential future competitors will dedicate significant resources to aggressively promote their products or develop new products or treatments. New treatment options may be developed that could compete more effectively with our products due to the prevalence of VTE and the research and technological progress that exist within the market.

***We have limited experience manufacturing our products in commercial quantities and we face a number of manufacturing risks that may adversely affect our manufacturing abilities.***

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 Irvine, California, where we manufacture, assemble, inspect, test, package and ship our products. We currently produce our ClotTriever and FlowTriever products at this facility, and we do not have additional facilities. If this facility 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, almost all of whom are single source suppliers for the items and materials that they supply;
- Our inability to secure components, sub-assemblies and materials in a timely manner, in sufficient quantities or on commercially reasonable terms;
- Our inability to maintain compliance with quality system requirements or pass regulatory quality inspections;
- Our failure to increase production capacity or volumes to meet demand;
- Our 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.

These risks are likely to be exacerbated by our limited experience with our current products and manufacturing processes. 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 some future products may share product features, components, sub-assemblies and materials with our existing products, the manufacture of these products may require modification of our 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 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.***

We rely on single source suppliers for the vast majority of components, sub-assemblies and materials for our products, as well as to sterilize our final assembled products before they are shipped to customers. These components, sub-assemblies and materials are critical and, for certain items, there are relatively few alternative sources of supply. These single source suppliers may be unwilling or unable to supply the necessary materials and components or manufacture and assemble our products reliably and at the levels we anticipate or that are required by the market. While our suppliers have generally met our demand for their products and services on a timely basis in the past, we cannot guarantee that they will in the future be able to meet our demand for their products, either because of acts of nature, the nature of our agreements with those suppliers or our relative importance to them as a customer, and our suppliers may decide in the future to discontinue or reduce the level of business they conduct with us.

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 or sterilization may be available, we cannot be certain whether they will be available if and when we need them, or that any alternative suppliers or providers would be able to provide the quantity and quality of components, materials and sterilization that we would need to manufacture and ship our products if our existing suppliers and providers were unable to satisfy our requirements. To utilize other sources, we would need to identify and qualify new providers to our quality standards and obtain any additional regulatory approvals required to change providers, which could result in manufacturing delays and increase our expenses.

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

- Interruption of supply or sterilization resulting from modifications to, or discontinuation of, a third party's operations;
- Delays in product shipments resulting from uncorrected defects, reliability issues or a third party's failure to produce components or complete sterilizations that consistently meet our quality specifications;
- Price fluctuations due to a lack of long-term supply arrangements with our third parties for key components or sterilization requirements;
- Inability to obtain adequate supply or services in a timely manner or on commercially reasonable terms;
- Difficulty identifying and qualifying alternative third parties for the supply of components or for sterilization of our products in a timely manner;
- Inability of third parties to comply with applicable provisions of the FDA's Quality System Regulations, or QSR, or other applicable laws or regulations enforced by the FDA and state regulatory authorities;
- Inability to ensure the quality of products manufactured or sterilization conducted by third parties;
- Production delays related to the evaluation and testing of products and services from alternative third parties and corresponding regulatory qualifications; and
- Delays in delivery by our suppliers and service providers.

Although we require our third-party suppliers and providers to supply us with components and services that meet our specifications 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 these third parties will not always act consistent with our best interests, and may not always supply components or provide services that meet our requirements or in a timely manner.

***If we fail to comply with our obligations in our intellectual property licenses, including our agreements with Inceptus Medical LLC, we could lose license rights that are important to our business.***

We are a party to an amended and restated technology agreement with Inceptus Medical, LLC, or Inceptus, under which Inceptus has granted us a worldwide, exclusive (even as to Inceptus), royalty-free license to certain of its intellectual property related to the braiding technologies underlying its patent in the defined field of use for the treatment of embolism and thrombosis in human vasculature other than carotid arteries, coronary vasculature and cerebral vasculature. In addition, we are party to a sublicense agreement with Inceptus, pursuant to which Inceptus has granted us a non-transferable, worldwide, exclusive sublicense to its patent rights related to the tubular braiding for the non-surgical removal of clots and, with respect to our ClotTriever, treatment of embolism and thrombosis in human vasculature other than carotid arteries, coronary vasculature and cerebral vasculature, which rights were originally granted to Inceptus pursuant to an intellectual property license agreement with Drexel University. Both of our products use braiding technology. For example, our ClotTriever uses the sublicensed tubular braiding technology for the clot collection bag, which provides embolic protection and helps to secure and remove clot during procedures to treat DVT.

These agreements impose, and we expect that any future license agreements will impose, certain diligence, royalty and other obligations on us. Pursuant to the sublicense agreement with Inceptus, we are obligated to pay a quarterly royalty, calculated as a low single-digit percentage of net sales of implantable and non-implantable licensed products, which includes our ClotTriever product, with a minimum quarterly payment amount of $1,500. Additionally, we are obligated to pay Inceptus a small administration fee within 30 days of the beginning of each quarter.

If we fail to comply with the terms and obligations of our intellectual property licenses, including the payment obligations described above, our rights may be reduced or terminated, in which event we may not be able to develop and market any product that is covered by our intellectual property licenses. In addition, Inceptus may terminate the sublicense agreement if we cease bona fide development and commercialization of all licensed products for a period of six consecutive months. The sublicense agreement with Inceptus automatically terminates upon the termination of the intellectual property license agreement with Drexel University, and we cannot guarantee Inceptus' compliance with the terms of such intellectual property license agreement. In the event of termination of the intellectual property license agreement with Drexel University, Drexel University will, in good faith, grant to us a direct license on terms no less favorable than those given to Inceptus by Drexel University by Inceptus. Termination of this license for failure to comply with such obligations or for other reasons, or reduction or elimination of our licensed rights under it or any other license, 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 a new license for a similar intellectual property or braiding technology. 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 sublicense, and any failure by us or our licensors, including Inceptus and Drexel University, to obtain, maintain, defend and enforce these rights could have a material adverse effect on our business. In some cases, including in the case of the intellectual property licensed to us by Inceptus and Drexel University, we do not have control over the prosecution, maintenance or enforcement of the intellectual property that we license or sublicense, and may not have sufficient ability to provide input into the prosecution, maintenance and defense process with respect to such intellectual property, 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 intellectual property.

***ClotTriever and FlowTriever involve risks and have contraindications, which may limit adoption.***

Risks of catheter-based thrombectomy procedures with our products include the risks that are common to endovascular procedures, including perforation, dissection, embolization, bleeding, infection and nerve injury. DVT procedures also include the additional risks of causing PE. We are aware of certain characteristics and features of catheter-based thrombectomy procedures that may prevent widespread market adoption, including the fact that physicians would need to adopt and learn a new procedure, and that a degree of 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 circumstances for certain patients. Our ClotTriever is contraindicated for use without anticoagulation; use in the cerebral, carotid or coronary vasculature; use in the pulmonary arteries; use in endarterectomy procedures or vessel dilation; removal of fibrous, adherent or calcified material; use in vessels less than six millimeters in diameter; and use with power injectors. Our FlowTriever is contraindicated for use in the cerebral, carotid or coronary vasculature; use in endarterectomy procedures or vessel dilation; removal of fibrous, adherent or calcified material; use with power injectors; and use in vessels less than six millimeters in diameter, with the largest 24 French catheter contraindicated for use in vessels less than eight millimeters in diameter.

***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 third-party 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 limited historical commercial experience, 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 and adoption 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, which would negatively impact our gross margins and impair the strength of our brand. Conversely, if we underestimate customer demand for our products or our own requirements for components, sub-assemblies and materials, our third-party 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 or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, and our third-party 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, profitability 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. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the level of demand for our products which may vary significantly;
- expenditures that we may incur to acquire, develop or commercialize additional products and technologies;
- sales and marketing efforts and expenses;
- pricing pressures;
- the rate at which we grow our sales force and the speed at which newly hired salespeople become effective;
- changes in the productivity of our sales force;
- our ability to expand the geographic reach of our sales force;
- the degree of competition in our industry and any change in the competitive landscape of our industry, including consolidation among our competitors or future partners;
- changes in coverage and reimbursement policies with respect to our products, and potential future products that compete with our products;
- positive or negative coverage in the media or clinical publications of our products or products of our competitors or our industry;

- the timing of customer orders or medical procedures using our products and the number of available selling days in any quarterly period, which can be impacted by holidays, the mix of products sold and the geographic mix of where products are sold;

- the timing and cost of, and level of investment in, research, development, licenses, regulatory approval, commercialization activities, acquisitions and other strategic transactions, or other significant events relating to our products, which may change from time to time;

- the cost of manufacturing our products, which may vary depending on the quantity of production and the terms of our agreements with third-party suppliers; and

- future accounting pronouncements or changes in our accounting policies.

