

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

**FORM S-1**  
REGISTRATION STATEMENT  
Under  
The Securities Act of 1933

**Inari Medical, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of incorporation or organization)

**3841**  
(Primary Standard Industrial Classification Code Number)

**45-2902923**  
(I.R.S. Employer Identification No.)

**9 Parker, Suite 100**  
**Irvine, CA 92618**  
**(877) 923-4747**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**William Hoffman**  
**Chief Executive Officer**  
**9 Parker, Suite 100**  
**Irvine, CA 92618**  
**(877) 923-4747**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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**Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.**

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer   
Non-accelerated filer

Accelerated filer   
Smaller reporting company   
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

**CALCULATION OF REGISTRATION FEE**

Title of Each Class of Securities To Be Registered	Proposed Maximum Aggregate Offering Price (1)(2)	Amount of Registration Fee
Common Stock, \$0.001 par value per share	\$	\$

- (1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.  
(2) Includes the aggregate offering price of additional shares that the underwriters have the option to purchase.

**The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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Pursuant to 17 C.F.R. Section 200.83**

**EXPLANATORY NOTE**

Pursuant to the applicable provisions of the Fixing America's Surface Transportation Act, we are not required to file our financial information for the historical 2017 annual period or for any interim period for 2018 or 2019 because we plan to file our financial information for the year ended December 31, 2019 in the first public filing of our registration statement. While the 2017 annual financial information and 2018 and 2019 interim financial information is otherwise required by Regulation S-X, we believe that it will not be required to be included in our registration statement at the time of the first public filing.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion.  
Preliminary Prospectus dated \_\_\_\_\_, 2020

**PROSPECTUS**

**Shares**



**Common Stock**

This is Inari Medical, Inc.'s initial public offering. We are selling \_\_\_\_\_ shares of our common stock.

We expect the public offering price to be between \$ \_\_\_\_\_ and \$ \_\_\_\_\_ per share. Currently, no public market exists for the shares of common stock. After pricing of the offering, we expect that the shares will trade on the Nasdaq Global Market under the symbol "NARI."

**We are an "emerging growth company" under the federal securities laws and are subject to reduced public company disclosure standards. See "Prospectus Summary—Implications of Being an Emerging Growth Company."**

**Investing in the common stock involves risks that are described in the "[Risk Factors](#)" section beginning on page 12 of this prospectus.**

	<u>Per Share</u>	<u>Total</u>
Public offering price	\$ _____	\$ _____
Underwriting discounts(1)	\$ _____	\$ _____
Proceeds, before expenses, to us	\$ _____	\$ _____

(1) We refer you to "Underwriting" for additional information regarding underwriting compensation.

The underwriters may also exercise their option to purchase up to an additional \_\_\_\_\_ shares of common stock from us at the initial public offering price, less the underwriting discounts, for 30 days after the date of this prospectus.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

The shares will be ready for delivery on or about \_\_\_\_\_, 2020.

**BofA Securities**

**Morgan Stanley**

**Canaccord Genuity**

**Wells Fargo Securities**

The date of this prospectus is \_\_\_\_\_, 2020

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We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares of common stock offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

**For investors outside the United States:** We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

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**PROSPECTUS SUMMARY**

*This summary highlights information contained in more detail elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should carefully read this prospectus in its entirety before investing in our common stock, including the sections titled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Special Note Regarding Forward-Looking Statements,” and our financial statements and the accompanying notes thereto included elsewhere in this prospectus.*

*Unless the context requires otherwise, references to “Inari,” the “Company,” “we,” “us,” and “our,” refer to Inari Medical, Inc.*

**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. These products have been used to treat more than 6,300 patients at approximately 400 hospitals across the United States, with approximately 90% of cases being performed since we launched our broader commercial efforts in the third quarter of 2018. We have experienced significant growth since we began commercializing our products and have had strong momentum in our business in 2019, with approximately 4,550 procedures performed using our products in 2019.

Historically, development efforts for mechanical thrombectomy devices have focused on arterial devices, which are then repurposed for use in the venous system. Given the significant differences between the arterial and venous systems and the clot that forms in each system, these devices have difficulty removing venous clot, which is often adhered to the vessel wall and is older, firmer and substantially larger than arterial clot.

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. The ClotTriever is a mechanical thrombectomy system designed to core, capture and remove large clots from large vessels and is used to treat DVT. The FlowTriever is a large bore catheter-based aspiration and mechanical thrombectomy system designed to remove large clots from large vessels to treat PE. Both products are designed to eliminate the need for thrombolytic drugs.

Our ClotTriever and FlowTriever have received 510(k) clearance from the FDA. The primary clinical study we have completed to date regarding the safety and effectiveness of our products is our FlowTriever Pulmonary Embolectomy Clinical Study, or FLARE study, which was conducted under an investigational device exemption, or IDE, and completed in October 2017. The FLARE study supported FDA 510(k) clearance of the FlowTriever for the treatment of PE, which was received in May 2018. The study met both of its primary endpoints, demonstrating the safety and effectiveness of the FlowTriever for the treatment of PE without the use of thrombolytic drugs. There were no device-related major adverse events. Of the 106 patients evaluated, four patients (3.8%) experienced six major adverse events in the 48 hours after treatment, all of which were determined to be procedure-related. We are committed to continuing to develop a strong base of clinical evidence and real-world patient outcomes to further support the safety and effectiveness of our products. We are currently enrolling two 500-patient registries to evaluate real-world outcomes after treating patients with our products,

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including longer term follow-up visits at up to two years after treatment with our ClotTriever and at up to six months after treatment with our FlowTriever. As of December 31, 2019, our ClotTriever registry and our FlowTriever registry had enrolled 93 and 117 patients, respectively. In addition, there are more than 10 ongoing investigator-initiated studies being conducted.

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, which consisted of 63 sales representatives as of December 31, 2019, and we are actively expanding our sales organization through additional sales representatives and territories. As we expand our network of hospital customers and leverage our expanding sales organization, we seek to increase awareness within these hospitals and with our target physicians, referring physicians and other stakeholders at the account level in order to drive greater adoption of our products as the preferred first-line solution for the treatment of venous diseases.

Overall, we generated revenue of \$            million, with a gross margin of    % and net losses of \$            million for the year ended December 31, 2019, compared to revenue of \$6.8 million, with a gross margin of 81.2% and net losses of \$10.2 million for the year ended December 31, 2018. Our accumulated deficit was \$            million as of December 31, 2019.

**Our Market**

VTE is a leading cause of death and disability worldwide and represents the third most common vascular diagnosis in the United States after myocardial infarction and stroke. Researchers estimate that approximately one million people present with VTE in the United States each year, resulting in approximately 296,000 deaths and direct health care costs in excess of \$10 billion per year.

VTE is a disease caused by blood clot formation in the veins of the body. DVT occurs when clot forms in the deep veins of the extremities of the body, such as the legs. PE occurs when a venous clot embolizes or becomes mobile, travels through the heart and gets lodged in the pulmonary arteries of the lungs. Venous clot that causes PE originates as DVT.

Of the estimated 668,000 new DVT diagnoses and 400,000 new PE diagnoses in the United States each year, we believe approximately 242,000 DVT patients and approximately 200,000 PE patients, could benefit from safe and effective treatment with our ClotTriever and FlowTriever products, respectively. This represents a potential annual addressable U.S. market opportunity for our current products of approximately \$3.6 billion based on the current average selling prices of our products. We also believe there is a substantial market opportunity outside the United States.

**Current Treatment Alternatives and Their Limitations**

There are several treatment options for DVT and PE patients, ranging from conservative medical management to advanced catheter-based interventions. We estimate that 68% of our target DVT patients and 90% of our target PE patients are treated with anticoagulants alone. We estimate that the remaining 32% of our target DVT patients and 10% of our target PE patients also receive additional treatment beyond anticoagulation. These treatments include mechanical thrombectomy and thrombolytic drugs. There is no consistent approach for determining whether a given patient receives anticoagulants alone or in conjunction with additional treatments.

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Due in part to the limitations and potential dangers of these additional treatments, most patients are treated with anticoagulation alone.

- *Anticoagulants.* The current standard of care for treating VTE is conservative medical management with anticoagulants, which are drugs designed to prevent further blood clotting but that do not break down or eliminate existing clots. Anticoagulants are intended to stop further clot formation while the body attempts to break down and remove clots using its natural mechanisms. Nearly all patients receive this treatment, many of whom remain on anticoagulants for the remainder of their lives.
- *Mechanical Thrombectomy.* Mechanical thrombectomy is an interventional procedure in which a catheter is used to remove clot from vessels in the body, typically by aspiration. Some mechanical thrombectomy devices use a hybrid approach that combines aspiration-based mechanical thrombectomy and localized delivery of thrombolytic drugs. We believe there are a number of drawbacks and limitations to existing mechanical thrombectomy treatment options, including: limited ability to remove large, older clots; limited ability to remove clot from the vessel wall; increased safety risks; and multi-stage treatment with multiple procedures.
- *Thrombolytic Drug Therapy.* Thrombolytic drugs accelerate the body's natural mechanisms for clearing clot by catalyzing the enzyme that breaks down the fibrin composition of clot. These drugs have demonstrated efficacy in breaking down newly-formed, fibrin-rich clot. However, thrombolytic drugs are generally not effective on older clot in which clot composition has changed from a fibrin matrix to a firmer collagen matrix. This transition in clot morphology begins early and progresses quickly, with collagen content reaching approximately 80% within three weeks. As a result, we believe that thrombolytic drug therapy does not adequately treat VTE. In addition, thrombolytic drugs carry substantial risks of severe bleeding, and many patients are contraindicated for treatment. Moreover, they are an expensive, resource intensive and time consuming treatment, which require patients to stay in the intensive care unit, or ICU, for monitoring.

We believe the historical bias for conservative medical management is largely due to the ineffectiveness of, and risks associated with, current alternative treatments, and the lack of mechanical tools capable of removing venous clot in a safe, effective and simple way. The standard of care for treatment of other thrombotic diseases, such as myocardial infarction and stroke, has evolved from the use of anticoagulants alone to anticoagulants together with thrombolytic drugs and eventually to anticoagulants together with definitive catheter-based interventions. We believe that the venous system represents the newest frontier for effective catheter-based mechanical treatments and that our products could be the catalyst to drive the same evolution of treatment and become the standard of care for VTE patients.

**Our Solution**

We believe our purpose-built ClotTrievers and FlowTrievers products offer significant clinical benefits and address the safety and effectiveness limitations of thrombolytic drugs and repurposed arterial devices for the treatment of VTE. We believe our products are transformational because they offer hospitals, physicians and patients the following key benefits:

- ***Capture and remove large clot burden from large vessels.*** Our products are mechanical thrombectomy devices specifically designed to remove significant clot volumes associated with VTE from large vessels.
- ***Liberate clot mechanically and remove venous clot from the vessel wall.*** We have designed our products to remove clot that has adhered to the vessel wall by incorporating unique components that

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enable them to mechanically engage and liberate the clot from the vessel wall and remove it from the body.

- ***Eliminate the need for thrombolytic drugs.*** Our products have been designed to treat VTE without the need for thrombolytic drugs.
- ***Remove clot safely with minimal blood loss.*** Our products have been used to treat more than 6,300 patients and have demonstrated an excellent safety profile.
- ***Offer simple, intuitive and easy to use solutions to physicians.*** We designed and developed our products to enable a short learning curve and consistent ease of use. Our products are designed to utilize standard endovascular skills possessed by our target physicians.
- ***Enable short, single-session treatment with improved hospital and physician efficiency.*** Our products are intended to facilitate short, single-session treatments for both DVT and PE, with the potential to reduce the length of ICU stay and total length of hospital stay.
- ***Require no capital investment.*** Both of our products are fully self-contained systems and do not require additional capital equipment to perform the procedure.

**Our Success Factors**

We believe the continued growth of our company will be driven by the following success factors:

- ***Sole focus on and deep understanding of the venous system and venous diseases;***
- ***Proprietary devices designed to safely and effectively remove large volumes of clot from large vessels while eliminating the need for thrombolytic drugs;***
- ***Large market opportunity for patients with unmet needs;***
- ***Rapidly scaling commercial organization leveraging unique insights;***
- ***Simple, intuitive and easy to use products with minimal training required;***
- ***Compelling hospital economics and improved hospital and physician efficiency; and***
- ***Unique culture of focus on patient care, driving value creation.***

**Our Growth Strategy**

Our mission is to treat and transform the lives of patients suffering from venous diseases. To accomplish this, we intend to establish our products as the standard of care for the treatment of venous diseases. The key elements of our growth strategy are:

- ***Continuing to expand our U.S. sales force;***
- ***Driving increased awareness and adoption of our products in existing and future hospital customers;***
- ***Building upon our base of clinical evidence;***

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- *Continuing to expand our portfolio of venous products; and*
- *Pursuing strategically adjacent markets and international opportunities.*

**Risks Associated with Our Business**

Our business is subject to a number of risks and uncertainties, including those highlighted in the section titled “Risk Factors” immediately following this Prospectus Summary. These risks include, but are not limited to, the following:

- 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.
- 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 have concluded that there is substantial doubt about our ability to continue as a going concern.
- Our business is dependent upon the broad adoption of our products and catheter-based thrombectomy procedures by hospitals, physicians and patients.
- Adoption of our ClotTrievers and FlowTrievers products requires approval by hospital value analysis committees, group purchasing organizations and integrated delivery networks, or the staff of hospitals or health systems.
- Adoption of our ClotTrievers and FlowTrievers products depends upon appropriate physician training, practice and patient selection.
- Adoption of our ClotTrievers and FlowTrievers 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.
- 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.
- Catheter-based treatment for PE is subject to a Medicare National Coverage Determination that may restrict Medicare coverage for procedures using our FlowTrievers product for the treatment of PE.
- 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 have identified material weaknesses in our internal control over financial reporting and may experience material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, 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.

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

**Corporate Information**

We were formed under the laws of the state of Delaware in July 2011 under the name Inceptus Newco1 Inc. and changed our name to Inari Medical, Inc. in September 2013.

Our principal executive offices are located at 9 Parker, Suite 100, Irvine, CA 92618 and our telephone number is (877) 923-4747. Our website address is [www.inarimedical.com](http://www.inarimedical.com). The information contained on, or that can be accessed through, our website is not incorporated by reference into, and is not a part of, this prospectus or the registration statement of which this prospectus forms a part. Investors should not rely on any such information in deciding whether to purchase our common stock.

Inari Medical, Inari Medical, Inc., ClotTrierer, FlowTrierer, our logo and other registered or common law trade names, trademarks or service marks of Inari appearing in this prospectus are the property of Inari. This prospectus contains additional trade names, trademarks and service marks of other companies that are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies. Solely for convenience, our trade names, trademarks and service marks referred to in this prospectus appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable licensor to these trade names, trademarks and service marks.

**Implications of Being an Emerging Growth Company**

We qualify as an "emerging growth company" as defined in Section 2(a) of the Securities Act of 1933, as amended, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable, in general, to public companies that are not emerging growth companies. These provisions include:

- the option to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;

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- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We will remain an emerging growth company until the earliest to occur of: (i) the last day of the first fiscal year in which our annual gross revenue exceeds \$1.07 billion; (ii) the date that we become a “large accelerated filer” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter; (iii) the date on which we have issued, in any three-year period, more than \$1.0 billion in non-convertible debt securities; and (iv) the last day of the fiscal year ending after the fifth anniversary of the completion of this offering.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide may be different than the information you receive from other public companies in which you hold stock.

Emerging growth companies can also take advantage of the extended transition period for complying with new or revised accounting standards. In other words, an emerging growth company can 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.

As a result of these elections, we do not know if some investors will find our common stock less attractive. The result may be a less active trading market for our common stock, and the price of our common stock may become more volatile.

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**The Offering**

Common stock offered by us	shares
Common stock to be outstanding after this offering	shares (or additional shares in full) shares if the underwriters exercise their option to purchase additional shares in full)
Option to purchase additional shares	We have granted the underwriters a 30-day option to purchase up to additional shares of our common stock at the public offering price, less the underwriting discounts and commissions.
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately \$ million (or approximately \$ million if the underwriters exercise their option to purchase additional shares in full), assuming an initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering to hire additional sales and marketing personnel and expand marketing programs in the United States, to fund product development and research and development activities and the remainder for working capital and general corporate purposes, See "Use of Proceeds."
Risk factors	Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 12 and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
Reserved share program	At our request, the underwriters have reserved for sale, at the initial public offering price, up to % of the shares offered by this prospectus for sale to some of our directors, officers, employees, distributors, dealers, business associates and related persons. If these persons purchase reserved shares, this will reduce the number of shares available for sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus.
Proposed Nasdaq Global Market symbol	"NARI."