***Our long-term growth depends on our ability to enhance our products, expand our indications and develop and commercialize additional products in a timely manner. If we fail to identify, acquire and develop other products, we may be unable to grow our business.***

The market for our products is highly 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. Developing products is expensive and time-consuming and could divert management's attention away from our core business. The success of any new product offering or product enhancements to our solution will depend on several factors, including our ability to:

- assemble sufficient resources to acquire or discover additional products;

- properly identify and anticipate physician and patient needs;

- develop and introduce new products and product enhancements in a timely manner;

- avoid infringing upon the intellectual property rights of third-parties;

- demonstrate, if required, the safety and efficacy of new products with data from preclinical studies and clinical trials;

- obtain the necessary regulatory clearances or approvals for expanded indications, new products or product modifications;

- be fully FDA-compliant with marketing of new devices or modified products;

- produce new products in commercial quantities at an acceptable cost;

- provide adequate training to potential users of our products;

- receive adequate coverage and reimbursement for procedures performed with our products; and

- develop an effective and dedicated sales and marketing team.

If we are unable to develop or improve 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.

In addition, we may choose to focus our efforts and resources on potential products or indications that ultimately prove to be unsuccessful, or to license or purchase a marketed product that does not meet our financial expectations. As a result, we may fail to

capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other potential products or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such potential products through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights, which could adversely impact our business, financial condition and results of operations.

***Changes in public health insurance coverage and government reimbursement rates for 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, the United States Department of Health and Human Services Centers for Medicare and Medicaid Services, or 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. Consolidation in the healthcare industry or group purchasing organizations could lead to demands for price concessions, which may affect our ability to sell our products at prices necessary to support our current business strategies.***

In an effort to reduce costs, many hospitals in the United States, including some of our customers, are 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 may reduce market prices for our products, thereby reducing our revenue and 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.

Healthcare costs have risen significantly over the past decade, which has resulted in or led to numerous cost reform initiatives by legislators, regulators and third-party payors. Cost reform has triggered a consolidation trend in the healthcare industry to aggregate purchasing power, which may create more requests for pricing concessions in the future. Additionally, GPOs, IDNs and large single accounts may continue to use their market power to consolidate purchasing decisions for hospitals. We expect that market demand, government regulation, third-party coverage and reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our customers, which may exert further downward pressure on the prices of our products.

***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 payors reimburse our customers for our products 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, or if we add more components to our systems, 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 negatively affect our business, financial condition and results of operations.

***We may be unable to manage the anticipated growth of our business.***

In order to grow, we need to expand our sales personnel, manufacturing operations and general and administrative 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 of processing data or inability to meet increased demand. For example, we recently implemented a new enterprise resource planning, or ERP, system that facilitates orderly maintenance of books and records and the preparation of financial statements. ERP system implementations are complex projects that require significant investment of capital and human resources, the reengineering of many business processes and the attention of many employees who would otherwise be focused on other aspects of our business. The transition to our new ERP system may be disruptive to our business if it does not work as planned or if we experience issues related to the implementation. If we encounter difficulty meeting market demand, quality standards or physician expectations, our reputation could be harmed and our business could suffer.

***We may experience delays in production or an increase in costs if our single manufacturing facility is damaged or becomes inoperable, or if we are required to vacate our facility.***

We currently maintain our research and development, manufacturing and administrative operations in a building located in Irvine, California, which is situated on or near earthquake fault lines, and we do not have additional facilities. 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 capabilities 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 may require regulatory review and approval of the new facility prior to commencing full-scale production and commercialization. Because of the time required to register and/or 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 that we lose our 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 or losses caused by earthquakes or losses we may suffer due to our products being replaced by competitors' products. The inability to perform our research, development and manufacturing activities, combined with our limited and localized 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 September 2024, and we may be unable to renew our lease or find a new facility on commercially reasonable terms, or at all. 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, financial condition and results of operations.

***Performance issues, service interruptions or price increases by our shipping carriers could negatively affect our business, financial condition and results of operations and harm our reputation and the relationship between us and the hospitals we work with.***

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of our ClotTriever or FlowTriever products to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our solution and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for our ClotTriever or FlowTriever products on a timely basis.

***Our products may become obsolete in the future.***

The medical device industry is characterized by rapid and significant change. There can be no assurance that other companies will not succeed in developing or marketing devices or products that are more effective than our products or that would render our products obsolete or noncompetitive. Additionally, new surgical procedures, medications and other therapies could be developed that replace or reduce the importance of our products. Accordingly, our success will depend in part on our ability to respond quickly to medical and other changes through the development and introduction of new products. Product development involves a high degree of risk, and there can be no assurance that our new product development efforts will result in any commercially successful products.

***We provide a limited warranty for our products.***

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. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in costs to us.

***We may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships with third-parties that may not result in the development of commercially viable products or product improvements or the generation of significant future revenue.***

In the ordinary course of our business, we may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances, partnerships or other arrangements to develop new products or product improvements and to pursue new markets. Proposing, negotiating and implementing collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or viable product improvements or result in significant revenue and could be terminated prior to developing any products.

Additionally, we may not be in a position to exercise sole decision making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our future collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with any future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we may have limited control over the amount and timing of resources that any future collaborators devote to our or their future products.

Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. These arrangements may consume management time and resources to establish and maintain. Further, these transactions and arrangements will be contractual in nature and will generally be terminable under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium. If we enter into in-bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce intellectual property protection for the licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. Further, entering into such license agreements could impose various diligence, commercialization, royalty or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license, which could adversely affect our competitive business position and harm our business prospects.

***Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.***

We do not carry insurance for all categories of risk that our business may encounter. Although we carry product liability insurance in the United States, 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 do not carry specific hazardous waste insurance coverage, and our insurance policies generally exclude coverage for damages and fines arising from hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

We also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would negatively affect our business, financial condition and results of operations.

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

Our future success depends in part upon patients having an experience with our products 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 venous dissection or puncture, embolization of clot, stroke, heart attack and death. If the results of catheter-based thrombectomy procedures with our products do not meet the expectations of the patients, or the patient experiences adverse events, it could discourage the patient and treating physician from referring our products to others. Dissatisfied patients may express negative opinions through social media. Any failure to meet patient expectations and any resulting negative publicity 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 will negatively affect our business, financial condition and results of operations.***

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 William Hoffman, our Chief Executive Officer, Andrew Hykes, our Chief Commercial Officer, Mitchell Hill, our Chief Financial Officer, and Dr. Thomas Tu, our Chief Medical 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 our sales professionals 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, clinical operations 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. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages.

In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. 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. Many of our employees have become or will soon become vested in a substantial amount of our common stock or a number of common stock options. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock, particularly after the expiration of the lock-up agreements described herein. Our future success also depends on our ability to continue to attract and retain additional executive officers and other key employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, it will negatively affect our business, financial condition and results of operations.

***The use, misuse or off-label use of our products may result in injuries that lead to product liability suits, which could be expensive, divert management's attention and harm our reputation and business. We may not be able to maintain adequate product liability insurance.***

Our products have been cleared by the FDA for specific indications and meet certain treatment parameters. If physicians expand the patient population in which they elect to use our products such that it is outside of the intended use that has been cleared by the FDA, then such use, misuse or off-label use of our products may result in outcomes and adverse events including death, potentially leading to product liability claims. Our products are not indicated for use in all patients with VTE and therefore cannot be marketed or advertised in the United States for certain uses without additional 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 procedures with our products. There may be increased risk of injury to patients if physicians attempt to use our devices off-label. 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 not effectively treat the applicable conditions and may expose us to product liability claims or litigation by our customers or their patients and may harm our reputation.

We currently market our ClotTriever product, which has been cleared by the FDA for the non-surgical removal of soft thrombi and emboli from blood vessels in the peripheral vasculature, for use in the peripheral vasculature. Although we believe that the current FDA-cleared indication covers the use of the ClotTriever for the treatment of DVT, we are in the process of seeking clearance for a specific indication for treatment of DVT and removal of the word "soft." However, the FDA may determine that the clinical data we have provided or will provide is insufficient to support this indication and therefore not grant or delay clearance. For example, in February 2020, the FDA requested that we provide additional information in connection with such submission, and we are currently in the process of collecting and analyzing the requested additional data. Further, the FDA may disagree with our belief that our existing indication is broad enough to cover indication for treatment of DVT, in which case the FDA could assert that we are marketing the product outside of its cleared indication for use.

Moreover, if the FDA or any foreign regulatory body determines that our promotional materials, activities or training constitute promotion of an off-label use, they could request that we modify our training or promotional materials or activities or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations. 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.