The number of shares of our common stock to be outstanding after this offering is based on 55,248,527 shares of our common stock outstanding as of December 31, 2019, which includes 45,651,216 shares of common stock issuable upon the conversion of all of our outstanding shares of convertible preferred stock and excludes:

- 39,713 shares of our common stock issuable upon the exercise of a warrant to purchase common stock outstanding as of December 31, 2019, with an exercise price of \$0.10 per share;

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- 110,000 shares of our common stock issuable upon the exercise of a warrant to purchase Series A convertible preferred stock outstanding as of December 31, 2019, with an exercise price of \$1.00 per share, which will convert into a warrant to purchase common stock immediately prior to the closing of this offering;
- 256,410 shares of our common stock issuable upon the exercise of a warrant to purchase Series B convertible preferred stock outstanding as of December 31, 2019, with an exercise price of \$1.17 per share, which will convert into a warrant to purchase common stock immediately prior to the closing of this offering;
- 5,829,739 shares of our common stock issuable upon the exercise of outstanding options under our 2011 Equity Incentive Plan as of December 31, 2019, at a weighted-average exercise price of \$0.63 per share;
- 4,094,552 shares of our common stock issuable upon the vesting and settlement of outstanding restricted stock units, or RSUs, under our 2011 Equity Incentive Plan as of December 31, 2019; and
- shares of our common stock reserved for future issuance under our equity compensation plans, consisting of (1) 716,950 shares of our common stock reserved for future issuance under our 2011 Equity Incentive Plan as of December 31, 2019, (2)        shares of our common stock reserved for future issuance under our 2020 Incentive Award Plan, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part, and (3)        shares of our common stock reserved for future issuance under our 2020 Employee Stock Purchase Plan, or ESPP, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part.

In addition, unless otherwise indicated, the information in this prospectus reflects and assumes:

- the filing of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, each of which will be in effect immediately prior to the closing of this offering;
- a -for- reverse stock split of our common stock to be effected on        , 2020;
- the automatic conversion of 45,651,216 shares of our convertible preferred stock outstanding as of December 31, 2019 into shares of our common stock immediately prior to the closing of this offering;
- the automatic conversion of all warrants to purchase shares of our convertible preferred stock outstanding as of December 31, 2019 into warrants to purchase 366,410 shares of our common stock immediately prior to the closing of this offering;
- no exercise of the outstanding options and warrants referred to above; and
- no exercise of the underwriters' option to purchase additional shares of our common stock.

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**Summary Financial Data**

The following tables summarize our financial data for the periods and as of the dates indicated. We derived our summary statement of operations data for the years ended December 31, 2018 and 2019 and the balance sheet data as of December 31, 2019 from our audited financial statements that are included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future. You should read the following information in conjunction with the sections titled “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and the accompanying notes thereto included elsewhere in this prospectus.

	<b>Year ended December 31,</b>	
	<b>2018</b>	<b>2019</b>
	<b>(in thousands, except share and per share data)</b>	
<b>Statement of Operations Data:</b>		
Revenue	\$ 6,829	\$
Cost of goods sold	1,281	—
Gross profit	5,548	—
Operating expenses:		
Research and development	3,990	—
Selling, general and administrative	10,698	—
Total operating expenses	14,688	—
Loss from operations	(9,139)	—
Other income (expense):		
Interest income	92	—
Interest expense	(887)	—
Other expenses	(218)	—
Total other expenses, net	(1,013)	—
Net loss and comprehensive loss	\$ (10,153)	\$
Net loss per share, basic and diluted (1)	\$ (1.41)	\$
Weighted average shares of common stock used to compute net loss per share, basic and diluted (1)	7,221,036	—
Pro forma net loss per share, basic and diluted (unaudited) (1)	—	—
Weighted average shares of common stock used to compute pro forma net loss per share, basic and diluted (unaudited) (1)	—	—

(1) See Note 2 to our audited financial statements included elsewhere in this prospectus for an explanation of the method used to calculate our historical and pro forma basic and diluted net loss per share.

	<b>As of December 31, 2019</b>		
	<b>Actual</b>	<b>Pro Forma (1)</b>	<b>Pro Forma As Adjusted (2)</b>
		<b>(unaudited)</b>	<b>(3)</b>
		<b>(in thousands)</b>	<b>(unaudited)</b>
<b>Balance Sheet Data:</b>			
Cash and cash equivalents	\$	\$	\$
Working capital (4)			
Total assets			
Total liabilities			
Warrant liabilities		—	—
Redeemable convertible preferred stock		—	—
Total stockholders’ deficit (equity)		—	—

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- (1) Reflects the automatic conversion of 45,651,216 shares of our convertible preferred stock into shares of our common stock immediately prior to the closing of this offering and the conversion of all warrants to purchase shares of our convertible preferred stock into warrants to purchase 366,410 shares of our common stock immediately prior to the closing of this offering.
- (2) Reflects the pro forma adjustments described in footnote (1) above and the sale by us of \_\_\_\_\_ shares of common stock in this offering at the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.
- (3) A \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately \$ \_\_\_\_\_, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, an increase (decrease) of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately \$ \_\_\_\_\_, assuming the shares of our common stock offered by this prospectus are sold at the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma information discussed above is illustrative only and will be adjusted based on the actual initial public offering price, the number of shares we sell and other terms of this offering that will be determined at pricing.
- (4) We define working capital as current assets less current liabilities. See our financial statements and the accompanying notes thereto included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

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**RISK FACTORS**

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this prospectus, including the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and the accompanying notes thereto included elsewhere in this prospectus, before investing in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risk and uncertainties that we are unaware of or that we deem immaterial may also become important factors that adversely affect our business. The realization of any of these risks and uncertainties could have a material adverse effect on our reputation, business, financial condition, results of operations, growth and future prospects, as well as our ability to accomplish our strategic objectives. In that event, the market price of our common stock could decline and you could lose part or all of your investment.*

**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 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 \$                    million, respectively, and we expect to continue to incur additional losses in the future. As of December 31, 2019, we had an accumulated deficit of \$                    million. To date, we have financed our operations primarily through equity and debt financings and from sales of our two products, the ClotTrier, for treatment of deep vein thrombosis, or DVT, and the FlowTrier, 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 will incur significant legal, accounting and other expenses that we did not incur as a private company. 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.

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To date, all of our revenue has been derived, and we expect it to continue to be substantially derived, from sales of our ClotTrievers and FlowTrievers. 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

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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.

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***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-Corner 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

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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, revenues 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

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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.

***Catheter-based treatment for PE is subject to a Medicare National Coverage Determination that may restrict Medicare coverage for procedures using our FlowTrievers 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 FlowTrievers product to treat PE. If NCD 240.6 is determined to exclude from Medicare coverage procedures that use our FlowTrievers 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 FlowTrievers product for the treatment of PE, which could result in claim denials and overpayments for our customers and significantly impact demand for the FlowTrievers, which would have a material adverse effect on our business, financial condition and results of operations.

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*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 ClotTrier and FlowTrier 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

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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 FlowTrieve 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;

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- 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 ClotTrier and FlowTrier 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

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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;

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- 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 ClotTrier, 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 ClotTrier 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 ClotTrier 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

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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.

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*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.

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*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.

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***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

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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

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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 ClotTrieve or FlowTrieve 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 ClotTrieve or FlowTrieve 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.

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***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 revenues.***

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 revenues 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

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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 ClotTrieve or FlowTrieve to meet patient expectations or the occurrence of adverse events from ClotTrieve or FlowTrieve 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

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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 ClotTrieve 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 ClotTrieve 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 clearance. 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

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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 beyond the proceeds of this offering 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. Since our inception, our operations have been financed primarily by net proceeds from the sale of our convertible preferred stock in private placements, indebtedness and, to a lesser extent, product revenue from sales of our ClotTrier or FlowTrier products. As of December 31, 2019, we had \$            million in cash and cash equivalents, and an accumulated deficit of \$            million. Based on our current planned operations, we expect that the anticipated proceeds of this offering, together with 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 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;

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- 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 this offering.

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 concluded that there is substantial doubt about our ability to continue as a going concern.***

In Note 1 to our financial statements, we disclose that there is substantial doubt about our ability to continue as a going concern. As a result, we received an audit report on our financial statements as of, and for the year ended, December 31, 2018, that includes an explanatory paragraph regarding our going concern uncertainty. If we are unable to obtain sufficient funding, we could be forced to delay, reduce or eliminate ongoing or planned clinical trials, expansion of our sales and marketing organization, all of our research and development programs, or liquidate our assets, and our financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. After the completion of this offering, future financial statements may disclose substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.

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***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 December 31, 2019, we had an aggregate of approximately \$ million in principal and interest 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 \$ 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. 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

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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 \$                    million and \$                    million, respectively, and U.S. federal and state research and development credit carryforwards of \$                    million and \$                    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 \$12,292,486 and \$                    for the years ended December 31, 2018 and 2019, respectively.

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***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 ClotTrierer and FlowTrierer 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;

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- 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.

***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. 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

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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.

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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 December 31, 2019, we held 17 U.S. patents, 14 pending U.S. patent applications, three issued foreign patents, 11 pending foreign patent applications and four pending Patent Cooperation Treaty applications, and we also licensed one U.S. patent 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 of 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

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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.

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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.

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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;

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- 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.

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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.

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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

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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.

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***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

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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 ClotTrievers and FlowTrievers 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;

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- 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, our products must comply with the essential requirements of the European Union, or 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 ClotTrier and FlowTrier 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

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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,

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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. 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

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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. 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

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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.

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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.

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***Changes in funding for 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 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, and statutory, regulatory, and policy changes. 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. If a prolonged government shutdown occurs, 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;

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- 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.

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

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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.

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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 civil monetary penalties up to \$100,000 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines of up to \$100,000 and imprisonment of up to 10 years. Similarly, violations can result in 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 civil fines and penalties ranging from \$11,181 to \$22,363 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 under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively referred to as the Affordable Care Act, and its implementing regulations, which require 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 civil monetary penalties of \$11,278 per failure up to an aggregate of \$169,170 per year (or up to an aggregate of \$1.128 million per year for “knowing failures”), for all payments, transfers of value or ownership or investment interests that are not timely, accurately,

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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 civil monetary penalties up to \$57,051 per violation, not to exceed \$1.71 million per calendar year for non-compliance of an identical provision, and, in certain circumstances, criminal penalties with fines up to \$250,000 per violation and/or imprisonment. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages on behalf of residents of his or her state;
- 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 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.

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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.

Although we have adopted policies and procedures designed to comply with these laws and regulations and conduct internal reviews of our compliance with these laws, our activities, including those relating to providing billing, coding, cover and reimbursement information about 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

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Consumer Privacy Act, or CCPA, on June 28, 2018, which takes 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 revenues 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

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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 made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may affect our business, the Affordable Care Act:

- Imposed an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions (described in more detail below), although the effective rate paid may be lower. Through a series of legislative amendments, the tax was suspended for 2016 through 2019. Absent further legislative action, the device excise tax will be reinstated on medical device sales starting January 1, 2020;

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

We do not yet know the full impact that the Affordable Care Act will have on our business. The taxes imposed by the Affordable Care Act and the expansion in the government's role in the U.S. healthcare industry may result in decreased profits to us, lower reimbursement by payors for our FlowTrier System and/or ClotTrier System, and/or reduced medical procedure volumes, all of which may have a material adverse effect on our business, financial condition and results of operations. The Trump administration and the U.S. Congress may take further action regarding the Affordable Care Act, including, but not limited to, repeal or replacement. Most recently, the Tax Cuts and Jobs Act of 2017 was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. Additionally, all or a portion of the Affordable Care Act and related subsequent legislation may be modified, repealed or otherwise invalidated through judicial challenge, which could result in lower numbers of insured individuals, reduced coverage for insured individuals and adversely affect our business. 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 inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. While the Texas District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

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 2027 unless additional Congressional action is taken. 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 FlowTrier and/or ClotTrier 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 FlowTrier and ClotTrier products;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

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Any changes of, or uncertainty with respect to, future coverage or reimbursement rates could affect demand for our FlowTrier System and/or ClotTrier 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 This Offering**

*Our common stock has never been publicly traded, and we expect that the price of our common stock will fluctuate substantially.*

Before this initial public offering, there has been no public market for our common stock. The initial public offering price for our common stock will be determined through negotiations between the underwriters and us and may vary substantially from the market price of our common stock following this offering. An active public trading market may not develop after completion of this offering or, if developed, may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other products, technologies or businesses using our shares as consideration. Furthermore, although we have been approved to list our common stock on the Nasdaq Global Market, even if listed, there can be no guarantee that we will continue to satisfy the continued listing standards of the Nasdaq Global Market. If we fail to satisfy the continued listing standards, we could be de-listed, which would have a negative effect on the price of our common stock.

Following this offering, 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;

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- 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 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. These fluctuations may be even more pronounced in the trading market for our common stock shortly following this offering. If the market price of shares of our common stock after this offering does not ever exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment.

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.

If a trading market for our common stock develops, the trading market will be 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. As a newly public company, 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.

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***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 may remain an “emerging growth company” until as late as December 31, 2025, the fiscal year-end following the fifth anniversary of the completion of this initial public offering, though we may cease to be an “emerging growth company” earlier under certain circumstances, including if (i) we have more than \$1.07 billion in annual revenue in any fiscal year, (ii) the market value of our common stock that is held by non-affiliates exceeds \$700 million as of any June 30 or (iii) we issue more than \$1.0 billion of non-convertible debt over a 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. As we work toward adopting and implementing the new revenue accounting standard, management will make 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 as we work toward implementing the new standard. 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.

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***If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.***

Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the pro forma as adjusted net tangible book value per share. As a result, investors purchasing common stock in this offering will incur immediate dilution of \$ \_\_\_\_\_ per share (or \$ \_\_\_\_\_ per share if the underwriters exercise their option to purchase additional shares in full), based on an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, and our pro forma as adjusted net tangible book value per share as of December 31, 2019. For more information on the dilution you may suffer as a result of investing in this offering, see the section of this prospectus entitled “Dilution.” If outstanding options or warrants are exercised in the future, you will experience additional dilution.

This dilution is due to the substantially lower price paid by our investors who purchased shares prior to this offering as compared to the price offered to the public in this offering.

***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. Immediately after this offering, we will have \_\_\_\_\_ shares of common stock outstanding based on the number of shares outstanding as of December 31, 2019. This includes the shares that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. Of the remaining shares, \_\_\_\_\_ shares are currently restricted as a result of securities laws or 180-day lock-up agreements (which may be waived, with or without notice, by BofA Securities, Inc. and Morgan Stanley & Co. LLC) but will be able to be sold after the offering as described in the section of this prospectus entitled “Shares Eligible for Future Sale.” Moreover, after this offering, holders of an aggregate of up to \_\_\_\_\_ shares of our common stock, including shares of our common stock issuable upon the conversion of the shares of our convertible preferred stock that will be outstanding immediately prior to the consummation of this offering, will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders as described in the section of this prospectus entitled “Description of Capital Stock—Registration Rights.” We also intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market, subject to volume limitations applicable to affiliates and the lock-up agreements described in the section of this prospectus entitled “Underwriting.”

***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.***

After this offering, our officers, directors and principal stockholders each holding more than 5% of our common stock will collectively control approximately \_\_\_\_\_ % of our outstanding common stock (assuming no exercise of the underwriters’ option to purchase additional shares of common stock). As a result, these stockholders, if they act together, will be able to control the management and affairs of our 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 may allocate the net proceeds from this offering in ways that you and other stockholders may not approve.***

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section titled “Use of Proceeds.” Because of the number and

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variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment, and the failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected results, which could cause our stock price to decline.

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

Upon completion of this offering, we expect to incur costs associated with corporate governance requirements that will become applicable to us as a public company, including rules and regulations of the SEC, 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 Market. These rules and regulations are expected to 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 will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs. Accordingly, increases in costs incurred as a result of becoming a publicly traded company may adversely affect our business, financial condition and results of operations.

We may also be subject to more stringent state law requirements. For example, on September 30, 2018, California signed into law Senator Bill 826, which generally requires public companies with principal executive offices in California to have a minimum number of females on the company’s board of directors. By December 31, 2019, each public company with principal executive offices in California is required to have at least one female on its board of directors. By December 31, 2021, each public company is required to have at least two females on its board of directors if the company has at least five directors, and at least three females on its board of directors if the company has at least six directors. The new law does not provide a transition period for newly listed companies. We are currently compliant with the requirements, but there are no assurances that we will be compliant in the future. If we fail to comply with this new law, we could be fined by the California Secretary of State, with a \$100,000 fine for the first violation and a \$300,000 for each subsequent violation, and our reputation may be adversely affected.

***We have identified material weaknesses in our internal control over financial reporting and may experience material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, 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.***

As a result of becoming a public company, we will be required, under Section 404 of the Sarbanes-Oxley Act to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting 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.

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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, 2018, 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.***

Upon the closing of this offering, we will become 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 SEC. 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.

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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.

***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 that will become effective upon the closing of this offering 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 chairman 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

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

Our amended and restated certificate of incorporation that will become effective upon the closing of this offering will specify 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 will also provide 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, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. 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 and officers. 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 court could find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in such action.

***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.

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**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus contains forward-looking statements. All statements contained in this prospectus other than statements of historical facts, including statements regarding our business strategy, plans, market growth and our objectives for future operations, are forward-looking statements. The words “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms and other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these words.

Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- estimates of our total addressable market, future results of operations, financial position, research and development costs, capital requirements and our needs for additional financing;
- our business model and strategic plans for our products, technologies and business, including our implementation thereof;
- competitive companies and technologies and our industry;
- our ability to commercialize, manage and grow our business by expanding our sales and marketing organization and increasing our sales to existing and new customers;
- third-party payor reimbursement and coverage decisions;
- commercial success and market acceptance of our products;
- our ability to accurately forecast customer demand for our products and manage our inventory;
- our ability to establish and maintain intellectual property protection for our products or avoid claims of infringement;
- FDA or other U.S. or foreign regulatory actions affecting us or the healthcare industry generally, including healthcare reform measures in the United States;
- the timing or likelihood of regulatory filings and approvals;
- our ability to hire and retain key personnel;
- our ability to obtain additional financing in this or future offerings;
- the volatility of the trading price of our common stock;
- our expectations regarding the use of proceeds from this offering; and
- our expectations about market trends.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this prospectus.

The forward-looking statements in this prospectus 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

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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 prospectus and are subject to a number of known and unknown risks, uncertainties, and assumptions, including those described in the section titled "Risk Factors." 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 prospectus 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. We undertake no obligation to update any of these forward-looking statements for any reason after the date of this prospectus or to conform these statements to actual results or revised expectations, except as required by law. The forward-looking statements contained in the prospectus are excluded from the safe harbor protection provided by the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, performance, and events and circumstances may be materially different from what we expect.

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**INDUSTRY, MARKET AND OTHER DATA**

This prospectus contains estimates and information concerning our industry, including market size and growth rates of the markets in which we participate, that are based on our management's estimates and research, as well as industry and general publications and research, surveys and studies conducted by third parties which we have not independently verified. Neither we nor the underwriters have independently verified the accuracy or completeness of any third-party information. Management's estimates are derived from publicly available information, their knowledge of our industry and their assumptions based on such information and knowledge, which we believe to be reasonable. This data involves a number of assumptions and limitations which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates.

The content of these third-party sources, except to the extent specifically set forth in this prospectus, does not constitute a portion of this prospectus and is not incorporated herein.

Certain monetary amounts, percentages, and other figures included elsewhere in this prospectus have been subject to rounding adjustments. Accordingly, figures shown as totals in certain tables or charts may not be the arithmetic aggregation of the figures that precede them, and figures expressed as percentages in the text may not total 100% or, as applicable, when aggregated may not be the arithmetic aggregation of the percentages that precede them.

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**USE OF PROCEEDS**

We estimate that the net proceeds to us from this offering will be approximately \$ \_\_\_\_\_ million (or approximately \$ \_\_\_\_\_ million if the underwriters exercise their option to purchase additional shares in full), assuming an initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately \$ \_\_\_\_\_ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1.0 million shares in the number of shares of common stock offered would increase (decrease) the net proceeds to us from this offering by approximately \$ \_\_\_\_\_ million, assuming the assumed initial public offering price stays the same, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purpose of this offering is to provide us with additional capital to support our operations. We intend to use the net proceeds from this offering as follows:

- approximately \$ \_\_\_\_\_ million to hire additional sales and marketing personnel and expand marketing programs in the United States;
- approximately \$ \_\_\_\_\_ million to fund product development and research and development activities; and
- the remainder for working capital and general corporate purposes.

We may also use a portion of the net proceeds from this offering to acquire, in-license or invest in products, technologies or businesses that complement our business. However, we do not have binding agreements or commitments for any acquisitions or investments outside the ordinary course of business at this time.

As of the date of this prospectus, we cannot specify with certainty the specific allocations or all of the particular uses for the net proceeds to be received upon completion of this offering. The expected use of net proceeds from this offering represents our intentions based upon our present plans and business conditions, which could change in the future as our plans and business conditions evolve. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application and specific allocations of the net proceeds of this offering. Pending the uses described above, we intend to invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments or other securities.

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**DIVIDEND POLICY**

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors our board of directors deems relevant, and subject to the restrictions contained in any future financing instruments. In addition, our ability to pay cash dividends is currently restricted by the terms of our credit facility with Signature Bank. Our ability to pay cash dividends on our capital stock in the future may also be limited by the terms of any preferred securities we may issue or agreements governing any additional indebtedness we may incur.

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**CAPITALIZATION**

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2019 on:

- an actual basis;
- a pro forma basis to give effect to (1) the automatic conversion of 45,651,216 shares of our convertible preferred stock into shares of our common stock, (2) the conversion of all warrants to purchase shares of our convertible preferred stock into warrants to purchase 366,410 shares of our common stock and the reclassification of our convertible preferred stock warrant liability to stockholders' equity, and (3) the filing of our amended and restated certificate of incorporation, in each case, immediately prior to the closing of this offering; and
- a pro forma as adjusted basis to give effect to the pro forma adjustments described above as well as the sale and issuance by us of \_\_\_\_\_ shares of our common stock in this offering at the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

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The pro forma and pro forma as adjusted information below is illustrative only and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at the pricing of this offering. You should read this information in conjunction with the sections titled “Use of Proceeds,” “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and the accompanying notes thereto included elsewhere in this prospectus.

	As of December 31, 2019		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share and per share data)		
Cash and cash equivalents	\$	\$	\$
Long-term debt			
Warrant liabilities		—	—
Redeemable convertible preferred stock, par value \$0.001 per share: 46,017,626 shares authorized, shares issued and outstanding, actual; and zero shares authorized, shares issued and outstanding, pro forma and pro forma as adjusted		—	—
Stockholders’ deficit:			
Preferred stock, par value \$0.001 per share; no shares authorized, issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, par value \$0.001 per share; 60,000,000 shares authorized, shares issued and outstanding, actual; and shares authorized, shares issued and outstanding, pro forma; and shares authorized, shares issued and outstanding, pro forma as adjusted			
Additional paid-in capital			
Accumulated deficit			
Total stockholders’ deficit (equity)			
Total capitalization	\$	\$	\$

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, additional paid-in capital, total stockholders’ equity (deficit) and total capitalization by approximately \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, an increase (decrease) of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, additional paid-in capital, total stockholders’ equity (deficit) and total capitalization by approximately \$ million, assuming the shares of our common stock offered by this prospectus are sold at the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

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The number of shares of our common stock to be outstanding after this offering is based on 55,248,527 shares of our common stock outstanding as of December 31, 2019, which includes 45,651,216 shares of common stock issuable upon the conversion of all of our outstanding shares of convertible preferred stock and excludes:

- 39,713 shares of our common stock issuable upon the exercise of a warrant to purchase common stock outstanding as of December 31, 2019, with an exercise price of \$0.10 per share;
- 110,000 shares of our common stock issuable upon the exercise of a warrant to purchase Series A convertible preferred stock outstanding as of December 31, 2019, with an exercise price of \$1.00 per share, which will convert into a warrant to purchase common stock immediately prior to the closing of this offering;
- 256,410 shares of our common stock issuable upon the exercise of a warrant to purchase Series B convertible preferred stock outstanding as of December 31, 2019, with an exercise price of \$1.17 per share, which will convert into a warrant to purchase common stock immediately prior to the closing of this offering;
- 5,829,739 shares of our common stock issuable upon the exercise of outstanding options under our 2011 Equity Incentive Plan as of December 31, 2019, at a weighted-average exercise price of \$0.63 per share;
- 4,094,552 shares of our common stock issuable upon the vesting and settlement of outstanding restricted stock units, or RSUs, under our 2011 Equity Incentive Plan as of December 31, 2019; and
- shares of our common stock reserved for future issuance under our equity compensation plans, consisting of (1) 716,950 shares of our common stock reserved for future issuance under our 2011 Equity Incentive Plan as of December 31, 2019, (2)        shares of our common stock reserved for future issuance under our 2020 Incentive Award Plan, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part, and (3)        shares of our common stock reserved for future issuance under our 2020 ESPP, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part.

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**DILUTION**

If you invest in our common stock in this offering, your interest will be diluted to the extent of the difference between the amount per share paid by purchasers of shares of our common stock in this initial public offering and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

As of December 31, 2019, our historical net tangible book value (deficit) was \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share of our common stock. Historical net tangible book value (deficit) per share represents our total tangible assets less total liabilities, less convertible preferred stock, divided by the number of shares of our common stock outstanding as of December 31, 2019.

As of December 31, 2019, our pro forma net tangible book value (deficit) was \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share of our common stock. Pro forma net tangible book value per share represents the amount of our total tangible assets reduced by the amount of our total liabilities and divided by the total number of shares of our common stock outstanding as of December 31, 2019 after giving effect to (1) the automatic conversion of 45,651,216 shares of our convertible preferred stock into shares of our common stock, (2) the conversion of all warrants to purchase shares of our convertible preferred stock into warrants to purchase 366,410 shares of our common stock and the reclassification of our convertible preferred stock warrant liability to stockholders' equity and (3) the filing of our amended and restated certificate of incorporation, in each case, immediately prior to the closing of this offering.

After giving further effect to our sale of \_\_\_\_\_ shares of our common stock in this offering at the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2019 would have been approximately \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share of our common stock. This represents an immediate increase in pro forma net tangible book value of \$ \_\_\_\_\_ per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately \$ \_\_\_\_\_ per share to new investors purchasing shares of our common stock in this offering at the assumed initial public offering price. We determine dilution by subtracting our pro forma as adjusted net tangible book value per share after this offering from the amount of cash that a new investor paid for a share of common stock in this offering.

The following table illustrates this dilution on a per share basis to new investors:

Assumed initial public offering price per share	\$
Historical net tangible book value per share as of December 31, 2019	\$ _____
Pro forma increase in net tangible book value per share	
Pro forma net tangible book value per share as of December 31, 2019	
Increase in pro forma net tangible book value per share attributable to new investors in this offering	\$ _____
Pro forma as adjusted net tangible book value per share after this offering	\$ _____
Dilution per share to new investors in this offering	\$ _____

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by \$ \_\_\_\_\_ per share and would increase (decrease) the dilution per share to new investors in this offering by \$ \_\_\_\_\_ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. An increase

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(decrease) of 1.0 million shares in the number of shares offered by us would increase (decrease) our pro forma as adjusted net tangible book value per share after this offering by \$ \_\_\_\_\_ per share and would increase (decrease) the dilution per share to new investors in this offering by \$ \_\_\_\_\_ per share, assuming the assumed initial public offering price remains the same, and after deducting the underwriting discounts and commissions and the estimated offering expenses payable by us.

If the underwriters' option to purchase additional shares of our common stock is exercised in full, our pro forma as adjusted net tangible book value per share after this offering would be \$ \_\_\_\_\_, the increase in pro forma net tangible book value per share attributable to new investors would be \$ \_\_\_\_\_ and the dilution per share to new investors would be \$ \_\_\_\_\_, in each case assuming an initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

The following table summarizes, on the pro forma as adjusted basis described above, as of December 31, 2019, the difference between existing stockholders and new investors purchasing shares of common stock in this offering with respect to the number of shares purchased from us, the total consideration paid to us and the average price per share paid by our existing stockholders or to be paid by new investors purchasing shares in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

	<u>Shares Purchased</u>		<u>Total Consideration</u>		<u>Average</u>
	<u>Number</u>	<u>Percent</u>	<u>Amount</u>	<u>Percent</u>	<u>Price</u>
Existing stockholders		%	\$	%	\$
New investors					
Total		100%		100%	

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors and total consideration paid by all stockholders by \$ \_\_\_\_\_ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters' option to purchase additional shares of our common stock is exercised in full, our existing stockholders would own \_\_\_\_\_% and our new investors would own \_\_\_\_\_% of the total number of shares of common stock outstanding upon the completion of this offering.

The dilution information discussed above is illustrative only and may change based on the actual initial public offering price and other terms of this offering. To the extent any outstanding warrants are exercised, or new options are issued or we issue additional shares of common stock or other equity or convertible debt securities in the future, there will be further dilution to investors participating in this offering.

The number of shares of our common stock to be outstanding after this offering is based on 55,248,527 shares of our common stock outstanding as of December 31, 2019, which includes 45,651,216 shares of common stock issuable upon the conversion of all of our outstanding shares of convertible preferred stock and excludes:

- 39,713 shares of our common stock issuable upon the exercise of a warrant to purchase common stock outstanding as of December 31, 2019, with an exercise price of \$0.10 per share;
- 110,000 shares of our common stock issuable upon the exercise of a warrant to purchase Series A convertible preferred stock outstanding as of December 31, 2019, with an exercise price of \$1.00

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per share, which will convert into a warrant to purchase common stock immediately prior to the closing of this offering;

- 256,410 shares of our common stock issuable upon the exercise of a warrant to purchase Series B convertible preferred stock outstanding as of December 31, 2019, with an exercise price of \$1.17 per share, which will convert into a warrant to purchase common stock immediately prior to the closing of this offering;
- 5,829,739 shares of our common stock issuable upon the exercise of outstanding options under our 2011 Equity Incentive Plan as of December 31, 2019, at a weighted-average exercise price of \$0.63 per share;
- 4,094,552 shares of our common stock issuable upon the vesting and settlement of outstanding restricted stock units, or RSUs, under our 2011 Equity Incentive Plan as of December 31, 2019; and
- shares of our common stock reserved for future issuance under our equity compensation plans, consisting of (1) 716,950 shares of our common stock reserved for future issuance under our 2011 Equity Incentive Plan as of December 31, 2019, (2)        shares of our common stock reserved for future issuance under our 2020 Incentive Award Plan, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part, and (3)        shares of our common stock reserved for future issuance under our 2020 ESPP, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part.

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**SELECTED FINANCIAL DATA**

The following tables present our selected financial data for the periods and as of the dates indicated. We derived our selected statement of operations data for the years ended December 31, 2018 and 2019 and the balance sheet data as of December 31, 2018 and 2019 from our audited financial statements that are included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future. You should read the following information in conjunction with the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and the accompanying notes thereto included elsewhere in this prospectus.

	<u>Year ended December 31,</u>	
	<u>2018</u>	<u>2019</u>
	<u>(in thousands, except share and per share data)</u>	
<b>Statement of Operations Data:</b>		
Revenue	\$ 6,829	\$
Cost of goods sold	1,281	_____
Gross profit	5,548	_____
Operating expenses:		
Research and development	3,990	_____
Selling, general and administrative	10,698	_____
Total operating expenses	14,688	_____
Loss from operations	(9,139)	_____
Other income (expense):		
Interest income	92	_____
Interest expense	(887)	_____
Other expenses	(218)	_____
Total other expenses, net	(1,013)	_____
Net loss and comprehensive loss	\$ (10,153)	\$ _____
Net loss per share, basic and diluted (1)	\$ (1.41)	\$ _____
Weighted average shares of common stock used to compute net loss per share, basic and diluted (1)	7,221,036	_____
Pro forma net loss per share, basic and diluted (unaudited) (1)		_____
Weighted average shares of common stock used to compute pro forma net loss per share, basic and diluted (unaudited) (1)		_____

(1) See Note 2 to our audited financial statements included elsewhere in this prospectus for an explanation of the method used to calculate our historical and pro forma basic and diluted net loss per share.