***We may need additional funding to finance our planned operations, 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.***

Since inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future. To date, our primary sources of capital have been the net proceeds we received through private placements of preferred stock, debt financing agreements, the sale of our common stock in our IPO and revenue from the sale of our products. As of June 30, 2020, we had $194.8 million in cash and cash equivalents, long-term debt of $30.0 million and an accumulated deficit of $40.9 million. Based on our current planned operations, we expect that our cash and cash equivalents and available borrowings will enable us to fund our operating expenses for at least 12 months from the date hereof. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

We expect to continue to invest in clinical trials and registries that are designed to provide clinical evidence of the safety and efficacy of our products, expanding our sales and marketing organization, and research and development of product improvements and future products. Moreover, we expect to incur additional expenses associated with operating as a public company, including legal,

accounting, insurance, exchange listing and SEC compliance, investor relations and other expenses. Because of these and other factors, we expect to continue to incur net losses and negative cash flows from operations for the foreseeable future. Our future funding requirements will depend on many factors, including:

- The degree and rate of market acceptance of our products and catheter-based thrombectomy procedures;
- Whether we acquire third-party companies, products or technologies;
- Repayment of debt;
- The scope and timing of investment in our sales force and expansion of our commercial organization;
- The impact on our business from the ongoing and global COVID-19 pandemic, or any other pandemic, epidemic or outbreak of an infectious disease;
- The scope, rate of progress and cost of our current or future clinical trials and registries;
- The cost of our research and development activities;
- The cost and timing of additional regulatory clearances or approvals;
- The costs associated with any product recall that may occur;
- The costs of attaining, defending and enforcing our intellectual property rights;
- The terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- 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 may also 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, and the price per share at which we sell additional shares of our common stock, or securities convertible into or exercisable or exchangeable for shares of our common stock, in future transactions may be higher or lower than the price per share paid by investors.

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 incur additional debt or issue additional equity, limitations on our ability to pay dividends, limitations on our ability to acquire or license intellectual property rights, 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.***

In December 2019, we prepaid and terminated our amended and restated loan and security agreement with East West Bank, or the Amended and Restated EWB Loan Agreement, and concurrently entered into a $40 million credit facility with Signature Bank, or the SB Credit Facility. The SB Credit Facility consists of a term loan of up to $25 million, which bears interest at an annual rate equal to the greater of 5.50% or Signature Bank's most recently announced prime rate plus 0.50%, and a revolving line of credit of $15 million, which bears interest at an annual rate equal to the greater of 5.0% or Signature Bank's most recently announced prime rate. As of June 30, 2020, we had an aggregate of approximately $30.0 million in principal outstanding under the SB Credit Facility. We must make interest payments under the SB Credit Facility, which has diverted and will continue to divert resources from other activities. For the year ended December 31, 2019, we incurred interest expense of $0.9 million related to our debt agreements, which included payments made under the Amended and Restated EWB Loan Agreement and, beginning in December 2019, the SB Credit Facility. For the six months ended June 30, 2020, we incurred interest expense of $0.8 million related to the SB Credit Facility. Our obligations under the SB Credit Facility are collateralized by substantially all of our assets, excluding intellectual property, and we are subject to customary financial and operating covenants limiting our ability to, among other things, relocate or dispose of assets, undergo a change in control, merge or consolidate, enter into certain transactions with affiliates, make acquisitions, incur debt, pay dividends, grant liens, store certain amounts of inventory or equipment with third parties and make investments, in each case subject to certain exceptions. The covenants related to the SB Credit Facility, 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 SB Credit Facility or other debt arrangements, 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 SB Credit Facility. If not waived, future defaults could cause all of the outstanding indebtedness under the SB Credit Facility to become immediately due and payable and terminate commitments to extend further credit and foreclose on the collateral granted to it to collateralize such indebtedness. 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.

In order to service this indebtedness and any additional indebtedness we may incur in the future, we need to generate cash from our operating activities. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory and other factors beyond our control. We cannot assure you that our business will be able to generate sufficient cash flow from operations or that future borrowings or other financings will be available to us in an amount sufficient to enable us to service our indebtedness and fund our other liquidity needs. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness instead of funding working capital, capital expenditures or other general corporate purposes, we will be less able to plan for, or react to, changes in our business, industry and in the economy generally. This may place us at a competitive disadvantage compared to our competitors that have less indebtedness.

***We may acquire other companies or technologies, which could fail to result in a commercial product or net sales, divert our management's attention, result in additional dilution to our stockholders and otherwise disrupt our business.***

Although we currently have no agreements or commitments to complete any such transactions and are not involved in negotiations to do so, we may in the future seek to acquire or invest in businesses, applications or technologies that we believe could complement or expand our portfolio, enhance our technical capabilities or otherwise offer growth opportunities. However, we cannot assure you that we would be able to successfully complete any acquisition we choose to pursue, or that we would be able to successfully integrate any acquired business, product or technology in a cost-effective and non-disruptive manner. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment.

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 fails to meet our expectations, our business, financial condition and results of operations may be negatively affected.

***Taxing authorities may successfully assert that we should have collected or in the future should collect sales and use, gross receipts, value added or similar taxes and may successfully impose additional obligations on us.***

One or more jurisdictions may seek to impose additional tax collection obligations on us, including for past sales. A successful assertion by a state, country, or other jurisdiction that we should have been or should be collecting additional sales, use, or other taxes

on our services could, among other things, result in substantial tax liabilities for past sales, create significant administrative burdens for us, discourage users from purchasing our products, or otherwise harm our business, results of operations and financial condition.

***Our ability to utilize our net operating loss carryforwards and research and development carryforwards may be limited.***

As of December 31, 2019, we had U.S. federal and state net operating loss carryforwards, or NOLs, of $30.5 million and $27.4 million, respectively, and U.S. federal and state research and development credit carryforwards of $0.9 million and $1.8 million, respectively. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change," generally defined as a greater than 50 percentage point change by value in its equity ownership over a rolling three-year period, is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, and its research and development credit carryforwards to offset future taxable income. Our existing NOLs and research and development credit carryforwards have been, and may in the future be, subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs and research and development credit carryforwards could be further limited by Sections 382 and 383 of the Code. In addition, our ability to deduct net interest expense may be limited if we have insufficient taxable income for the year during which the interest is incurred, and any carryovers of such disallowed interest would be subject to the limitation rules similar to those applicable to NOLs and other attributes. Future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Code. For these reasons, in the event we experience a future change of control, we may not be able to utilize a material portion of the NOLs, research and development credit carryforwards or disallowed interest expense carryovers, even if we attain profitability.

In addition, the tax benefit of NOLs, temporary differences and credit carryforwards are required to be recorded as an asset to the extent that we assess that realization is more likely than not. We believe that recognition of the deferred tax asset arising from these future tax benefits is not likely to be realized and, accordingly, have provided a valuation allowance of $11.5 million and $11.8 million for the years ended December 31, 2018 and 2019, respectively.

***The impact of the Tax Cuts and Jobs Act on our financial results is not entirely clear and could differ materially from the financial statements provided herein.***

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act, or the TCJA, that significantly reformed the Code. The TCJA, among other things, contained significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; limitation of the tax deduction for interest expense; limitation of the deduction for NOLs and elimination of NOL carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such tax losses may be carried forward indefinitely); and modifying or repealing many business deductions and credits. The financial statements contained herein reflect the effects of the TCJA based on current guidance.

However, there remain uncertainties and ambiguities in the application of certain provisions of the TCJA, and, as a result, we made certain judgments and assumptions in the interpretation thereof. The U.S. Treasury Department and the Internal Revenue Service may issue further guidance on how the provisions of the TCJA will be applied or otherwise administered that differs from our current interpretation. In addition, the TCJA could be subject to potential amendments and technical corrections, any of which could materially lessen or increase certain adverse impacts of the legislation on us.

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

Our long-term strategy is to increase our international presence, including securing regulatory approvals in targeted countries outside the United States. We have applied to affix the Conformité Européene, or CE, mark to our ClotTriever and FlowTriever products, allowing us to commercialize in Europe in the future. This strategy may include establishing and maintaining physician outreach and education capabilities outside of the United States and expanding our relationships with international payors. 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 payor reimbursement regimes, government payors or patient self-pay systems;
- 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 payors;
- 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.

***The United Kingdom's withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business.***

On January 31, 2020, the United Kingdom, or the UK, withdrew from the European Union, or the EU, following its referendum in June 2016. The terms of the UK's withdrawal from the EU provide for a transitional period until December 31, 2020, during which the status quo is maintained and the UK government will attempt to negotiate the terms of its future relationship with the EU. Nevertheless, the withdrawal has created significant uncertainty about the future relationship between the UK and the EU, including with respect to the laws and regulations that will apply as the UK determines which EU laws to replace or replicate. The withdrawal has also given rise to calls for the governments of other EU member states to consider withdrawal. These developments, or the perception that any of them could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these factors could depress economic activity and restrict our access to capital, which could have a material adverse effect on our business, financial condition and results of operations and reduce the price of our common stock.

***Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or our customer's 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. We are taking measures to implement policies and procedures designed to ensure compliance with applicable data security and privacy-related laws and regulations and protect sensitive information from unauthorized access or disclosure. However, our information technology, or IT, and infrastructure, and that of our third-party billing and collections provider and other technology partners and providers, may be vulnerable to cyber attacks by hackers or viruses or breaches 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. For example, companies have experienced an increase in phishing and social engineering attacks from third-parties in connection with the COVID-19 global pandemic. 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, and such breakdowns or breaches could adversely affect our business, our financial condition and our reputation.

***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. The U.S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, the U.S. Foreign Corrupt Practices Act, or the FCPA, and other federal statutes and regulations, including those established by the Office of Foreign Assets Control, or OFAC. In addition, the U.K. Bribery Act of 2010, or the Bribery Act, prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that fails to prevent bribery by anyone associated with the organization can be charged under the Bribery Act unless the organization can establish the defense of having implemented adequate procedures to prevent bribery. Under these laws and regulations, as well as other anti-corruption laws, anti-money laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties and other sanctions.

We are in the process of further enhancing policies designed to ensure compliance by us and our directors, officers, employees, representatives, consultants and agents with the FCPA, OFAC restrictions, the Bribery Act and other export control, anti-corruption, anti-money-laundering and anti-terrorism laws and regulations. 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, nor can we assure you that our business partners have not engaged and will not engage in conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct. 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**

***Our success will depend on our, and any of our current and future licensors', ability to obtain, maintain and protect our intellectual property rights.***

Our commercial success will depend in part on our, and any of our current or future licensors', success in obtaining and maintaining issued patents, trademarks and other intellectual property rights in the United States and elsewhere and protecting our proprietary technology. If we, or any of our current or future licensors, do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies or the goodwill we have acquired in the marketplace and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

Our intellectual property coverage includes protection provided by patents licensed through the Inceptus License and Inceptus Sublicense. We rely on Inceptus to maintain the patents and otherwise protect the intellectual property we license directly from them pursuant to the Inceptus License. We further rely on Drexel University to maintain the patents and otherwise protect the intellectual property we sublicense from Inceptus pursuant to the Inceptus Sublicense. Our licensors, including Inceptus and Drexel University, may not successfully prosecute the intellectual property applications, including patent applications, that we have licensed, may fail to maintain these patents, or may determine not to pursue litigation against other companies that are infringing this intellectual property, or may pursue such litigation less aggressively than we would. If, in the future, we no longer have rights to one or more of these licensed patents or other licensed intellectual property, our intellectual property coverage may be compromised, which, in turn, could affect our ability to protect our products and defend them against competitors. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects.

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 products, 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, despite our efforts to enter into confidentiality agreements with our employees, consultants, clients and other vendors who have access to such information, our trade secrets, data and know-how could be subject to unauthorized use, misappropriation, or disclosure to unauthorized parties, 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.

We own numerous issued patents and pending patent applications. As of June 30, 2020, we held 18 U.S. patents (including one allowed matter), which are expected to expire between November 2032 and April 2037, 14 pending U.S. patent applications, three issued foreign patents, 16 pending foreign patent applications and two pending Patent Cooperation Treaty applications, excluding our licensed and sublicensed patents. We also licensed two U.S. patents and sublicensed one U.S. patent. The patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and therefore, the scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty.

Though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Patents, if issued, may be challenged, deemed unenforceable, invalidated or circumvented. Proceedings challenging our patents could result in either loss of the patent, or denial or the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own may not provide any protection against competitors. Furthermore, an adverse decision may result in a third party receiving a patent right sought by us, which in turn could affect our ability to commercialize our products. Competitors could purchase our products and attempt to replicate or reverse engineer some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our patents, or develop and obtain patent protection for more effective technologies, designs or methods. We may be unable to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, former employees and current employees. Further, the laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our products are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our products, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- Any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our products;

- Any of our pending patent applications will issue as patents;
- We will be able to successfully commercialize our products on a substantial scale, if approved, before our relevant patents we may have expire;
- We were the first to make the inventions covered by each of our patents and pending patent applications;
- We were the first to file patent applications for these inventions;
- Others will not develop similar or alternative technologies that do not infringe our patents; any of our patents will be found to ultimately be valid and enforceable;
- Any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- We will develop additional proprietary technologies or products that are separately patentable; or
- Our commercial activities or products will not infringe upon the patents of others.

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.

The U.S. federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights.” March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license to itself. Our business relies heavily on the Inceptus Sublicense, which is a sublicense from Drexel University that is explicitly subject to all applicable U.S. government rights, including, but not limited to, any applicable requirement that products, which result from such intellectual property and are sold in the United States, must be substantially manufactured in the United States. Thus we cannot be sure that some of our intellectual property will be free from government rights or regulations pursuant to the Bayh-Dole Act. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

***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 U.S. Patent and Trademark Office, or 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.

***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.

***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 our technologies or 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, patent applications or other intellectual property, 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.

Any lawsuits relating to intellectual property rights could subject us to significant liability for damages and invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following:

- Stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property;

- Lose the opportunity to license our intellectual property to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others; incur significant legal expenses;
- Pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing;
- Pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;
- Redesign those products or technologies that contain the allegedly infringing intellectual property, which could be costly, disruptive and infeasible; and
- Attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all, or from third parties who may attempt to license rights that they do not have.

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.

Any litigation or claim against us, even those without merit and even those where we prevail, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages (which may be increased up to three times of awarded damages) and/or substantial royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. We could encounter delays in product introductions while we attempt to develop alternative methods or products. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products.

In addition, we generally indemnify our customers with respect to infringement by our products of the proprietary rights of third parties. However, third parties may assert infringement claims against our customers. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products.

Similarly, interference or derivation proceedings provoked by third parties or brought by the 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 or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors may infringe our issued patents 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 or other intellectual property infringement proceeding, a court may decide that a patent or other intellectual property of ours is invalid or unenforceable, in whole or in part, construe the patent's claims or other intellectual property narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents or other intellectual property do not cover the technology in question. Furthermore, even if our patents or other intellectual property 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 or other intellectual property at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business position, financial condition and results of operations.

***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 the unwanted use is outside the scope of the provisions of the contracts or 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 development or business 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 products 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 or products similar to ours or competing technologies or products, 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.

***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 any patents or patent applications 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 in those jurisdictions, as well as elsewhere 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. 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.***

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.

***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. 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**

***Our products and operations are subject to extensive government regulation and oversight in the United States.***

Our products are regulated as medical devices. We and our products are subject to extensive regulation in the United States, including by the FDA, and may in the future be subject to regulation elsewhere and by the FDA's foreign counterparts. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices: design, development, manufacturing and release; laboratory, preclinical and clinical testing; labeling, packaging, content and language of instructions for use and storage; product safety and efficacy; establishment registration and device listing; marketing, sales and distribution; pre-market clearance and approval; service operations; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market studies; and product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA enforces these regulatory requirements through, among other means, periodic unannounced inspections. We do not know whether we will be found compliant in connection with any future FDA inspections. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances or approvals; withdrawals or suspensions of current approvals, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties.

***We may not receive, or may be delayed in receiving, the necessary clearances or approvals for our future products or modifications to our current products, and failure to timely obtain necessary clearances or approvals for our future products or modifications to our current products would adversely affect our ability to grow our business.***

In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive either clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, or approval of a pre-market approval application, or PMA, from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. 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 are sometimes required to support substantial equivalence. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices.

Modifications to products that are approved through a PMA application generally require FDA approval. Similarly, certain modifications made to products cleared through a 510(k) may require a new 510(k) clearance. Both the PMA approval and the 510(k) clearance process can be expensive, lengthy and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, a device may not be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory clearances or approvals could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the device, which may limit the market for the device.

In the United States, we have obtained clearance of our ClotTriever and FlowTriever products through the 510(k) clearance process. Any modification to these systems that has not been previously cleared may require us to submit a new 510(k) premarket notification and obtain clearance, or submit a PMA and obtain FDA approval prior to implementing the change. Specifically, any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major

change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have made modifications to 510(k)-cleared products in the past and have determined based on our review of the applicable FDA regulations and guidance that in certain instances new 510(k) clearances or PMA approvals were not required. We may make modifications or add additional features in the future that we believe do not require a new 510(k) clearance or approval of a PMA. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMA applications for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.