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	<u>As of December 31,</u>	
	<u>2018</u>	<u>2019</u>
	(in thousands)	
<b>Balance Sheet Data:</b>		
Cash and cash equivalents	\$ 21,834	\$
Working capital (1)	23,837	
Total assets	26,901	
Total liabilities	12,177	
Warrant liabilities	213	
Redeemable convertible preferred stock	54,170	
Total stockholders' equity (deficit)	(39,446)	

(1) We define working capital as current assets less current liabilities. See our financial statements and the accompanying notes thereto included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

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**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 in conjunction the section titled “Selected Financial Data” and our financial statements and the accompanying notes thereto included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should read the sections titled “Risk Factors” and “Special Note Regarding Forward-Looking Statements” for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

**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 ClotTrievers 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 FlowTrievers product is the first thrombectomy system FDA-cleared for the treatment of pulmonary embolism, or PE. These products have been used to treat more than 6,300 patients at approximately 400 hospitals across the United States, with approximately 90% of cases being performed since we launched our broader commercial efforts in the third quarter of 2018. We have experienced significant growth since we began commercializing our products and have had strong momentum in our business in 2019, with approximately 4,550 procedures performed using our products in 2019.

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 ClotTrievers and FlowTrievers 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, which consisted of 63 sales representatives as of December 31, 2019, and we are actively expanding our sales organization through additional sales representatives and territories.

To date, our primary sources of capital have been private placements of preferred stock, debt financing arrangements and revenue from sales of our products. Since inception, we have raised a total of \$54.2 million in net proceeds from private placements of preferred stock. As of December 31, 2018, we had cash and cash equivalents of \$21.8 million, long-term debt of \$10.1 million and an accumulated deficit of \$40.1 million. For the year ended December 31, 2018, we generated revenue of \$6.8 million and our net loss was \$10.2 million.

**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.

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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:

Procedure <sup>(1)</sup>	Three Months Ended			
	March 31, 2019	June 30, 2019	Sept. 30, 2019	Dec. 31, 2019
DVT	342	498	676	959
PE	281	396	576	834

(1) We define a procedure as any instance in which a physician treats DVT or PE using our products and for which we have a record that the procedure was performed.

## Components of our Results of Operations

### Revenue

We currently derive all our revenue from the sale of our ClotTrievers and FlowTrievers 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 year ended December 31, 2018. 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 the year ended December 31, 2019, % of our revenue was derived from the sale of our ClotTrievers and % of our revenue was derived from the sale of our FlowTrievers.

### 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 FlowTrievers may involve one or more Triever aspiration catheters and one or more FlowTrievers catheters. We charge customers the same price for each FlowTrievers 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

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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.

***Other Expenses***

Other expenses primarily consist of gains and losses resulting from the remeasurement of the fair value of our preferred stock warrant liability at each balance sheet date. We will continue to record adjustments to the estimated fair value of the preferred stock warrants until they are exercised, which we expect to occur in connection with this offering. At that time, the final fair value of the warrant liability will be reclassified to stockholders' (equity)/deficit and we will no longer record any related periodic fair value adjustments.

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**Results of Operations**

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

<u>(in thousands except percentages)</u>	Year Ended December 31,		<u>Change \$</u>	<u>Change %</u>
	2018	2019		
Revenue	\$ 6,829	100.0%	\$	
Costs of goods sold	1,281	18.8%		
Gross profit	5,548	81.2%		
Operating expenses:				
Research and development	3,990	58.4%		
Selling, general and administrative	10,698	156.7%		
Total operating expenses	14,688	215.1%		
Loss from operations	(9,140)	(133.9%)		
Other income (expense)				
Interest income	92	1.3%		
Interest expense	(887)	(13.0%)		
Other expenses	(218)	(3.2%)		
Net loss and comprehensive loss	\$(10,153)	(148.7%)	\$	

**Comparison of Years Ended December 31, 2018 and 2019**

*Revenue.* Revenue increased \$            million, or   %, to \$            million during the year ended December 31, 2019, compared to \$6.8 million during the year ended December 31, 2018. The increase in revenue was due to an increase in the number of products sold and an increase in the average selling prices of our products.

*Cost of Goods Sold and Gross Margin.* Cost of goods sold increased \$            million, or   %, to \$            million during the year ended December 31, 2019, compared to \$1.3 million during the year ended December 31, 2018. This increase was due to the increase in the number of products sold and additional manufacturing overhead costs as we relocated to our new facility in Irvine, California and invested significantly in our operational infrastructure to support anticipated future growth. Gross margin for the year ended December 31, 2019 increased to   %, compared to 81.2% in the year ended December 31, 2018. Gross margin increased due to an increase in the average selling prices of our products and improved operating leverage.

*Research and Development Expenses.* R&D expenses increased \$            million, or   %, to \$            million during the year ended December 31, 2019, compared to \$4.0 million during the year ended December 31, 2018. The increase in R&D expenses was primarily due to an increase of \$            million of personnel-related expenses and \$            million of clinical study and registry expenses.

*Selling, General and Administrative Expenses.* SG&A expenses increased \$            million, or   %, to \$            million during the year ended December 31, 2019, compared to \$10.7 million during the year ended December 31, 2018. The increase in SG&A costs was primarily due to an increase of \$            million in personnel-related expenses as a result of increased headcount of our sales organization, increased commissions due to higher revenue and an increase in the number of products sold, an increase of \$            million in professional fees, an increase of \$            million in travel costs and an increase of \$            million in marketing costs.

*Interest Income.* Interest income increased \$            million, or   %, to \$            million during the year ended December 31, 2019, compared to \$0.1 million during the year ended December 31, 2018. The increase in interest income was primarily due to an increase in cash and cash equivalents.

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*Interest Expense.* Interest expense increased \$            million, or    %, to an expense of \$            million during the year ended December 31, 2019, compared to an expense of \$0.9 million during the year ended December 31, 2018. This increased expense was primarily due to the additional interest expense associated with \$            million of additional borrowings during 2019. As of December 31, 2018, the aggregate outstanding principal balance under the amended and restated loan and security agreement with East West Bank was \$10.0 million. As of December 31, 2019, the aggregate outstanding principal balance under the credit facility with Signature Bank was \$            million.

*Other Expenses.* Other expenses increased \$            million or    % to \$            million for the year ended December 31, 2019, compared to \$0.2 million for the year ended December 31, 2018. The increase was primarily due to the remeasurement of our convertible preferred stock warrant liability and the recognition of the related loss from the change in its fair value of \$            million and a loss on extinguishment of debt related to the refinancing of our debt facility of \$            million.

**Liquidity and Capital Resources**

To date, our primary sources of capital have been private placements of preferred stock, debt financing agreements and revenue from the sale of our products. As of December 31, 2018, we had cash and cash equivalents of \$21.9 million, \$10.0 million of principal outstanding under the amended and restated loan and security agreement with East West Bank and an accumulated deficit of \$40.1 million.

In Note 1 to our financial statements, we disclose that there is substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm issued an explanatory paragraph regarding our going concern uncertainty in its report on our financial statements as of and for the year ended December 31, 2018. Based on our planned operations, we do not expect that our cash and cash equivalents will be sufficient to fund our operations for at least 12 months after the date the financial statements are issued without raising additional capital through equity or debt financing, or potential additional collaboration proceeds. These conditions raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to successfully secure sources of financing and ultimately achieve profitable operations. Based on our planned operations, we expect that the anticipated proceeds of this offering, together with 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. If these sources are insufficient to satisfy our liquidity requirements, we may seek to raise additional funds through future equity or debt financings. If we raise additional funds by issuing equity securities, our stockholders would experience dilution. Additional debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. There can be no assurance that our efforts to procure additional financing will be successful or that, if they are successful, the terms and conditions of such financing will be favorable to us or our stockholders. If we are unable to raise additional financing when needed, we may be required to delay, reduce, or terminate the development, commercialization and marketing of our products, liquidate our assets and scale back our business and operations.

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**Cash Flows**

The following table summarizes our cash flows for each of the years ended December 31:

<u>(in thousands)</u>	<u>Year Ended December 31,</u>	
	<u>2018</u>	<u>2019</u>
Net cash (used in) provided by:		
Operating activities	\$(10,892)	\$
Investing activities	(753)	
Financing activities	26,758	
Net increase (decrease) in cash and cash equivalents	<u>\$ 15,113</u>	<u>\$</u>

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

Net cash used in operating activities for the year ended December 31, 2019 was \$            million, consisting primarily of a net loss of \$            million and an increase in net operating assets of \$            million, partially offset by non-cash charges of \$            million. The increase in net operating assets was primarily due to an increase in accounts receivable and inventories to support the growth of our operations, partially offset by increases in accounts payable and accrued liabilities, due to timing of payments and growth of our operations. The non-cash charges primarily consisted of depreciation, stock-based compensation, non-cash interest expense and other charges related to the amended and restated loan and security agreement with East West Bank and credit facility with Signature Bank, and the change in fair value of the preferred stock warrant liability.

Net cash used in operating activities for the year ended December 31, 2018 was \$10.9 million, consisting primarily of a net loss of \$10.2 million and an increase in net operating assets of \$1.5 million, partially offset by non-cash charges of \$0.8 million. The increase in net operating assets was primarily due to an increase in accounts receivable of \$2.2 million due to increase in sales and inventories of \$0.6 million to support the growth of our operations, partially offset by increases in accounts payable of \$0.4 million and accrued liabilities of \$0.8 million due to timing of payments and growth of our operations. Non-cash charges consisted primarily of \$0.3 million in depreciation, stock-based compensation of \$0.3 million, non-cash interest expense and other charges related to the amended and restated loan and security agreement with East West Bank of \$0.1 million and the change in fair value of the convertible preferred stock warrants of \$0.1 million.

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

Net cash used in investing activities in the year ended December 31, 2019 was \$            million consisting of purchases of property and equipment.

Net cash used in investing activities in the year ended December 31, 2018 was \$0.8 million consisting of purchases of property and equipment.

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

Net cash provided by financing activities in the year ended December 31, 2019 of \$            million primarily relates to proceeds of \$            million from additional borrowings under the credit facility with Signature Bank, and \$            million proceeds from the exercise of stock options.

Net cash provided by financing activities in the year ended December 31, 2018 of \$26.8 million primarily relates to net proceeds of \$26.9 million from the issuance of our Series C convertible preferred stock and \$0.2 million of debt financing costs.

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**Indebtedness**

In April 2016, we entered into a loan and security agreement with East West Bank, or the EWB Loan Agreement, providing for a term loan of up to \$10.0 million, available in two \$5.0 million tranches. In connection with the EWB Loan Agreement, we issued warrants to purchase 256,410 shares of our Series B convertible preferred stock to East West Bank. These warrants have an exercise price of \$1.17 per share and expire in 2026. In March 2018, we entered into an amended and restated loan and security agreement with East West Bank, or the Amended and Restated EWB Loan Agreement, to extend the maturity date of the term loan to March 2022 and to extend an interest-only period of the term loan to April 2020. The Amended and Restated EWB Loan Agreement provided for two six-month extensions to the interest-only period, which are available at our written election following the achievement of specified FDA clearance and revenue milestones. Together, these extensions provided for a potential interest-only period under the Amended and Restated EWB Loan Agreement through April 2021. In connection with the EWB Loan Agreement, we paid a facility fee of \$100,000 and aggregate final prepayment fees and interest payments of approximately \$133,000. As of December 31, 2018, the aggregate outstanding principal balance under the Amended and Restated EWB Loan Agreement was \$10.0 million.

The term loan under the Amended and Restated EWB Loan Agreement bore interest at an annual rate equal to the prime rate plus 2.50% (8.00% as of December 31, 2018). Under the terms of the Amended and Restated EWB Loan Agreement, the prime rate was equal to the greater of 4.5% per year and the variable annual rate of interest most recently announced by East West Bank as its “prime rate.” We were required to make monthly payments of interest only through April 2020, subject to the two six-month extensions described above. Following the interest-only periods, we were required to make payments of interest and principal in monthly installments through maturity of the term loan in March 2022. The Amended and Restated EWB Loan Agreement provided that we could prepay the term loan without penalty or premium. The term loan was secured by substantially all our assets, including intellectual property under certain conditions, and we were subject to certain reporting and financial covenants. As of December 31, 2018, we were in compliance with or received waivers for all covenants under the Amended and Restated EWB Loan Agreement.

In December 2019, we prepaid and terminated the Amended and Restated EWB Loan Agreement and concurrently entered 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 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 our achievement of at least \$60 million of trailing 12 month revenue no later than August 2020.

The maturity date of the new term loan is in December 2024. We are required to make monthly payments of interest only 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 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%. Under the SB Credit Facility, the prime rate for the term loan is equal to the variable annual rate of interest most recently announced by Signature Bank as its “prime rate.” Following the expiry of the interest-only period or any extension thereof, we are required to make payments of interest and principal in equal monthly installments through the maturity of the term loan in December 2024. Under the revolving line of credit, we may borrow, repay and re-borrow up to 80% of eligible accounts receivable up to a maximum of \$15 million.

The maturity date of the revolving line of credit is in December 2022 and can be extended to December 2024 if we are able to raise at least \$75 million in gross proceeds from an initial public offering. We are required to make monthly payments of interest only through maturity of the revolving line of credit, at which point the

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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. Under the SB Credit Facility, the prime rate for the revolving line is equal to the variable annual rate of interest most recently announced by Signature Bank as its “prime rate.”

We 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. The SB Credit Facility is secured by substantially all our assets, excluding intellectual property. The SB Credit Facility includes a double negative pledge on our intellectual property. We may prepay the SB Credit Facility at any time without penalty or premium. The SB Credit Facility includes certain reporting and financial covenants, including a financial covenant that requires us to maintain minimum revenue requirements. Pursuant to this covenant, revenue is measured monthly and we are required to achieve trailing 12 month revenues 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 loan by mutual agreement based on the Company’s annual forecast. In addition, the SB Credit Facility includes a covenant that limits our ability to make any distributions or dividends except in specific limited circumstances. As of December 31, 2019, we were in compliance with all covenants contained in the SB Credit Facility.

### Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined by applicable regulations of the SEC, 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

Our principal obligations consist of the operating lease for our facility and our Amended and Restated EWB Loan Agreement. The following table shows our contractual obligations due by period as of December 31, 2018:

(in thousands)	Payments Due by Period				Total
	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years	
Operating lease obligations (1)	\$ 216	\$ 224	\$ —	\$ —	\$ 440
Amended and Restated EWB Loan Agreement	—	8,750	1,390	—	10,140
	<u>\$ 216</u>	<u>\$8,974</u>	<u>\$1,390</u>	<u>\$ —</u>	<u>\$10,580</u>

(1) We lease our facility in Irvine, California under a five-year lease agreement that expires in December 2020.

### Critical Accounting Policies and Estimates

Management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

While our significant accounting policies are more fully described in Note 2 to our financial statements included in this prospectus, we believe the following discussion addresses our most critical accounting policies, which are those that are most important to our financial condition and results of operations and require our most difficult, subjective and complex judgments.

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***Revenue Recognition***

We sell our products to hospitals in the United States utilizing our direct sales force. Generally, we provide training to the hospital staff prior to the first purchase of product by the hospital, and this training can include several cases utilizing free of charge product. The cost of training products provided at no charge is included in cost of sales. We provide a 30-day right of return period.

We recognize revenue when all the following criteria are met, which is generally when the goods are delivered to the customer:

- Appropriate evidence of a binding arrangement exists with the customer;
- The sales price is established with the customer;
- The shipment of the product has been received by the customer; and
- Collection of the corresponding receivable from the customer is reasonably assured at the time of sale.

***Accounts Receivable***

We record trade accounts receivable 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.

***Inventories***

Inventories, which includes material, labor and overhead costs, are stated at the lower of cost, determined on a first-in, first-out basis, or net realizable value. We regularly review inventory quantities in process and on hand, and when appropriate, record a provision for obsolete and excess inventory after consideration of actual loss experience, projected future demand, and remaining shelf life. Our policy is to write 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 our estimates of future demand for a particular product. If the estimate of future demand is inaccurate based on actual sales, we may increase the write down for excess inventory for that component and record a charge to inventory impairment in the accompanying statements of operations and comprehensive loss.

***Common Stock Valuation and Stock-Based Compensation***

We maintain an equity incentive plan that permits the grant of share-based awards, such as stock grants and incentives and non-qualified stock options to employees, directors, consultants and advisors. Awards granted under the equity incentive plan have a term of 10 years and generally vest over a four-year period with a straight-line vesting and a 25% one-year cliff.

We recognize compensation costs related to stock options granted to employees based on the estimated fair value of the awards on the date of grant, net of estimated forfeitures. We estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option pricing model. The grant date fair value of stock-based awards is expensed on a straight-line basis over the period during which the employee is required to provide service in exchange for the award, which is typically the vesting period.

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We estimate the fair value of our stock-based awards using the Black-Scholes option pricing model, which requires the input of highly subjective assumptions. Our assumptions are as follows:

*Fair Value of Common Stock.* As our common stock has never been publicly traded, the fair value of the shares of our common stock underlying the stock options has historically been determined by our board of directors after considering independent third-party valuation reports. Because there had previously been no public market for our common stock, our board of directors determined the fair value of our common stock at the time of grant of the option by considering a number of objective and subjective factors, including valuations of comparable companies, sales of our convertible preferred stock, our operating and financial performance and the general and industry-specific economic outlook.

*Expected Term.* We do not believe we are able to rely on our historical exercise and post-vesting termination activity to provide accurate data for estimating the expected term for use in determining the fair value-based measurement of our options. Therefore, we have opted to use the “simplified method” for estimating the expected term of options, which is the average of the weighted average vesting period and contractual term of the options.

*Expected Volatility.* Since our common stock has never been publicly traded, the expected volatility is derived from the average historical volatilities of comparable peer public companies within our industry over a period approximately equal to the expected term of the options.

*Risk-free Interest Rate.* The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for zero-coupon U.S. Treasury notes with remaining terms similar to the expected term of the options.

*Dividend Rate.* We assumed the expected dividend to be zero as we have never paid dividends and have no current plans to do so.

In addition to the assumptions used in the Black-Scholes option pricing model, we also estimated a forfeiture rate to calculate the stock-based compensation for our equity awards at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on management’s expectation using historical forfeiture patterns. We will continue to use judgment in evaluating the expected volatility and expected terms utilized for our stock-based compensation calculations on a prospective basis. As we continue to accumulate additional data, we may have refinements to our assumptions, which could materially impact our future stock-based compensation expense.

We amortize all stock-based compensation on a straight-line basis over the requisite service period of the awards, which is generally the same as the vesting period of the awards.

We expect to continue to grant stock options and other equity-based awards in the future, and to the extent that we do, our stock-based compensation expense recognized in future periods will likely increase.

***Estimated fair value of convertible preferred stock warrants***

We have issued freestanding warrants to purchase shares of convertible preferred stock to banks in connection with our debt. We account for these warrants as a liability in our financial statements because the underlying instrument into which the warrants are exercisable contains deemed liquidation provisions that are outside our control.

The warrants are recorded at fair value using the Black-Scholes option pricing model. The warrants are subject to remeasurement at each balance sheet date with any changes in fair value being recognized as a component of other income (expense), net in the statements of operations. We will continue to adjust the liability

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for changes in fair value until the earlier of (i) exercise or expiration of the warrants, or (ii) the completion of this offering or a change of control, at which time outstanding convertible preferred stock warrants will be exercised for shares of common stock and the related final fair value of the warrant liability will be reclassified to stockholders' deficit.

**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 December 31, 2018, we had \$10.0 million in variable rate debt outstanding under the Amended and Restated EWB Loan Agreement. Payments under the Amended and Restated EWB Loan Agreement were due in monthly installments through March 2022. Interest under the Amended and Restated EWB Loan Agreement accrued at an annual rate equal to the prime rate plus 2.50% (8.00% as of December 31, 2018). Under our SB Credit Facility, we are required to make monthly installments from December 2021 through December 2024, and the term loan accrues interest at an annual rate equal to the greater of 5.50% or the prime rate plus 0.50%.

***Credit Risk***

As of December 31, 2018, our cash and cash equivalents were maintained with two financial institutions in the United States, and our current deposits are likely in excess of insured limits. We 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 December 31, 2018.

***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.

**JOBS Act Accounting Election**

As an emerging growth company under the JOBS Act, we are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. Thus, an emerging growth company can 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.

**Recently Issued Accounting Pronouncements**

See Note 2 to our financial statements included in this prospectus for new accounting pronouncements not yet adopted as of the date of this prospectus.

**Related Parties**

For a description of our related party transactions, see "Certain Relationships and Related Party Transactions."

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**BUSINESS**

**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 ClotTrievers 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 FlowTrievers product is the first thrombectomy system FDA-cleared for the treatment of pulmonary embolism, or PE. These products have been used to treat more than 6,300 patients at approximately 400 hospitals across the United States, with approximately 90% of cases being performed since we launched our broader commercial efforts in the third quarter of 2018. We have experienced significant growth since we began commercializing our products and have had strong momentum in our business in 2019, with approximately 4,550 procedures performed using our products in 2019.

VTE is a disease caused by blood clot formation in the veins of the body and is a leading cause of death and disability worldwide. VTE represents the third most common vascular diagnosis in the United States after myocardial infarction and stroke. Researchers estimate that approximately one million people present with VTE in the United States each year, with approximately 668,000 new patients diagnosed with DVT and approximately 400,000 new patients diagnosed with PE each year. VTE results in approximately 296,000 deaths in the United States each year and industry sources estimate that VTE-related direct health care costs exceed \$10 billion per year.

Of the estimated 668,000 new DVT diagnoses and 400,000 new PE diagnoses in the United States each year, we believe approximately 242,000 DVT patients and approximately 200,000 PE patients, could benefit from safe and effective treatment with our ClotTrievers and FlowTrievers products, respectively. This represents a potential annual addressable U.S. market opportunity for our current products of approximately \$3.6 billion based on the current average selling prices of our products. We also believe there is a substantial market opportunity outside the United States.

The current standard of care for treating VTE is conservative medical management with anticoagulants, which are drugs designed to prevent further blood clotting but that do not break down or eliminate existing clots. Anticoagulants are intended to stop further clot formation while the body attempts to break down and remove clots using natural mechanisms. Nearly all patients receive this treatment, many of whom remain on anticoagulants for the remainder of their lives. We estimate that 68% of our target DVT patients and 90% of our target PE patients are treated with anticoagulants alone. We estimate that the remaining 32% of our target DVT patients and 10% of our target PE patients also receive additional treatment using mechanical thrombectomy or thrombolytic drug therapy.

Historically, development efforts for mechanical thrombectomy devices have focused on arterial devices, which are then repurposed for use in the venous system. Given the significant differences between the arterial and venous systems and the clot that forms in each system, these devices have difficulty removing venous clot, which is often adhered to the vessel wall and is older, firmer and substantially larger than arterial clot.

Thrombolytic drugs accelerate the body's natural mechanisms for breaking down clot, which are generally not effective on venous clot. These drugs also are associated with a risk of spontaneous major bleeding, including catastrophic bleeding in the brain. In addition, these drugs are expensive and require monitoring in a critical care setting, such as the intensive care unit, or ICU.

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

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ClotTrier and FlowTrier products. The ClotTrier is a mechanical thrombectomy system designed to core, capture and remove large clots from large vessels and is used to treat DVT. The FlowTrier is a large bore catheter-based aspiration and mechanical thrombectomy system designed to remove large clots from large vessels to treat PE. Both products are designed to eliminate the need for thrombolytic drugs.

We believe our products are transformational because they offer hospitals, physicians and patients the following key benefits:

- *Capture and remove large clot burden from large vessels.*
- *Liberate clot mechanically and remove venous clot from the vessel wall.*
- *Eliminate the need for thrombolytic drugs.*
- *Remove clot safely with minimal blood loss.*
- *Offer simple, intuitive and easy to use solutions to physicians.*
- *Enable short, single-session treatment with improved hospital and physician efficiency.*
- *Require no capital investment.*

We believe the historical bias for conservative medical management is largely due to the ineffectiveness of, and risks associated with, current alternative treatments, and the lack of mechanical tools capable of removing venous clot in a safe, effective and simple way. The standard of care for treatment of other thrombotic diseases, such as myocardial infarction and stroke, has evolved from the use of anticoagulants alone to anticoagulants together with thrombolytic drugs and eventually to anticoagulants together with definitive catheter-based interventions. We believe our products could be the catalyst to drive the same evolution of treatment for venous diseases, establishing our products as the standard of care for DVT and PE.

Our ClotTrier and FlowTrier have received 510(k) clearance from the FDA. The primary clinical study we have completed to date regarding the safety and effectiveness of our products is our FlowTrier Pulmonary Embolectomy Clinical Study, or FLARE study, which was completed in October 2017. The FLARE study supported FDA 510(k) clearance of the FlowTrier for the treatment of PE, which was received in May 2018. The study met both of its primary endpoints, demonstrating the safety and effectiveness of the FlowTrier for the treatment of PE without the use of thrombolytic drugs. There were no device-related major adverse events. Of the 106 patients evaluated, four patients (3.8%) experienced six major adverse events in the 48 hours after treatment, all of which were determined to be procedure-related. We are committed to continuing to develop a strong base of clinical evidence and real-world patient outcomes to further support the safety and effectiveness of our products. We are currently enrolling two 500-patient registries: ClotTrier Outcomes, or CLOUT, for DVT and FlowTrier All-Corner Registry for Patient Safety and Hemodynamics, or FLASH, for PE. As of December 31, 2019, CLOUT and FLASH had enrolled 93 and 117 patients, respectively. In addition, there are more than 10 ongoing investigator-initiated studies being conducted. We believe these efforts will generate a robust cadence of publications, drive adoption of our products, increase awareness of venous diseases and inform the design of future definitive clinical trials.

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, which consisted of 63 sales representatives as of December 31, 2019, and we are actively expanding our sales organization through additional sales representatives and territories.

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We have experienced significant growth since we began commercializing our products in the United States. We generated revenue of \$ \_\_\_\_\_ million, with a gross margin of \_\_\_\_\_ % and net losses of \$ \_\_\_\_\_ million for the year ended December 31, 2019, compared to revenue of \$6.8 million, with a gross margin of 81.2% and net losses of \$10.2 million for the year ended December 31, 2018. Our accumulated deficit was \$ \_\_\_\_\_ million as of December 31, 2019.

**Our Success Factors**

We believe the continued growth of our company will be driven by the following success factors:

- ***Sole focus on and deep understanding of the venous system and venous diseases.*** We are pioneering the development and commercialization of devices that are designed and purpose-built for the specific characteristics of the venous system, its diseases and its unique clot morphology. Treatment of the venous system and its diseases presents a different set of challenges and requirements than the arterial system, and represents a new frontier for the application of catheter-based solutions. Historically, development efforts have focused on repurposing arterial devices for use in the venous system. Given the significant differences between the arterial and venous systems, these efforts have largely been ineffective in treating VTE. Inari's sole focus on the venous system and deep knowledge of our target market has enabled us to understand the unmet needs of our patients and physicians. This has allowed us to rapidly innovate and enhance our products and has informed our clinical and educational programs.
- ***Proprietary devices designed to safely and effectively remove large volumes of clot from large vessels while eliminating the need for thrombolytic drugs.*** Our ClotTriever and FlowTriever products are minimally-invasive devices designed to remove large volumes of clot from the venous system, without the use of thrombolytic drugs. They work simply, safely and effectively, and facilitate short, single-session treatments for both DVT and PE. Historically, patients suffering from DVT and PE were primarily treated with anticoagulants, which are drugs designed to prevent further blood clotting but that do not break down or eliminate existing clots. Other drug-based alternatives, including catheter-directed thrombolysis, are also used with limited effectiveness and, in some cases, with major bleeding. We believe our purpose-built venous thrombectomy products offer significant treatment benefits and have the potential to become the standard of care for DVT and PE.
- ***Large market opportunity for patients with unmet needs.*** In the United States, we estimate there are approximately 242,000 DVT patients and 200,000 PE patients each year that could benefit from treatment with our ClotTriever and FlowTriever products, respectively. We estimate that 68% of these target DVT patients and 90% of these target PE patients are treated with conservative medical management involving anticoagulants alone, which do not break down or eliminate existing clot. As a result, we believe there is a significant unmet need for safe and effective treatment and removal of existing clot in patients with these diseases. We believe the historical bias for conservative medical management is largely due to the ineffectiveness of, and risks associated with, current alternative treatments, and the lack of mechanical tools capable of removing venous clot in a safe, effective and simple way. The standard of care for treatment of other thrombotic diseases, such as myocardial infarction and stroke, has evolved from the use of anticoagulants alone to anticoagulants together with thrombolytic drugs and eventually to anticoagulants together with definitive catheter-based interventions. We believe that our products could be the catalyst to drive the same evolution of treatment for venous diseases. We estimate the potential annual total addressable market for our products in the United States is approximately \$3.6 billion, assuming the current average selling prices of our products, and that there is also a significant opportunity for our products outside the United States.

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- ***Rapidly scaling commercial organization leveraging unique insights.*** Our most important relationships are between our sales representatives and physicians. Our front-line sales representatives attend over 80% of the procedures in which our products are used, which puts us at the intersection of the patient, product and physician. We have developed systems and processes to harness the information gained from these interactions and we leverage this information to rapidly iterate products, introduce and execute physician education and training programs and scale our sales organization. We are rapidly expanding our network of sales representatives. As of December 31, 2019, we had 63 sales representatives, up from 21 sales representatives as of December 31, 2018.
- ***Simple, intuitive and easy to use products with minimal training required.*** Our products are minimally invasive, easy to use, single-use devices that do not require capital equipment or the use of thrombolytic drugs. We designed and developed our products to enable a short learning curve and consistent ease of use. Our products are designed to utilize standard endovascular skills possessed by our target physicians. Our target physicians are interventional cardiologists, interventional radiologists and vascular surgeons, each of which can readily learn the required additional techniques for use of our products. We believe this simplicity and ease of use will continue to help drive adoption of our products.
- ***Compelling hospital economics and improved hospital and physician efficiency.*** We believe our products can reduce the cost of treating DVT and PE. We designed our products to eliminate the need for expensive thrombolytic drugs. These drugs require a costly ICU stay and carry a significant risk of major bleeding, which is an expensive and dangerous complication. Our products facilitate short, single-session treatments for both DVT and PE, and we believe have the potential to reduce the total length of hospital stay and improve hospital economics. In addition, our products can drive hospital and physician efficiency. We believe these economic benefits support the approval of our products by hospital value analysis committees, group purchasing organizations and integrated delivery networks, which reduces a key barrier to adoption by our physician customers.
- ***Unique culture of focus on patient care, driving value creation.*** We believe that VTE patients have been poorly understood, under treated and mostly ignored by industry participants. Our key purpose is to serve and improve the quality of life of these patients, our patients. We believe that the clot itself matters and that removing it can have a profound impact on the lives of our patients over the short and long term. We believe it is our responsibility to ensure as many of our patients as possible are treated safely, effectively and simply. We have implemented hiring and recruiting systems to carefully select professionals who share our beliefs and goals. We believe that extraordinary outcomes are possible when a group of people commit, together, to ideas and purposes bigger than themselves and bigger than business. We pursue our key purpose with a team of people who commit themselves to a cause and to each other.

### **Our Growth Strategy**

Our mission is to treat and transform the lives of patients suffering from venous diseases. To accomplish this, we intend to establish our products as the standard of care for the treatment of venous diseases. The key elements of our growth strategy are:

- ***Continuing to expand our U.S. sales force.*** We currently sell our products to approximately 400 of the approximately 1,500 hospitals in the United States with a catheterization laboratory, or cath lab, where interventional procedures can be performed. VTE patients present to, and can be treated at, any of these hospitals, whereas some other diseases, such as stroke, require referrals to tertiary care facilities for advanced treatment. We had 63 sales representatives as of December 31, 2019. We plan to rapidly and efficiently grow our sales organization in order to target and expand our network

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of hospital and physician customers, and believe there is a significant opportunity to grow our business through this continued expansion of our commercial footprint.