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 or implementation of our clinical trials or the interpretation of data from preclinical studies or clinical trials;
- Serious and unexpected adverse device effects experienced by participants in our clinical trials;
- The data from our preclinical 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;
- The manufacturing process or facilities we use may not meet applicable requirements; and
- 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.

In order to sell our products in member countries of the European Economic Area, or the EEA, which is comprised of the 27 Member States of the EU plus Norway, Liechtenstein and Iceland, and the UK (until the end of the transition period on December 31, 2020 provided for in the withdrawal agreement between the EU and the UK), our products must comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93/42/EEC). Compliance with these requirements is a prerequisite to be able to affix the CE mark to our products, without which they cannot be sold or marketed in the EEA. To demonstrate compliance with the essential requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directive, a conformity assessment procedure requires the intervention of an organization accredited by a member state of the EEA to conduct conformity assessments, or a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. If we fail to remain in compliance with applicable European laws and directives, we would be unable to continue to affix the CE mark to our products, which would prevent us from selling them within the EEA.

***Failure to comply with post-marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market.***

Even though we have obtained FDA clearance for our ClotTriever and FlowTriever products in the United States, we are subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, import, export, registration, and listing of devices. For example, we must submit periodic reports to the FDA as a condition of 510(k) clearance. These reports include information about failures and certain adverse events associated with the device after its clearance. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation.

The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. Even after we have obtained the proper regulatory clearance to market a device, we have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. The FDA, state and foreign regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, which may include any of the following sanctions:

- Untitled letters, warning letters or adverse publicity;
- Fines, injunctions, consent decrees and civil penalties;
- Recalls, termination of distribution, administrative detention, or seizure of our products;
- Customer notifications or repair, replacement or refunds;
- Operating restrictions or partial suspension or total shutdown of production;
- Delays in or refusal to grant our requests for future clearances or approvals or foreign marketing authorizations of new products, new intended uses, or modifications to existing products;
- Withdrawals or suspensions of our current 510(k) clearances, resulting in prohibitions on sales of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- Criminal prosecution.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and results of operations.

In addition, the FDA may change its clearance policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay clearance or approval of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new clearances or approvals, increase the costs of compliance or restrict our ability to maintain our clearances of our current products. For example, the FDA recently announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. For more information, see "—Legislative or regulatory reforms in the United States or the EU may 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."

***Our products must be manufactured in accordance with federal and state regulations, and we could be forced to recall our devices or terminate production if we fail to comply with these regulations.***

The methods used in, and the facilities used for, the manufacture of our products must comply with the FDA's QSR, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices. Furthermore, we are required to maintain, and to verify that our suppliers maintain, facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our former facility in Irvine, California was audited by the FDA in August 2016 which resulted in the issuance of two Form-483 observations regarding (i) our procedures for Medical Device Event Reports, which did not specify submitting a supplemental report to the FDA within 30 days after receiving new information from a complainant, and (ii) our risk management report and evaluation protocol, which were not completed prior to human use evaluation. Written responses correcting the observations were provided to the FDA 15 days after receipt and, in November 2016, the FDA notified us that the inspection was closed. Neither of these Form-483 observations will

impact our current facility. However, no FDA inspection has been conducted at our current facility in Irvine, California. As described below, we initiated a voluntary recall of three lots of our Triever aspiration catheters in March 2020, and it is possible that the FDA will conduct an announced or unannounced inspection of our facility to review our procedures and operations. Our products will also be subject to similar state regulations, various laws and regulations of foreign countries governing manufacturing and a requirement for adherence to industry standards of the International Standards Organization, or ISO, in connection with our medical device operations to maintain future CE marks.

Our third-party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's refusal to grant pending or future clearances or approvals for our products; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us, our suppliers, or our employees.

We have received ISO 13485:2016 certification for our quality management system. ISO certification generally includes recertification audits every third year, scheduled annual surveillance audits and periodic unannounced audits.

We can provide no assurance that we will be found to remain in compliance with the QSR or ISO standards upon a regulator's review. If the FDA or the California Department of Public Health, or other regulator, inspects any of our facilities and discovers compliance problems, we may have to cease manufacturing and product distribution until we can take the appropriate remedial steps to correct the audit findings. Any of the actions noted above could significantly and negatively affect supply of our products. Taking corrective action may be expensive, time-consuming and a distraction for management. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and experience reduced sales and increased costs.

***Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could negatively affect our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.***

We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance or approval, seizure of our products or delay in clearance or approval of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. For example, in March 2020, we initiated a voluntary recall of three lots of our Triever aspiration catheters (371 products in total) because of a potential leak and failure to seal in the hemostasis valve on the catheters, which could result in the loss of vacuum pressure and aspiration during use. We voluntarily initiated this recall after we received customer reports regarding potential leaks involving 12 products in the three impacted lots. All affected customers have been notified and have responded to the recall notice. We have not received any customer reports following the recall notice and there have been no reported adverse patient outcomes resulting from the impacted products. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

If we initiate a correction or removal for our products to reduce a risk to health posed by them or to remedy a violation of law that may present a risk to health, we would be required to submit a report to the FDA and may be required to submit similar notifications to other regulatory authorities. This report could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our products. Furthermore, the submission of these reports, to the extent made publicly available in accordance with FDA regulations, could be used by competitors against us and cause physicians to delay or cancel product orders, which will harm our reputation.

If we assess a potential quality issue or complaint as not requiring either field action or regulatory notification, regulators may review documentation of that decision during a subsequent audit. If regulators disagree with our decision, or take issue with either our investigation process or the resulting documentation, regulatory agencies may impose sanctions and we may be subject to regulatory enforcement actions, including warning letters, all of which will negatively affect our business, financial condition and results of operations.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new clearances or approvals for the device before we may market or distribute the corrected device. Seeking such clearances or approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and will negatively affect our reputation, business, financial condition and results of operations.

***If we do not obtain and maintain international regulatory registrations, clearances or approvals for our products, we will be unable to market and sell our products outside of the United States.***

Any future sales of our products outside of the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the United States. While the regulations of some countries may not impose barriers to marketing and selling our products or only require notification, others require that we obtain the clearance or approval of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations, clearances or approvals, can be expensive and time-consuming, and we may not receive regulatory clearances or approvals in each country in which we plan to market our products or we may be unable to do so on a timely basis. The time required to obtain registrations, clearances or approvals, if required by other countries, may be longer than that required for FDA clearance or approval, and requirements for such registrations, clearances or approvals may significantly differ from FDA requirements. If we modify our products, we may need to apply for regulatory clearances or approvals before we are permitted to sell the modified product.

In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we have received. If we are unable to maintain our authorizations in a particular country, we will no longer be able to sell the applicable product in that country.

Regulatory clearance or approval by the FDA does not ensure registration, clearance or approval by regulatory authorities in other countries, and registration, clearance or approval by one or more foreign regulatory authorities does not ensure registration, clearance or approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining registration or regulatory clearance or approval in one country may have a negative effect on the regulatory process in others.

***Legislative or regulatory reforms in the United States or the EU may 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.***

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. In May 2019, the FDA solicited public feedback on these proposals. The FDA requested public feedback on whether it should consider certain actions that might require new authority, such as whether to sunset certain older devices that were used as predicates under the 510(k) clearance pathway. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation. Accordingly, it is unclear the extent to which any

proposals, if adopted, could impose additional regulatory requirements on us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance, or restrict our ability to maintain our current clearances, or otherwise create competition that may negatively affect our business.

More recently, in September 2019, the FDA finalized guidance describing an optional "safety and performance based" premarket review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA intends to develop and maintain a list of device types appropriate for the "safety and performance based" pathway and will continue to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible. The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain new 510(k) clearances or otherwise create competition that may negatively affect our business.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay regulatory clearance or approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. 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.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member states, the regulations would be directly applicable (i.e., without the need for adoption of EEA member state laws implementing them) in all EEA member states and are intended to eliminate current differences in the regulation of medical devices among EEA member states. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation.

The Medical Devices Regulation will, however, only become effective three years after publication (in 2020). Once effective, the new regulations will among other things:

- Strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- Establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- Improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- Set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- Strengthen the rules for the assessment of certain high-risk devices, which may have to undergo an additional check by experts before they are placed on the market.

These modifications may have an effect on the way we conduct our business in the EEA.

***Interim, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publicly disclose interim, top-line or preliminary data from our clinical registries and trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular registry, study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, top-line or preliminary results that we report may differ from future results of the same registry, study or trial, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim, top-line or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim, top-line or preliminary data we previously published. As a result, interim, top-line and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. For example, we have reported interim data from our ongoing CLOUT registry trial elsewhere in this prospectus. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our products and product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

***Changes in funding for, or disruptions caused by global health concerns impacting, the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed, cleared or approved or commercialized in a timely manner, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory, and policy changes and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new devices to be reviewed and/or approved or cleared by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone inspections of foreign manufacturing facilities and products, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Other regulatory authorities may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting business as usual or conducting inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

***The clinical trial process is lengthy and expensive with uncertain outcomes. We have limited data and experience regarding the safety and efficacy of our products. Results of earlier studies may not be predictive of future clinical trial results, or the safety or efficacy profile for such products.***

Clinical testing is difficult to design and implement, can take many years, can be expensive and carries uncertain outcomes. We are currently enrolling patients in our CLOUT and FLASH registries and may in the future conduct additional clinical trials for our future products. The results of preclinical studies and clinical trials of our products conducted to date and ongoing or future studies and trials of our current, planned or future products may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we

will achieve similar results in future clinical trials. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical trials have nonetheless failed to produce strong results in later clinical trials. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials. We incur substantial expense for, and devote significant time to, clinical trials but cannot be certain that the trials will continue to result in commercial revenue. Failure can occur at any stage of clinical testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned.

The initiation and completion of any of clinical trials may be prevented, delayed, or halted for numerous reasons. We may experience delays in our ongoing clinical trials for a number of reasons, which could adversely affect the costs, timing or successful completion of our clinical trials, including related to the following:

- We may be required to submit an Investigational Device Exemption, or IDE, application to FDA, which must become effective prior to commencing certain human clinical trials of medical devices, and FDA may reject our IDE application and notify us that we may not begin clinical trials;
- Regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- Regulators and/or institutional review boards, or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- We may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- Clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- The number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- Our third-party contractors, including those manufacturing products or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- We might have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- We may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and/or regulatory authorities for re-examination;
- Regulators, IRBs, or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- The cost of clinical trials may be greater than we anticipate;
- Clinical sites may not adhere to our clinical protocol or may drop out of a clinical trial;
- We may be unable to recruit a sufficient number of clinical trial sites;

- Regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;

- Approval policies or regulations of FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval; and

- Our current or future products may have undesirable side effects or other unexpected characteristics.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in our planned and ongoing clinical trials. For example, since the outbreak of the COVID-19 pandemic, we have observed a decrease in new patient enrollment in our registries. If COVID-19 continues to spread, we may experience disruptions that could have a material adverse impact on our clinical trial plans and timelines, including:

- delays in receiving authorizations from local regulatory authorities 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 contract 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 denial of regulatory approval of our product candidates.

Patient enrollment in clinical trials and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, patient compliance, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved for the indications we are investigating. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures, monitoring or follow-up to assess the safety and efficacy of a product candidate, or they may be persuaded to participate in contemporaneous clinical trials of a competitor's product candidate. In addition, patients participating in our clinical trials may drop out before completion of the trial or experience adverse medical events unrelated to our

products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delays, or result in the failure of the clinical trial.

Clinical trials must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our devices produced under current good manufacturing practice, or cGMP, requirements and other regulations. Furthermore, we may rely on CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we may have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with good clinical practice, or GCP, requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

Even if our future products are cleared or approved in the United States, commercialization of our products in foreign countries would require clearance or approval by regulatory authorities in those countries. Clearance or approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. Any of these occurrences could have an adverse effect on our business, financial condition and results of operations.

***We are subject to certain federal, state and foreign fraud and abuse laws, health information privacy and security laws and transparency laws that could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.***

There are numerous U.S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims and physician transparency laws. Our business practices and relationships with providers are subject to scrutiny under these laws. We may also be subject to privacy and security regulation related to patient, customer, employee and other third-party information by both the federal government and the states and foreign jurisdictions in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. 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. The U.S. government has interpreted this law broadly to apply to the marketing and sales activities of manufacturers. 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 significant civil monetary penalties, 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 significant criminal fines and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;

- The federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal healthcare programs that are false or fraudulent. These laws can apply to manufacturers who provide information on coverage, coding, and reimbursement of their products to persons who bill third-party payors. 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 significant civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- 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 Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, 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;

- The federal Physician Payments Sunshine Act which requires certain applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, or CHIP, to report annually to the DHHS Centers for Medicare and Medicaid Services, or CMS, information related to payments and other transfers of value to physicians, which is defined broadly to include other healthcare providers and teaching hospitals, and applicable manufacturers and group purchasing organizations, to report annually ownership and investment interests held by physicians and their immediate family members. Additionally, on October 25, 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. Failure to submit required information may result in significant civil monetary penalties (and additional penalties 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 of 2009, or HITECH Act, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements. Failure to comply with the HIPAA privacy and security standards can result in significant civil monetary penalties, and, in certain circumstances, criminal penalties with fines 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;

- The FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- Federal and state laws and regulations regarding billing and claims payment applicable to our products and regulatory agencies enforcing those laws and regulations; 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 payor, 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 EU 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.

These laws and regulations, among other things, constrain our business, marketing and other promotional and research activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of our products. We have entered into consulting agreements with physicians, including some who have ownership interests in us, which could be viewed as influencing the purchase of or use of our products in procedures they perform. Compensation under some of these arrangements includes the provision of stock or stock options. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

Any action brought against us for violations of these laws or regulations, even if 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, with potential liability under the federal False Claims Act including mandatory treble damages and significant per-claim penalties.

To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business, financial condition and results of operations. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to.

Our activities, including those relating to providing billing, coding, coverage and reimbursement information about procedures using our products to our customers and the sale and marketing of our products, may be subject to scrutiny under these laws. 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. 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 significant penalties, including significant criminal, civil, and administrative penalties, damages, fines, exclusion from participation in government programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputation harm and disgorgement and we could be required to curtail, restructure or cease our operations. Any of the foregoing consequences will negatively affect our business, financial condition and results of operations.

***We are subject to governmental regulations and other legal obligations, particularly related to privacy, data protection and information security, and we are subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices. Our actual or perceived failure to comply with such obligations could harm our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue.***

In the conduct of our business, we may at times process personal data, including health-related personal data. The U.S. federal government and various states have adopted or proposed laws, regulations, guidelines and rules for the collection, distribution, use and storage of personal information of individuals. We may also be subject to U.S. federal rules, regulations and guidance concerning data security for medical devices, including guidance from the FDA. According to the Federal Trade Commission, or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. State privacy and security laws vary from state to state and, in some cases, can impose more restrictive requirements than U.S. federal law.

In addition, certain state and non-US laws, such as the European Union General Data Protection Regulation (2016/679), or GDPR, govern the privacy and security of health information in certain circumstances, some of which are more stringent than U.S. federal law and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Where state laws are more protective, we must comply with the stricter provisions. In addition to fines and penalties that may be imposed for failure to comply with state law, some states also provide for private rights of action to individuals for misuse of personal information. For example, California enacted the California Consumer Privacy Act, or CCPA, on June 28, 2018, which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. In Europe, the GDPR went into effect in May 2018 and introduces strict requirements for processing the personal data of European Union data subjects. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenue of the noncompliant company, whichever is greater.

Any actual or perceived failure by us or the third parties with whom we work to comply with privacy or security laws, policies, legal obligations or industry standards, or any security incident that results in the unauthorized release or transfer of personally

identifiable information, may result in governmental enforcement actions and investigations including by European Data Protection Authorities and U.S. federal and state regulatory authorities, fines and penalties, litigation and/or adverse publicity, including by consumer advocacy groups, and could cause our customers, their patients and other healthcare professionals to lose trust in us, which could harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

We cannot assure you that any third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, results of operations and financial condition. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, storage and transmission of such information. Increasing use of social media could also give rise to liability, breaches of data security or reputational damage.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, CROs, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

***Our employees, consultants, and other commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, consultants, and other commercial partners and business associates may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate the regulations of the FDA and other regulators (both domestic and foreign), including those laws requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the United States and internationally or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry, including the sale of medical devices, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter misconduct by our employees, consultants and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of operations, any of which could adversely affect our business, financial condition and results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees and reputational harm, and divert the attention of management in defending ourselves against any of these claims or investigations.

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

Our research, development and manufacturing operations involve the use of hazardous substances, such as isopropyl alcohol and various adhesives. We are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, handling, generation, manufacture, treatment, discharge and disposal of, hazardous substances. Our products may also contain hazardous substances, and they are subject laws and regulations relating to labelling requirements and to their sale, collection, recycling, treatment, storage and disposal. Compliance with these laws and regulations may be expensive and noncompliance could result in substantial fines and penalties. Environmental laws and regulations also impose liability for the remediation of releases of hazardous substances into the environment and for personal injuries resulting from exposure to hazardous substances, and they can give rise to substantial remediation costs and to third-party claims, including for property damage and personal injury. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence, and they tend to become more stringent over time, imposing greater compliance costs and increased risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations, or releases of or exposure to hazardous substances, will not occur in the future or have not occurred in the past, including as a result of human error, accidents, equipment failure or other causes. The costs of complying with environmental laws and regulations, and liabilities that may be imposed for violating them, or for remediation obligations or responding to third-party claims, could negatively affect our business, financial condition and results of operations.