- ***Driving increased awareness and adoption of our products in existing and future hospital customers.*** As we expand our network of hospital customers, we intend to increase awareness within these hospitals in order to drive greater adoption of our products as the preferred first-line solution for the treatment of venous diseases. To accomplish this, we conduct regular national, regional and local training and educational programs for both interventional and non-interventional physicians. In addition, we are leveraging our expanding sales organization to increase the awareness of our products with our target physicians, referring physicians and other stakeholders at the account level. Our goal is to increasingly drive towards small sales territories that allow for deeper engagement within existing hospital customers. This strategy enables our sales representatives to have regular and targeted communications to convey the benefits of our products to non-interventional physicians, such as emergency department physicians and pulmonologists. These physicians often play an important role in helping to determine patient care. We also train our sales representatives to communicate the clinical and economic benefits of our products with hospital administrators. We believe this comprehensive approach is key to continuing to drive increased adoption of our products within existing and new hospital customers.
- ***Building upon our base of clinical evidence.*** We are committed to continuing to build upon our base of clinical evidence, which we believe will help drive increased awareness and adoption of our products. The primary clinical study we have completed to date is our FLARE study, which established the safety and effectiveness of the FlowTrievers for the treatment of PE without the use of thrombolytic drugs. We are currently enrolling two 500-patient registries, CLOUT for DVT and FLASH for PE, and there are more than 10 ongoing investigator-initiated studies being conducted. These studies will evaluate and assess real-world patient outcomes and we believe they will generate a robust cadence of publications, drive adoption of our products, increase awareness of venous diseases and inform the design of future definitive clinical trials.
- ***Continuing to expand our portfolio of venous products.*** We are currently focused on three key goals as we develop additional and next generation venous products for commercialization. First, we seek to continue to enhance the effectiveness, efficiency and ease of use of our current products. Second, we plan to expand the application of our thrombectomy technology to areas of the body that are not addressed by our existing products. Third, we are developing solutions beyond thrombectomy to address other unmet needs.
- ***Pursuing strategically adjacent markets and international opportunities.*** We believe there is an opportunity to leverage our commercial footprint to expand beyond venous into adjacent vascular markets. In addition, venous diseases are prevalent worldwide, and we believe there is a significant opportunity for our products outside the United States. Although we are primarily focused on addressing the significant domestic market opportunity, in time we expect to commercialize our solutions internationally as well.

## Market Overview

### Our Market

Industry sources estimate that approximately 668,000 patients in the United States are diagnosed with DVT each year. Of these, approximately 242,000 patients, or 38%, have DVT located in the iliofemoral region and are candidates for treatment using our ClotTrievers product. Ilio-femoral DVT, located in the thigh and pelvis, is the most clinically relevant form of this condition due to its large clot volume, poor long-term prognosis and higher risk of adverse outcomes. We believe the ClotTrievers offers an innovative solution for these 242,000

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patients that is safe and more effective than current treatment alternatives. This represents an approximately \$1.6 billion per year U.S. market opportunity for DVT based on the current average selling price of the ClotTrievers.

Industry sources estimate that approximately 400,000 patients in the United States are diagnosed with PE each year. Of these, approximately 200,000 patients, or 50%, have PE that is severe enough to cause right heart strain. PE with right heart strain is associated with a larger clot burden, higher acute mortality and poor long-term prognosis. We believe the FlowTrievers offers an innovative solution for these 200,000 patients that is safe and more effective than current treatment alternatives. This represents an approximately \$2.0 billion per year U.S. market opportunity for PE based on the current average selling price of the FlowTrievers.

Collectively, the potential annual addressable U.S. market for our current products is approximately \$3.6 billion. We also believe there is a substantial market opportunity for DVT and PE outside the United States.

***Venous and Arterial Systems and Clot Morphology***

The vascular system is made up of vessels that carry and circulate blood throughout the body. The system consists of the arterial system, a network of vessels that carry oxygenated blood away from the heart to the body, and the venous system, a network of vessels that return blood from the body back to the heart. The arterial system is characterized by high velocity blood flow under high pressure. As blood moves through arteries to the body, arteries gradually taper in the direction of blood flow and branch off into smaller vessels, terminating in capillaries. Venous blood flow travels at a lower velocity and under lower pressure than arterial blood flow. Veins carry blood back to the heart and, as a result, enlarge in the direction of blood flow. Due to these important differences, the clinical presentation and clot morphology of venous diseases differ significantly from arterial diseases. As a result, VTE presents a specific set of challenges and corresponding requirements for effective treatment solutions.

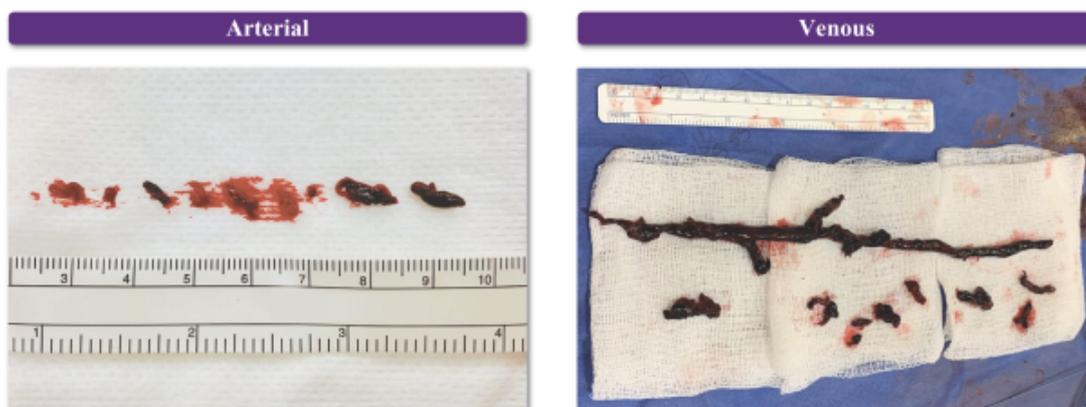
A blood clot initially forms as a fibrin-rich, gel-like substance. It can occur in response to slowing blood flow, damage to a blood vessel or a patient's inherent increased tendency to clot.

Due to the characteristics of the arterial system, clot that forms in arteries quickly becomes occlusive, which causes sudden and dramatic symptoms that require the patient to quickly seek medical attention. Examples of conditions caused by arterial clot include myocardial infarction, or MI, and stroke. As these clots are discovered quickly, they are soft and fibrin-rich. Further, these clots are small because they form in smaller vessels. For example, arterial clot that causes MI or stroke is generally about the size of a grain of rice. In addition, arterial clot is usually not adhered to the wall of the artery.

Due to the characteristics of the venous system, the volume of venous clot gradually increases and adheres to the vessel wall, growing inwards towards the center of the vessel (thicker) and along the vessel wall (longer), further restricting blood flow through the affected vein. Venous clot can develop over days or weeks before causing symptoms severe enough to prompt the patient to seek medical attention. During this time, as venous clot ages, its fibrin composition is rapidly replaced by a firmer collagen matrix. For example, according to a published study, the collagen content of a clot can reach 20% within one week and 80% within three weeks. The body's natural mechanisms for breaking down and removing clot targets fibrin. Therefore, as a clot ages it generally becomes more resistant to the body's natural ability to break down and eliminate it. As a result, by the time patients seek medical attention, their venous clot has likely become resistant to the natural mechanisms for treatment and has become quite significant in size.

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The following images depict examples of arterial and venous clots:



***Venous Thromboembolism***

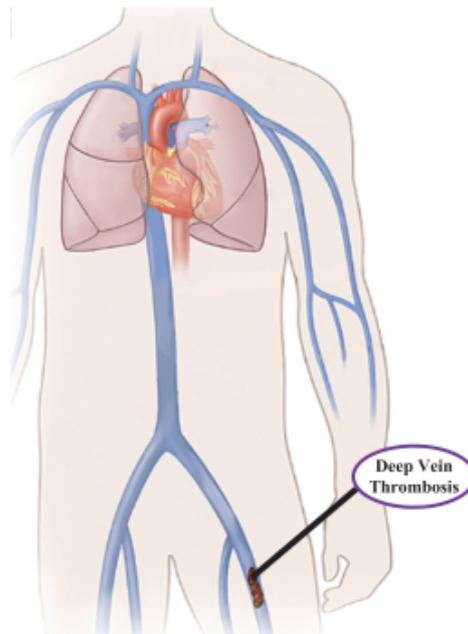
Venous thromboembolism, or VTE, is a disease caused by blood clot formation in the venous system. VTE has two distinct manifestations – deep vein thrombosis, or DVT, and pulmonary embolism, or PE. VTE is a leading cause of death and disability worldwide and represents the third most common vascular diagnosis in the United States after myocardial infarction and stroke. According to industry sources, PE is the third leading cause of cardiovascular death in the United States and is the most common cause of preventable deaths in hospitals in the United States. Researchers estimate that there are up to approximately one million VTE patients in the United States each year. VTE results in approximately 296,000 deaths in the United States each year and industry sources estimate that VTE-related direct health care costs exceed \$10 billion per year.

***Deep Vein Thrombosis***

DVT occurs when clot forms in the deep veins of the extremities of the body, such as the legs. While DVT can occur in any deep vein, it commonly occurs in the iliac, femoral and popliteal veins, which are located in the pelvis, thigh and knee, respectively.

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The image below depicts the location of DVT in the patient's body:



A variety of factors can contribute to the development of clots that can cause DVT including: compression on the vein, surgery, trauma or bone fracture, long periods of bed rest, reduced blood flow from immobility, cancer, pregnancy, birth control pills and varicose veins. In addition, certain people are genetically predisposed for increased clotting. Typical symptoms of DVT include:

- swelling in the foot, ankle or leg, usually on one side;
- cramping pain in the affected leg, usually beginning in the calf;
- unexplained pain in the foot or ankle;
- warm skin; and
- discoloration of the skin, usually bluish or reddish.

Upon presentation, DVT can be readily diagnosed via a standard ultrasound imaging assessment that is usually performed in the emergency room.

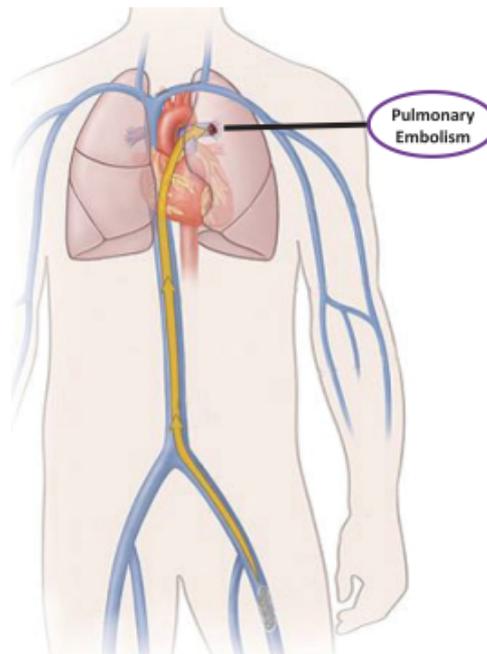
Symptoms can persist and worsen over time if left untreated. In addition, the location of the DVT can have a significant impact on prognosis and the ability to treat the affected vein. For example, iliofemoral DVT is typically the most dangerous and has large clot volume, poor long-term prognosis and a higher risk of adverse outcomes. Approximately 50% of patients suffering from DVT will develop post-thrombotic syndrome, or PTS, which is caused by chronic scarring and occlusion of vessels. PTS is a severe, lifestyle-limiting disease that is characterized by chronic pain, swelling and skin ulcers. Approximately 90% of patients with PTS are unable to work 10 years after diagnosis.

*Pulmonary Embolism*

PE occurs when a venous clot embolizes or becomes mobile, travels through the heart and gets lodged in the pulmonary arteries of the lungs. Venous clot that causes PE originates as DVT.

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The image below depicts the location of PE in the patient's body:



A blood clot in the pulmonary arteries increases pressure in these vessels, which causes an increase in the workload of the heart. This initiates a cascade of events, leading to trouble breathing, chest pain, coughing blood, rapid heartbeat and passing out. Upon presentation, PE can be readily diagnosed via a computerized tomography, or CT, scan of the chest.

The most serious complication associated with PE is death, usually due to cardiovascular collapse from sudden failure of the heart, specifically the right ventricle. As many as 50% of patients who survive have long-term residual pulmonary vascular obstruction due to the body's inability to break down and eliminate the clot. These patients may experience significant impaired function of the heart and lungs, shortness of breath, reduced exercise capacity and lifestyle limitations. In addition, these patients have a statistically higher rate of recurrent PE, pulmonary hypertension, heart failure and death.

PE is often characterized and stratified based on risk to the patient. High risk, or massive, PE is characterized by right heart strain and low systemic blood pressure, and has a mortality rate of up to 50%. Intermediate risk, or submassive, PE is characterized by right heart strain with normal systemic blood pressure, and has a mortality rate of 12-15%. Low risk, or minor PE, has minimal risk of mortality. Approximately 5%, 45% and 50% of PE patients are categorized as high risk, intermediate risk and low risk, respectively.

***Current Treatment Alternatives and Their Limitations***

There are several treatment options for DVT and PE patients, ranging from conservative medical management to advanced catheter-based interventions. We estimate that 68% of our target DVT patients and 90% of our target PE patients are treated with anticoagulants alone. We estimate that the remaining 32% of our target DVT patients and 10% of our target PE patients also receive additional treatment beyond anticoagulation. These treatments include mechanical thrombectomy, thrombolytic drugs and surgery. There is no consistent approach for determining whether a given patient receives anticoagulants alone or in conjunction with additional

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treatments. Due in part to the limitations and potential dangers of these additional treatments, most patients are treated with anticoagulation alone.

*Anticoagulant Drugs*

Conservative medical management with anticoagulant drugs is, and for several decades has been, the primary treatment for DVT and PE. Nearly all patients receive this treatment, many of whom remain on anticoagulants for the remainder of their lives. Anticoagulants do not break down or eliminate existing blood clots. Instead, anticoagulants are intended to stop the formation of additional blood clots and limit the growth of existing blood clots while the body attempts to break down and remove clots using natural mechanisms. Anticoagulation is often initiated on an inpatient basis via intravenous blood thinners, such as heparin or enoxaparin. Patients generally remain in the hospital for several days for monitoring while on these drugs. Once stabilized, the patient is transitioned to oral therapy with either Coumadin or a direct-acting oral anticoagulant, such as Eliquis or Xarelto, and is then discharged from the hospital. Patients can remain on these drugs for months or years, and some patients will remain on these drugs for the remainder of their lives.

*Mechanical Thrombectomy*

Mechanical thrombectomy is an interventional procedure in which a catheter is used to remove clot from vessels in the body, typically by aspiration. There are dozens of catheters available for this type of procedure, although these devices were almost all originally designed for use in the arterial system, which involves the removal of soft, small clots from small vessels. For example, the Penumbra Indigo system is a mechanical thrombectomy system that was initially designed for use in the arterial system. Although this system is not yet approved for treatment of PE, the system met its primary endpoint in a recent clinical trial, demonstrating safety and efficacy for aspiration-based mechanical thrombectomy in patients with acute PE.

Some mechanical thrombectomy devices use a hybrid approach that combines aspiration-based mechanical thrombectomy and localized delivery of thrombolytic drugs. For example, the AngioJet Rheolytic Thrombectomy System, or AngioJet, uses a catheter to deliver a high velocity stream of saline and thrombolytic drug to the clot and then aspirate the clot.

We believe there are a number drawbacks and limitations to existing mechanical thrombectomy treatment options and that existing options do not adequately treat VTE for several reasons, including:

- *Limited ability to remove large, older clots.* Due to the characteristics of the venous system and venous clot morphology, by the time VTE is diagnosed, the underlying clot can be significant in size and hardened as a result of the change in composition from a fibrin matrix to a firmer collagen matrix. Most current mechanical thrombectomy devices are designed to aspirate fresher arterial clot, which is small and soft. As a result, these devices can be inadequate and ineffective for removing the larger, older clots associated with VTE.
- *Limited ability to remove clot from the vessel wall.* Unlike arterial clots, venous clots attach to the vessel wall. Most current mechanical thrombectomy products are aspiration-based systems. Aspiration alone does not always liberate venous clot from the vessel wall. As a result, while some clot can be removed by aspiration, significant residual clot can remain in the vein following aspiration.
- *Increased safety risks.* Rheolytic-based aspiration systems create a risk of damage to red blood cells due to the high shear forces involved with the therapy. These damaged cells can in turn cause a slow heart rate, low blood pressure and kidney dysfunction. For example, one rheolytic system has an FDA black box warning for the treatment of PE. For DVT, the duration of treatment with rheolytic systems is frequently limited to reduce the risk of acute kidney injury.

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- *Multi-stage treatment with multiple procedures.* Mechanical thrombectomy procedures are often performed as one part of a multi-stage treatment for DVT that is combined with thrombolytic drug therapy. Multi-stage treatment increases cost and decreases efficiency for the hospital, and increases risk and inconvenience for the patient. In multi-stage treatment, the initial mechanical thrombectomy takes place in the cath lab. The initial procedure is often insufficient at removing clot, which necessitates the placement of thrombolytic catheters to infuse thrombolytic drugs. The patient is then sent to the ICU for one or more days for monitoring during infusion. The patient is then returned to the cath lab for catheter removal, further assessment of clot burden and additional treatment.

*Thrombolytic Drugs and Catheter-Directed Thrombolysis*

Thrombolytic drugs accelerate the body's natural mechanisms for clearing clot by catalyzing the enzyme that breaks down the fibrin composition of clot. These drugs have demonstrated efficacy in breaking down newly-formed, fibrin-rich clot. However, thrombolytic drugs are generally not effective on older clot in which clot composition has changed from a fibrin matrix to a firmer collagen matrix.

Treatment with thrombolytic drugs is associated with a risk of spontaneous major bleeding, including catastrophic bleeding in the brain. To address some of this risk, catheter-directed thrombolysis was developed to deliver a smaller dose of thrombolytic drug directly to the site of the clot. The catheter-directed procedure involves placing a small catheter into a vein, usually at the knee or groin, and through the clot. Thrombolytic drugs are then infused through the catheter into the clot for several hours to several days. Thrombolytic drugs are always delivered in a critical care setting, such as the ICU, due to the significant bleeding risk.

Thrombolytic drugs can also be administered via catheters that simultaneously emit ultrasonic energy. For DVT and PE, the EKOS EndoWave Infusion Catheter System, or EKOS, is designed to increase the efficiency of thrombolysis by accelerating the destruction of clot using ultrasound.

We believe that thrombolytic drug therapy does not adequately treat VTE for several reasons, including:

- *Limited effectiveness in breaking down venous clot.* We believe that thrombolytic drugs do not have a significant impact on venous clot. Thrombolytic drugs accelerate the body's natural mechanisms for clearing clot by catalyzing the enzyme that breaks down the fibrin composition of clot. Due to the characteristics of the venous system and venous clot morphology, by the time thrombolytic drugs are administered, the composition of the underlying clot will often have changed from a fibrin matrix to a firmer collagen matrix. This transition in clot morphology begins early and progresses quickly, with collagen content reaching approximately 80% within three weeks. Thrombolytic drugs are generally not effective on this type of older clot, which means that all or a portion of the underlying clot can remain following treatment with thrombolytic drugs.
- *Substantial risks of severe bleeding and contraindications.* Treatment with thrombolytic drugs is associated with a risk of spontaneous major bleeding, including catastrophic bleeding in the brain. The overall rate of major bleeding with thrombolytic drugs is over 20%, including a 2-3% risk of intracranial hemorrhage. Lower dose catheter-directed thrombolysis can help to reduce this risk, however, major bleeding has been observed in up to 10% of patients who received catheter-based thrombolysis in studies in which patients were carefully selected for treatment. Thrombolytic drugs are contraindicated in up to 50% of VTE patients, including, among others, patients who are elderly, have had a recent surgery or stroke or that have active bleeds, which further limits their utility as a treatment option.

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- *Expensive, resource intensive and time consuming treatment.* Treatment with thrombolytic drugs requires intensive monitoring of the patient in a critical care setting, such as the ICU, due to the significant bleeding risk. Further, catheter-directed thrombolysis can require ongoing treatment for several hours to several days as thrombolytic drugs are infused into the clot, the entirety of which is monitored in the ICU. This is inconvenient and uncomfortable for the patient, time consuming for the provider and expensive for the payor. In addition, ICU beds are in limited supply and high demand at many hospitals, so treatment with thrombolytic drugs can have important implications for hospitals, physicians and other critically ill patients.

*Other Treatment Options*

Other treatment options for DVT include stenting and intravascular filters to catch clot in the event that it embolizes. In addition, open surgical embolectomy is used in a very limited number of critical patients. Open surgical embolectomy is an invasive open chest surgery in which blood flow is stopped and a ventilator is used while surgeons physically remove clot from the patient. According to a published study, less than 250 open surgical embolectomy procedures are performed in the United States each year.

**Our Solution**

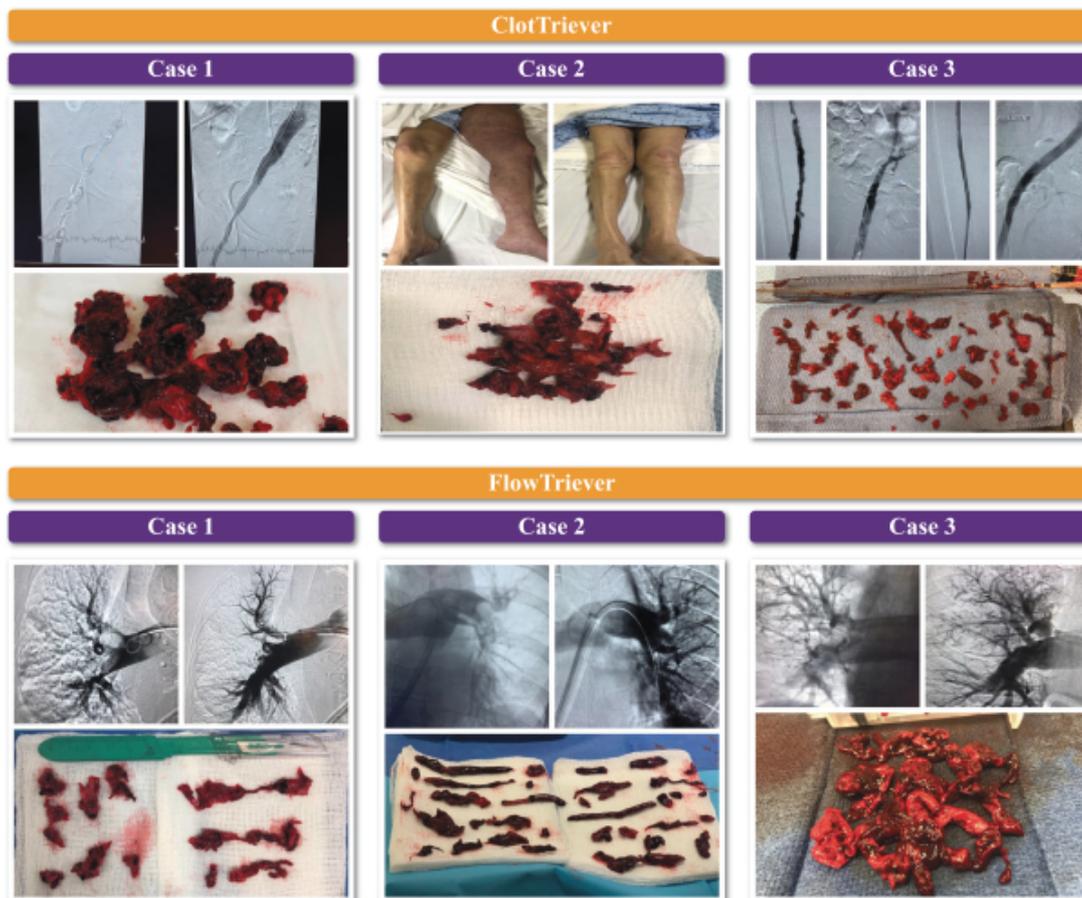
We believe that the venous system represents the newest frontier for effective catheter-based mechanical treatments. The treatment of other thrombotic diseases, such as myocardial infarction and stroke, has evolved from the use of anticoagulants to thrombolytic drugs and eventually to definitive catheter-based interventions. We believe this evolution has contributed to improved treatment outcomes and decreased mortality rates for these diseases. We believe this evolution of treatment to definitive catheter-based intervention has not yet occurred for VTE because existing devices do not safely and effectively remove venous clot. For example, while the number of annual PE diagnoses has generally increased over time, we believe existing treatment options have not had a meaningful impact on mortality rates. We believe our purpose-built ClotTriever and FlowTriever products offer significant clinical benefits and address the safety and effectiveness limitations of thrombolytic drugs and repurposed arterial devices for the treatment of VTE. We believe our products could be the catalyst to drive the evolution of treatment for VTE and have the potential to become the standard of care for treatment of VTE patients.

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***Key Benefits of our ClotTriever and FlowTriever Products***

We believe the ClotTriever and FlowTriever are transformational devices that address the specific characteristics and requirements of the venous system and venous clot morphology and offer hospitals, physicians and patients the following key benefits:

- ***Capture and remove large clot burden from large vessels.*** Our ClotTriever and FlowTriever products are mechanical thrombectomy devices specifically designed for the clinical and technical challenges of DVT and PE, respectively. As such, both systems are capable of capturing and removing the significant clot volumes associated with VTE from large vessels. The images below depict examples of results and clot volume removed from procedures using our products:



- ***Liberate mechanically and remove venous clot from the vessel wall.*** As venous clot ages and its composition changes from a fibrin matrix to a firmer collagen matrix, the body begins to absorb the clot into the vessel wall and the clot becomes adhered, making it more difficult to remove. We have designed our products to address this challenge by incorporating unique components that enable them to mechanically engage and liberate the clot from the vessel wall and remove it from the body.
- ***Eliminate the need for thrombolytic drugs.*** Our products have been designed to remove large clot volumes from large vessels without the need for thrombolytic drugs. Treatment without

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thrombolytic drugs is beneficial for several important reasons. First, many patients who are contraindicated for use of thrombolytic drugs can potentially be treated with our products. Second, avoiding thrombolytic drugs eliminates the significant risk of bleeding associated with these drugs. Third, thrombolytic drugs are usually administered by continuous infusion for several hours or days while the patient is monitored in the ICU, which is expensive. Patients treated using our products often avoid the ICU entirely.

- **Remove clot safely with minimal blood loss.** Our products have been used to treat more than 6,300 patients and have demonstrated an excellent safety profile. Our mechanical approach to clot removal helps to minimize bleeding complications associated with other treatment options.
- **Offer simple, intuitive and easy to use solutions to physicians.** We designed and developed our products to enable a short learning curve and consistent ease of use. Our products are designed to utilize standard endovascular skills possessed by our target physicians. Our target physicians are interventional cardiologists, interventional radiologists and vascular surgeons, each of which can readily learn the required additional techniques for use of our products. In addition, our products employ mechanical and aspiration mechanisms of action that are already familiar to the operating physician.
- **Enable short, single-session treatment with improved hospital and physician efficiency.** Our products are intended to facilitate short, single-session treatments for both DVT and PE, with the potential to reduce the length of ICU stay and total length of hospital stay. Both of our products are designed for multiple passes during the procedure to maximize clot removal. As a result, our products can eliminate the need for thrombolytic drugs, which require monitoring in the ICU and often require a second procedure to remove infusion catheters, assess clot burden and determine whether further treatment is needed. We estimate the average device usage time for treatment with the ClotTriever is between 30 and 45 minutes and the average procedure time for treatment with the FlowTriever is between 75 and 90 minutes. We believe these short, single-session treatments result in less discomfort and more convenience for the patient, lower costs for the hospital and more efficient workflow for both the hospital and the physician.
- **Require no capital investment.** Both of our products are fully self-contained systems and do not require additional capital equipment to perform the procedure. This eliminates an important barrier to hospital adoption and makes the procedure simpler for the physicians and staff.

### **ClotTriever**

The ClotTriever is a mechanical thrombectomy system designed to core, capture and remove large clots from large vessels and is used to treat DVT. The ClotTriever is a single-use, sterile system that is deployed over a wire and does not require capital equipment. The FDA cleared the ClotTriever for the non-surgical removal of soft thrombi and emboli from peripheral blood vessels in February 2017. As of December 31, 2019, the ClotTriever had been used to treat 2,947 patients.

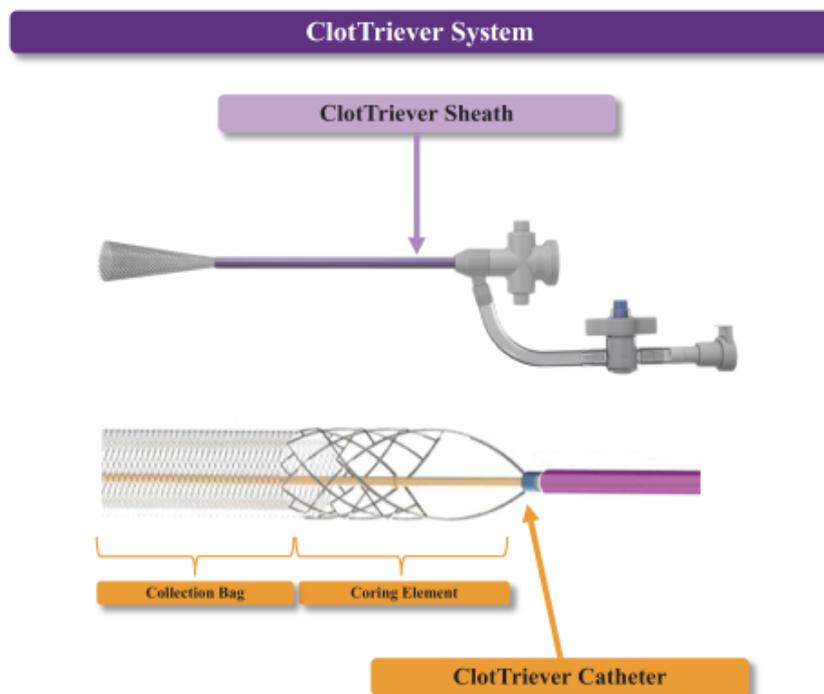
The ClotTriever system consists of two components:

- **ClotTriever sheath** – The ClotTriever sheath is a 15 cm sheath that features a self-expanding nitinol mesh funnel at its tip designed to maximize clot removal. In addition, the sheath features a stopcock for aspiration and a hemostatic valve for catheter insertion. It is packaged with a custom designed large bore 60 cc syringe that fits the sheath's wide flush/aspiration port to help facilitate effective aspiration.
- **ClotTriever catheter** – The ClotTriever catheter is designed to safely core and collect clot from the vessel wall for extraction through the ClotTriever sheath. The ClotTriever catheter is a catheter that

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features an expandable nitinol coring element at its leading edge. A braided nitinol clot collection bag is attached behind the coring element and is designed to collect clot and provide embolic protection. The catheter has a working length of 74 cm and can accommodate vessels between 6-16 mm in diameter. The catheter handle has a mechanism that is used to apply tension to the coring element.

The image below depicts the components of the ClotTrieversystem:



*Procedure*

A ClotTrieversystem procedure is performed in a cath lab, interventional suite or operating room. The patient is typically placed on his or her stomach on the procedure table. Using standard endovascular techniques, the procedure begins with a needle puncture in the back of the leg to gain access to the vein. A guidewire is inserted and advanced through the clot and is positioned beyond the clot. The ClotTrieversheath is then advanced over the guidewire and positioned in the vein in the back of the leg. Once in position, the self-expanding nitinol mesh funnel is deployed from the tip of the sheath. The funnel expands to the wall of the vein and helps to ensure efficient capture and removal of the clot. Next, the ClotTrieverscatheter is advanced over the guidewire and through the sheath. The catheter is advanced over the guidewire through the clot and is positioned beyond the clot in the inferior vena cava for deployment.

The catheter is then unsheathed to expose the self-expanding nitinol coring element and collection bag. Using the catheter's handle mechanism, tension is then applied to the coring element, which expands to the wall of the vein. The catheter is then slowly retracted back towards the sheath, coring and liberating the clot from the vessel wall and capturing it within the collection bag, which provides embolic protection throughout the duration of the retraction. Clot removal is entirely mechanical, which minimizes blood loss and does not require the use of thrombolytic drugs or a stay in the ICU. The catheter is slowly retracted back through the diseased vessel until the coring element of the catheter connects with the funnel of the sheath. Using the same handle mechanism, tension is then removed from the coring element and the catheter is withdrawn through the sheath. As the

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catheter enters the sheath, the clot is safely collapsed and elongated inside the collection bag. After the catheter has been fully removed from the body, any remaining clot particles in the sheath can be removed using aspiration.

Once removed from the body, we have developed techniques that enable the efficient removal of clot from the catheter, which can then be reinserted for additional passes to remove more clot. There is an average of four passes per case. Upon completion of the treatment, the sheath is removed from the patient and the physician completes standard closure of the access site. We estimate the current average device usage time for the treatment with the ClotTrievers to be between 30 and 45 minutes and that the ClotTrievers remove an average of 80-90% of the target clot.

*Pricing*

The vast majority of ClotTrievers procedures use a single ClotTrievers catheter and single ClotTrievers sheath. Each component is priced and packaged separately. We do not offer consignment for the ClotTrievers.