***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. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products. The Affordable Care Act, or ACA, 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 ACA:

- Imposed a new federal excise tax on the sale of certain medical devices, which was suspended, effective January 1, 2016, and permanently repealed in December 2019;
- 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.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. By way of example, the Tax Cuts and Jobs Act of 2017, or TCJA, was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas (Texas District Court Judge) ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, although it is unclear when the Supreme Court will make a decision. It is also unclear how other efforts to challenge, repeal or replace the ACA will impact the law and our business. Any expansion in the government's role in the U.S. healthcare industry may result in decreased profits to us, lower reimbursement by payors for procedures using our FlowTriever system and/or ClotTriever system, and/or reduced medical procedure volumes, any of which may have a material adverse effect on our business, financial condition or results of operations.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. The Budget Control Act of 2011, 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. The Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, which was signed into law on March 27, 2020, designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, temporarily suspended these reductions from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. Additionally, the American Taxpayer Relief Act of 2012, 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 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 which could limit reimbursement for healthcare products and services or otherwise result in reduced demand for our FlowTriever and/or ClotTriever or additional pricing pressure and have a material adverse effect on our industry generally and on our customers. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may negatively affect our business, financial condition and results of operations. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- our ability to set a price that we believe is fair for our FlowTriever and ClotTriever products;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Any changes of, or uncertainty with respect to, future coverage or reimbursement rates could affect demand for our FlowTriever system and/or ClotTriever system, which in turn could impact our ability to successfully commercialize these devices and could have a material adverse effect on our business, financial condition and results of operations.

**Risks Related to Ownership of Our Common Stock**

***The price of our common stock may fluctuate substantially or may decline regardless of our operating performance and you could lose all or part of your investment.***

The market price of our common stock may be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control or are related in complex ways, including:

- Changes in analysts' estimates, investors' perceptions, recommendations by securities analysts 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;
- Future sales of our common stock or other securities, by us or our stockholders, as well as the anticipation of lock-up releases or lock-up waivers;
- The trading volume of our common stock;
- 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 payors;
- 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 or product enhancements 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 addition, the trading prices for common stock of other medical device companies have been highly volatile as a result of the COVID-19 pandemic. The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

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.

***Securities analysts may not publish favorable research or reports about our business or may publish no information at all, which could cause our stock price or trading volume to decline.***

Our stock price and trading volume may be heavily influenced by the way analysts and investors interpret our financial information and other disclosures. If securities or industry analysts do not publish research or reports about our business, delay publishing reports about our business, or publish negative reports about our business, regardless of accuracy, our common stock price and trading volume could decline.

The trading market for our common stock is influenced to some extent by the research and reports that industry or financial analysts publish about us and our business. We do not control these analysts. We may be slow to attract research coverage and the analysts who publish information about our common stock will have had relatively little experience with us or our industry, which could affect their ability to accurately forecast our results and could make it more likely that we fail to meet their estimates. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us provide inaccurate or unfavorable research or issue an adverse opinion regarding our stock price, our stock price could decline. If one or more of these analysts cease coverage of us or fail to publish reports covering us regularly, we could lose visibility in the market, which in turn could cause our stock price or trading volume to decline.

Even if our common stock is actively covered by analysts, we do not have any control over the analysts or the measures that analysts or investors may rely upon to forecast our future results. Over-reliance by analysts or investors on any particular metric to forecast our future results may lead to forecasts that differ significantly from our own.

***We are an emerging growth company and we cannot be certain if the reduced disclosure requirements applicable to us will make our common stock less attractive to investors.***

We are an “emerging growth company,” as defined in the JOBS Act, and we expect to take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not emerging growth companies. In particular, while we are an emerging growth company, we will not be required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act; we will be exempt from any rules that could be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotations or a supplement to the auditor’s report on financial statements; we will be subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and we will not be required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved.

In addition, while we are an emerging growth company we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of this extended transition period and, as a result, our operating results and financial statements may not be comparable to the operating results and financial statements of companies who have adopted the new or revised accounting standards.

We will remain an emerging growth company until the earlier of (1) December 31, 2025, the fiscal year-end following the fifth anniversary of the completion of our IPO, (2) the last day of the fiscal year (a) in which we have total annual gross revenue of at least $1.07 billion or (b) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non- affiliates exceeds $700 million as of the prior June 30th and (3) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Investors may find our common stock less attractive to the extent we rely on the exemptions and relief granted by the JOBS Act. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline or become more volatile.

***If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.***

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. In connection with our adoption and implementation of the new revenue accounting standard, management made judgments and assumptions based on our interpretation of the new standard. The new revenue standard is principle-based and interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice and guidance may evolve. If our assumptions change or if actual circumstances differ from our assumptions, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

***A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell their shares, could result in a decrease in the market price of our common stock. As of June 30, 2020, we had 48,360,081 shares of common stock outstanding. A significant percentage of these outstanding shares of common stock are currently restricted as a result of market standoff and lock-up agreements entered into in connection with the IPO. These shares will become available to be sold 180 days after May 21, 2020. Shares held by directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act. The underwriters of the IPO may, in their discretion, permit out stockholders to sell shares prior to the expiration of the restrictive provisions contained in those lock-up agreements.

Moreover, certain of our stockholders have rights, subject to some conditions, to require us to file registration statements covering their shares to include their shares in registration statements that we may file for ourselves or our stockholders, subject to market standoff and lockup agreements. We intend to register shares of common stock that we have issued and may issue under our employee equity incentive plans. Once we register these shares, they will be able to be sold freely in the public market upon issuance, subject to existing market standoff or lock-up agreements.

The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell their shares.

***Our directors, officers and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.***

As of June 30, 2020, our officers, directors and principal stockholders each holding more than 5% of our common stock will collectively control approximately 66% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to control the management and affairs of the Company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change of control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of our other stockholders.

***We have incurred and expect to continue to incur significant additional costs as a result of being a public company, and our management is required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.***

As a public company. we have incurred and expect to continue to incur costs associated with corporate governance requirements that are applicable to us as a public company, including rules and regulations of the U.S. Securities and Exchange Commission, under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, and the Exchange Act, as well as the rules of the Nasdaq Global Select Market. These rules and regulations significantly increase our accounting, legal and financial compliance costs and make some activities more time-consuming. We expect such expenses to further increase after we are no longer an emerging growth company. We also expect these rules and regulations to make it more expensive for us to maintain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of

directors or as executive officers. Furthermore, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. Accordingly, increases in costs incurred as a result of being a publicly traded company may adversely affect our business, financial condition and results of operations.

***We have previously identified material weaknesses in our internal control over financial reporting and may identify material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, as a result of which, we may not be able to accurately report our financial condition or results of operations which may adversely affect investor confidence in us and, as a result, the value of our common stock.***

Under Section 404 of the Sarbanes-Oxley Act, we are required to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting beginning with our Annual Report on Form 10-K for the year ended December 31, 2021. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual and interim financial statements will not be detected or prevented on a timely basis.

We are further enhancing internal controls, processes and related documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective.

In connection with the preparation of our financial statements for the year ended December 31, 2019, we concluded there were material weaknesses in our internal controls over financial reporting. The material weaknesses that were identified related to the segregation of duties throughout various financial processes and our documentation of internal controls. We are taking steps to remediate the material weaknesses in our internal controls over financial reporting, including implementing our new ERP system and control procedures and identifying gaps in our skills base and expertise of the staff required to meet the financial reporting requirements of a public company. While we continue to implement our plan to remediate the material weaknesses, we may not be able to do so and our initiatives may prove not to be successful.

We cannot assure you that there will not be material weaknesses or significant deficiencies 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. The effectiveness of our controls and procedures may be limited by a variety of factors, including:

- Faulty human judgment and simple errors, omissions or mistakes;
- Fraudulent action of an individual or collusion of two or more people;
- Inappropriate management override of procedures; and
- The possibility that any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial control.

Our management and independent registered public accounting firm did not perform an evaluation of our internal control over financial reporting during any period in accordance with the provisions of Sarbanes-Oxley Act. Had we performed an evaluation and had our independent registered public accounting firm performed an audit of our internal control over financial reporting in accordance with the provisions of Sarbanes-Oxley Act, additional control deficiencies amounting to material weaknesses may have been identified. We are in the very early stages of the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404(a) of Sarbanes-Oxley Act. We may not be able to complete our evaluation, testing or any required remediation in a timely fashion. If we fail to comply with Section 404(a) or to remedy these material weaknesses or identify new material weaknesses by the time we have to issue that report, we will not be able to certify that our internal controls over financial reporting are effective, which may cause investors to lose confidence in our financial statements, and the trading price of our common stock may decline. If we fail to remedy any material weakness, our financial statements may be inaccurate, our access to the capital markets may be restricted and the trading price of our common stock may suffer.

***Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.***

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules

and forms of the U.S. Securities and Exchange Commission. We believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. For example, we define a procedure as any instance in which a physician treats DVT or PE using our products. We estimate the number of procedures performed based on records created by our sales representatives. However, this metric has limitations as we only have records for the procedures where our sales representatives have notice that a procedure has been performed. Even when notified, our sales representatives may not accurately record, be delayed in recording, or not record, the procedures, which may not be detected or corrected by our disclosure controls and procedures in a timely manner or at all. As a result, the estimated number of procedures does not reflect the actual number of procedures performed using our products, which may be lower or higher for each particular period.

***Provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. Among others, these provisions include that:

- Our board of directors has the exclusive right to expand the size of our board of directors and to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;

- Our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three-year terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;

- Our stockholders may not act by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;

- A special meeting of stockholders may be called only by the chair of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;

- Our amended and restated certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;

- Our board of directors may alter our bylaws without obtaining stockholder approval;

- The required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;

- Stockholders must provide advance notice and additional disclosures in order to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of our company; and

- Our board of directors is authorized to issue shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

***Our amended and restated certificate of incorporation provides 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 specifies that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving actions brought against us by stockholders; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation also provides that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. Under the Securities Act, federal and state courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Accordingly, there is uncertainty as to whether a court would enforce such a forum selection provision as written in connection with claims arising under the Securities Act. We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, these provisions may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a future court could find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in such action. If a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

***Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.***

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. Any determination to pay dividends in the future will be at the discretion of our board of directors and may be restricted by any future debt or preferred securities or future debt agreements we may enter into. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

***Sales of Unregistered Securities.***

In June 2020, we issued 27,810 shares of common stock upon the exercise of common stock warrants for proceeds of $3,971.

In June 2020, we issued 74,723 shares of common stock upon the net exercise of 77,030 of Series A preferred stock warrants.

***Use of Proceeds from the IPO***

On May 27, 2020, we completed our IPO and issued 9,432,949 shares of our common stock at an IPO proceeds of $19.00 per share (inclusive of 1,230,384 shares of common stock pursuant to the full exercise of the underwriters' option to purchase additional shares in the IPO). We received net proceeds from the IPO of approximately $163.0 million, after deducting the underwriting discount of $12.6 million and offering expenses of $3.7 million. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates. BofA Securities Inc. and Morgan Stanley & Co LLC acted as joint lead bookrunning managers for the IPO. Wells Fargo Securities LLC and Canaccord Genuity LLC acted as co-managers.

Shares of our common stock began trading on the Nasdaq Global Select Market on May 22, 2020. The offer and sale of the shares were registered under the Securities Act on Registration Statement on Form S-1 (File No. 333-2365685), which was declared effective on May 21, 2020.

There has been no material change in the expected use of the net proceeds from our IPO as described in our final prospectus, dated May 21, 2020, filed with the U.S. Securities and Exchange Commission on May 26, 2020 pursuant to Rule 424(b) of the Securities Act.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

| Exhibit Number | Description | Form | Incorporated by reference | | |
|---|---|---|---|---|---|
| | | | File Number | Exhibit | Filing Date |
| 3.1 | Amended and Restated Certificate of Incorporation | 8-K | 001-39293 | 3.1 | 5/28/2020 |
| 3.2 | Amended and Restated Bylaws | 8-K | 001-39293 | 3.2 | 5/28/2020 |
| 4.1 | Form of Certificate of Common Stock | S-1 | 333-236568 | 4.1 | 2/21/2020 |
| 4.2 | Second Amended and Restated Investors' Rights Agreement by and between Inari Medical, Inc. and certain investors, dated March 29, 2018 | S-1 | 333-236568 | 4.2 | 2/21/2020 |
| 4.3 | Warrant to purchase common stock, issued by Inari Medical, Inc. to Croton Partners, LLC, dated February 19, 2015 | S-1 | 333-236568 | 4.3 | 2/21/2020 |
| 4.4 | Warrant to purchase Series A preferred stock, issued by Inari Medical, Inc. to Silicon Valley Bank, dated December 10, 2014 | S-1 | 333-236568 | 4.4 | 2/21/2020 |
| 4.5 | Warrant to purchase Series B preferred stock, issued by Inari Medical, Inc. to East West Bank dated April 29, 2016 | S-1 | 333-236568 | 4.5 | 2/21/2020 |
| 10.1 | Form of Indemnification Agreement between Inari Medical, Inc. and its directors and officers | S-1/A | 333-236568 | 10.1 | 5/5/2020 |
| 10.3# | 2011 Equity Incentive Plan | S-1 | 333-236568 | 10.3 | 2/21/2020 |
| 10.4# | Form of Stock Option Agreement pursuant to 2011 Equity Incentive Plan | S-1 | 333-236568 | 10.4 | 2/21/2020 |
| 10.5# | Form of Restricted Stock Unit Agreement pursuant to 2011 Equity Incentive Plan | S-1 | 333-236568 | 10.5 | 2/21/2020 |
| 10.6# | 2020 Incentive Award Plan | S-1/A | 333-236568 | 10.6 | 5/18/2020 |
| 10.6.1# | Form of Option Agreement pursuant to 2020 Incentive Award Plan | S-1/A | 333-236568 | 10.6.1 | 5/18/2020 |
| 10.6.2# | Form of Restricted Stock Unit Agreement pursuant to 2020 Incentive Award Plan | S-1/A | 333-236568 | 10.6.2 | 5/18/2020 |
| 10.7# | 2020 Employee Stock Purchase Plan | S-1/A | 333-236568 | 10.7 | 5/18/2020 |
| 10.12# | Employment Agreement, dated as of March 5, 2020, by and between Inari Medical, Inc. and William Hoffman | S-1/A | 333-236568 | 10.12 | 5/5/2020 |
| 10.13# | Employment Agreement, dated as of March 5, 2020, by and between Inari Medical, Inc. and Mitchell Hill | S-1/A | 333-236568 | 10.13 | 5/5/2020 |
| 10.14# | Employment Agreement, dated as of March 5, 2020, by and between Inari Medical, Inc. and Andrew Hykes | S-1/A | 333-236568 | 10.14 | 5/5/2020 |
| 10.15# | Non-Employee Director Compensation Program | S-1/A | 333-236568 | 10.15 | 5/5/2020 |
| 31.1 | Certification of Principal Executive Officer pursuant to 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 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† | Certifications of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | | | | |

| | |
|---|---|
| 32.2† | Certifications of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS | XBRL Instance Document |
| 101.SCH | XBRL Taxonomy Extension Schema Document |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document |

# Indicates management contract or compensatory plan.

† The certifications attached as Exhibit 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are deemed furnished and not filed with the U.S. Securities and Exchange Commission and are not to be incorporated by reference into any filing of Inari 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 this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Inari Medical, Inc.

Date: August 11, 2020 By: /s/ William Hoffman

**William Hoffman**
**Chief Executive Officer and President**
**(Principal Executive Officer)**

Date: August 11, 2020 By: /s/ Mitchell Hill

**Mitchell Hill**
**Chief Financial Officer**
**(Principal Financial Officer and**
**Principal Accounting Officer)**

**Exhibit 31.1**

**CERTIFICATION PURSUANT TO**
**RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,**
**AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, William Hoffman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Inari 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

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

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

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

5. The registrant's other certifying officer(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.

Date: August 11, 2020

By: /s/ William Hoffman

**William Hoffman**
**Chief Executive Officer and President**
**(Principal Executive Officer)**

**Exhibit 31.2**

**CERTIFICATION PURSUANT TO**
**RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,**
**AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Mitchell Hill, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Inari 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

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

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

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

5. The registrant's other certifying officer(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.

Date: August 11, 2020

By: /s/ Mitchell Hill

**Mitchell Hill**
**Chief Financial Officer**
**(Principal Financial Officer and**
**Principal Accounting Officer)**

**Exhibit 32.1**

**CERTIFICATION 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 Inari Medical, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: August 11, 2020

By: /s/ William Hoffman

**William Hoffman**
**Chief Executive Officer and President**
**(Principal Executive Officer)**

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**Exhibit 32.2**

**CERTIFICATION 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 Inari Medical, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: August 11, 2020

By: /s/ Mitchell Hill

**Mitchell Hill**
**Chief Financial Officer**
**(Principal Financial Officer and**
**Principal Accounting Officer)**

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.