***FlowTrievers***

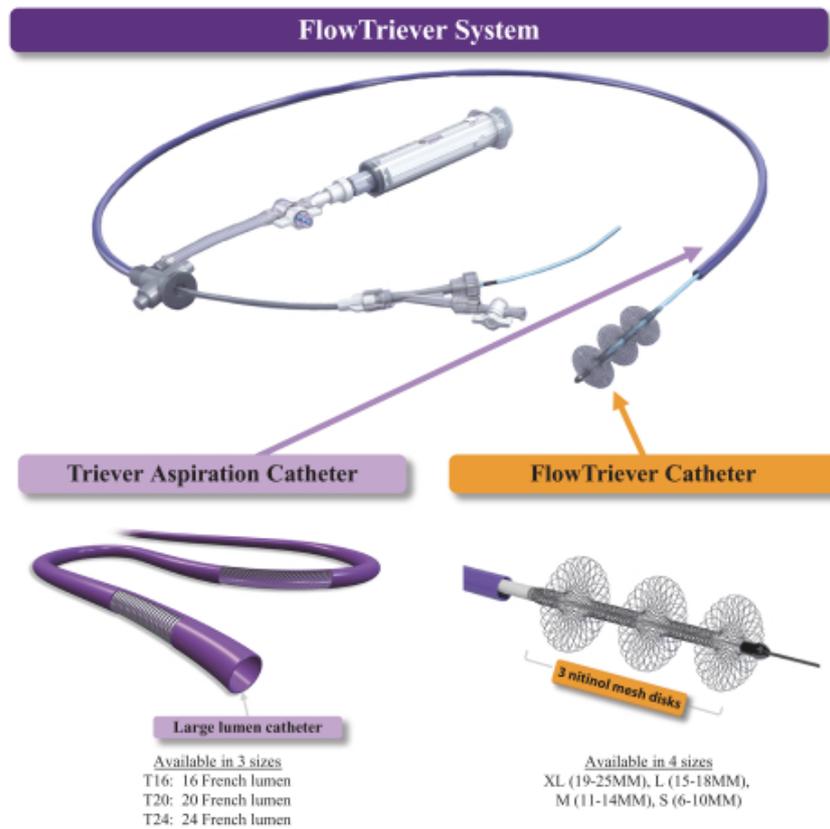
The FlowTrievers is a large bore catheter-based aspiration and mechanical thrombectomy system designed to remove large clots from large vessels to treat PE. The FlowTrievers is a single-use, sterile system that is deployed over a wire and does not require capital equipment. The FDA cleared the FlowTrievers for the non-surgical removal of thrombi and emboli from blood vessels in the peripheral vasculature in February 2015. In May 2018, we received clearance for labeling for the treatment of PE. As of December 31, 2019, the FlowTrievers had been used to treat 2,732 patients.

The FlowTrievers consists of two main components:

- Trier aspiration catheters – Trier aspiration catheters are highly trackable, large lumen catheters that provide a conduit for aspiration and clot removal. Trier aspiration catheters are available in three sizes, 16, 20 and 24 French. Each Trier aspiration catheter is a single lumen catheter featuring a stopcock with a port designed for flush or aspiration, and a proximal hemostasis valve for catheter insertion, if needed. The Trier aspiration catheters are packaged with a custom designed large bore 60 cc syringe that fits the sheath's wide flush/aspiration port to facilitate effective aspiration and limit blood loss.
- FlowTrievers catheter – FlowTrievers catheters are designed to engage, liberate and deliver the clot to the Trier aspiration catheter for extraction. FlowTrievers catheters are delivered to the clot through the Trier aspiration catheter. Each FlowTrievers catheter consists of a coaxial shaft and features three self-expanding nitinol mesh disks at its distal end that are designed to maximize clot liberation and removal. These disks are available in four sizes ranging from 6 to 25 millimeters in diameter.

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The image below depicts the components of the FlowTrieversystem:



*Procedure*

A FlowTrieversystem procedure is performed in a cath lab, interventional suite or operating room. The patient is typically placed on his or her back on the procedure table. Using standard endovascular techniques, the procedure begins with a needle puncture in a large vein in either the groin or the neck. A guidewire is inserted and advanced through the venous system, through the right side of the heart, and is passed through the target clot in the pulmonary artery. The large bore Trierer aspiration catheter is then advanced over the guidewire to the target clot. Once the Trierer aspiration catheter is in position, the stopcock on the back of the system is closed and the large bore 60 cc syringe is attached. The syringe is used to create a strong vacuum. Opening the stopcock releases the vacuum. This vacuum, when delivered through the large bore Trierer aspiration catheter, creates a high flow aspiration, which we call the Whoosh, that draws clot into the Trierer aspiration catheter. The flow volume is limited by the large bore 60 cc syringe, which helps to minimize blood loss. Multiple passes and aspirations are possible depending on the clot volume and number of vessels to be treated. We estimate the median blood loss from procedures using the FlowTrieversystem to be 280 cc.

If clot remains following aspiration, the FlowTrieversystem catheter may be advanced through the Trierer aspiration catheter to just beyond the clot. We estimate that the FlowTrieversystem catheter is used in approximately 50-60% of cases. Once in position, the FlowTrieversystem catheter is unsheathed to deploy the self-expanding nitinol mesh disks into the clot. The FlowTrieversystem catheter is then slowly pulled back toward the Trierer aspiration catheter, disrupting the clot and delivering it to the Trierer aspiration catheter. The Trierer aspiration catheter can be used for further aspiration if needed.

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Upon completion of the treatment, all devices and wires are removed from the patient and the physician completes standard closure of the entry site. We estimate the average device usage time for treatment with a FlowTrievers is between 40 and 50 minutes, and the average procedure time for treatment with a FlowTrievers is between 75 and 90 minutes and that the FlowTrievers removes an average of 75% of the target clot.

*Pricing*

The use of the FlowTrievers system varies significantly based on the specific patient's diagnosis and disease characteristics. For example, some patients are treated using aspiration alone and, as a result, the relevant procedure uses one or more FlowTrievers aspiration catheters but does not require a FlowTrievers catheter. Other patients are treated using aspiration in combination with mechanical engagement of the clot, in which case the procedure uses one or more Triever aspiration catheters and one or more FlowTrievers catheters. Due to the variability in use across procedures, we price the FlowTrievers on a per procedure basis. As a result, a customer is charged the same price for each procedure that uses the FlowTrievers system, regardless of what combination of products is used to treat the patient. We believe that this approach provides greater pricing certainty, can help to preserve hospital economics and emphasizes clinical considerations in determining device use for any given procedure. Each component is packaged separately. We do not currently offer consignment for the FlowTrievers system.

*FlowTrievers for DVT*

A portion of patients with DVT present with anatomical complexities and lesion types that require more involved procedures and techniques to treat their disease. In these cases, physicians may elect to use one or more components of our FlowTrievers system to treat DVT, with or without the ClotTrievers. Year-to-date as of November 30, 2019, we estimate that approximately 12% of our DVT procedures were performed using only our FlowTrievers system and approximately 8% of our DVT procedures were performed using our ClotTrievers and at least one component of the FlowTrievers system. We believe the cross-treatment application of our products reflects the complexity of venous disease, versatility of our product portfolio and the value of a comprehensive venous solution.

**Clinical Data**

The primary clinical study we have completed to date is our FlowTrievers Pulmonary Embolectomy Clinical Study, or FLARE study, which established the safety and effectiveness of the FlowTrievers for the treatment of PE without the use of thrombolytic drugs. We are committed to continuing to develop a strong base of clinical evidence and real-world patient outcomes to further support the safety and effectiveness of our products. We are currently enrolling two 500-patient registries: CLOUT for DVT and FLASH for PE. In addition, there are more than 10 ongoing investigator-initiated studies being conducted. We believe these efforts will generate a robust cadence of publications, drive adoption of our products, increase awareness of venous diseases and inform the design of future definitive clinical trials, with the goal of establishing our products as the standard of care for treatment of DVT and PE.

*ClotTrievers*

The FDA granted 510(k) clearance of the ClotTrievers in February 2017 based on a determination that the ClotTrievers was substantially equivalent to a legally marketed predicate device. We were not required by the FDA to conduct clinical studies on the ClotTrievers prior to seeking clearance. We are aware of a significant number of case reports, as well as independent research by various hospitals and researchers, that provide clinical evidence supporting the use of the ClotTrievers. To continue to build on our base of clinical evidence for the treatment of DVT using the ClotTrievers, we are currently enrolling patients in the CLOUT registry to evaluate real-world patient outcomes using the ClotTrievers in up to 500 patients.

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*CLOUT Registry*

The CLOUT registry is a prospective, multi-center, single-arm registry designed to evaluate real-world patient outcomes and capture several longer term outcome measures. We plan to enroll up to 500 patients with lower extremity DVT at up to 50 sites across the United States. The registry will enroll all-comer patients, including patients with bilateral DVT and clots of any age, with a primary analytic dataset that will include 91 patients with unilateral DVT of less than six weeks' duration. We believe data from the registry will generate a robust cadence of publications and, ultimately, will inform the design of future definitive clinical trials with the goal of establishing the ClotTriever as the standard of care for treatment of DVT. As of December 31, 2019, we have enrolled 93 patients in the CLOUT registry.

Eligible patients must meet inclusion criteria specified for the registry. Generally, patients must exhibit lower extremity DVT affecting, alone or in combination, the femoral, common femoral, iliac veins or inferior vena cava, or IVC. Notably, there are no exclusions for age of clot. Patients will be excluded if they have received a prior venous stent in the target venous segment, have IVC aplasia or hypoplasia or other congenital anatomic anomalies of the IVC or iliac veins, have an IVC filter in place at the time of treatment, have allergy, hypersensitivity or thrombocytopenia from heparin or iodinated contrast agents that cannot be adequately pre-treated, have a life expectancy of less than one year, have long-term non-ambulatory status, have known hypercoagulability, which is the tendency to have or form clot as a result of inherited or acquired molecular defects, that cannot be medically managed throughout the study period or do not have an available lower extremity venous access site for the procedure.

The primary outcome measures will be evaluated in the primary analytic dataset, which is expected to include 91 patients with unilateral DVT of less than 6 weeks' duration. The primary safety endpoint is the composite of patients that experience major adverse events, including death, major bleeding, symptomatic PE or rethrombosis of the target venous segment, within 30 days of treatment using the ClotTriever. The primary effectiveness outcome measure is the rate of technical success from the procedure, which is defined as the complete or near complete (75% or greater) removal of clot from the target venous segment. Secondary safety outcomes that are also being reported include minor bleeding, access site complications and device and procedure-related death. Secondary effectiveness outcome measures include recurrent DVT and scores on various clinical symptom tests. In addition, there are follow-up visits for patients at up to two years from the date of treatment.

Initial results from the first 50 patients in the registry were presented at the Vascular InterVentional Advances, or VIVA, conference in November 2019. These initial results included procedural outcomes and information from these patients and outcomes from 33 patients for which follow-up data was collected 30 days after treatment. We believe these initial results demonstrate the ability of the ClotTriever to successfully treat a range of clot in patients with DVT in a single session and without the need for thrombolytic drugs. For example, clot was removed in all patients and 76.5% of patients met the study's primary effectiveness endpoint of complete or near complete removal of clot. Of the 33 patients for which follow-up data was collected regarding post-thrombotic syndrome, or PTS, 25 patients (75.8%) showed complete reversal of their PTS within 30 days of treatment. Patients experienced statistically significant improvements in disease severity and quality of life scores within 30 days of treatment, with no device or procedure-related major adverse events. One patient (2.0%) died on day 23 after treatment because of sepsis and kidney failure associated with metastatic lung cancer. No bleeding complications were reported. We believe these results are even more impressive given the complexity of the patient population. For example, over half of the patients enrolled previously received alternative DVT treatment in the 30 days prior to treatment using the ClotTriever. In addition, approximately three quarters of the patients enrolled had clots estimated to be more than two weeks old, which we believe represents a patient population that has never been previously studied for purposes of DVT thrombectomy. Almost all patients were treated in a single session and the median thrombectomy time was 38 minutes.

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Below is a summary of the outcomes information presented at the VIVA conference in November 2019:

<b>Measure</b>	<b>Baseline pre-treatment</b>	<b>At 30 days post-treatment</b>	<b>P-value</b>
Villalta score (1)	10	3	<0.01
PTS rate (2)	93.9%	24.2%	<0.01
Moderate/severe PTS rate (3)	51.5%	9.1%	<0.01
Revised Venous Clinical Severity Score (4)	6	3	<0.01
EuroQol-5 Dimension Score (5)	0.79	0.88	<0.01
Numeric Pain Rating Scale score (6)	3	0	<0.01

- (1) Villalta score is a disease score specific for post-thrombotic syndrome, or PTS, that is used to diagnose and categorize the severity of the condition. Points are provided for five symptoms (pain, cramps, heaviness, paresthesia and pruritus) and six clinical signs (pretibial edema, skin induration, hyperpigmentation, redness, venous ectasia and pain on calf compression). Points are based on severity and range from 0 (not present) to 3 (severe). Generally, a score of 5 or greater results in a PTS diagnosis, while a score of 5-9 signifies mild disease, 10-14 signifies moderate disease and 15 or greater, or the presence of an ulcer, signifies severe disease.
- (2) Percent of patients with PTS.
- (3) Percent of patients with moderate or severe PTS.
- (4) Revised Venous Clinical Severity Score is a disease score that is used to diagnose and categorize the severity of venous disease. Points are provided for a variety of metrics, including pain, varicose veins, venous edema, skin pigmentation, inflammation, induration, active ulcer characteristics and use of compression therapy. Points are based on severity and range from 0 (none) to 3 (severe). A lower score signifies less severe venous disease.
- (5) EuroQol-5 Dimension is a widely used instrument to evaluate generic quality of life. The instrument is a preference-based measure with one question for each of the five dimensions that comprise the instrument: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Answers can be converted into an index with scores of 0 signifying death or worst possible health and 1 signifying perfect or best possible health.
- (6) The Numeric Pain Rating Scale is an unidimensional measure of pain intensity in adults. It is an 11 point scale from 0 (no pain) to 10 (most pain imaginable) that is based on patient selection of a value that is most in line with the intensity of pain that they have experienced in the prior 24 hours.

Below is a summary of the procedural information presented at the VIVA conference in November 2019:

<b>Procedural information</b>	<b>Total (median [interquartile range] or n (%))</b>
Subacute/chronic clot (older than 2 weeks)	37/50 (74.0%)
Previous treatment of current DVT in 30 days prior to treatment	27/50 (54.0%)
Single-session treatment	48/49 (98.0%)
Number of ClotTriever passes	4.0 [3.0, 4.0], n=49
Thrombectomy time (minutes) (1)	38.0 [25.0, 62.0], n=45
Estimated blood loss (cc)	27.5 [25, 75], n=42
Length of stay: Hospital (days)	2 [0, 3.5], n=47
Length of stay: ICU (days) (2)	0, n=50

(1) Amount of time ClotTriever used during procedure.

(2) Two patients had ICU stays of 1 day each.

**FlowTriever**

The safety, effectiveness and clinical advantages of the FlowTriever have been observed in our first clinical trial, the FLARE study, and have also been observed in multiple post-market studies completed by

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various hospitals and research organizations. The FLARE study was conducted under an investigational device exemption, or IDE, approved by the FDA, and was conducted to evaluate the safety and effectiveness of the FlowTrieve for use in the removal of clot from the pulmonary arteries and in the treatment of acute PE. The study supported FDA 510(k) clearance for the FlowTrieve. The results of the study were published in May 2019 in the *Journal of the American College of Cardiology: Cardiovascular Interventions*. We believe that additional safety and effectiveness data from a broader range of patients is important to drive adoption of our product. As such, we are currently enrolling patients in the FlowTrieve All-Corner Registry for Patient Safety and Hemodynamics, or FLASH registry, to evaluate real-world patient outcomes using the FlowTrieve in up to 500 patients. We anticipate initial interim results from the FLASH registry to be presented in the third quarter of 2020. As adoption of the FlowTrieve continues to expand, we expect various hospitals and researchers to conduct additional studies.

*FLARE Study*

Our first clinical trial, the FLARE study, was a prospective, single-arm, multicenter IDE study conducted at 18 sites across the United States from April 2016 to October 2017. The study evaluated the treatment of 106 patients with intermediate risk PE using the first generation FlowTrieve. The study met both of its primary endpoints, which demonstrated safety and effectiveness and represented what we believe to be the first demonstration of successful treatment of PE without the use of thrombolytic drugs or its consequent ICU stay. Data from the study supported FDA 510(k) clearance for the FlowTrieve.

All patients enrolled in the study were symptomatic for 14 days or less, with clinical signs and presentation consistent with PE, including documented proximal PE by computed tomography, or CT, angiography, and a site-reported right ventricle/left ventricle, or RV/LV, ratio of 0.9 or greater by CT. Patients were required to have a stable heart rate and systolic blood pressure and to be deemed medically eligible for an interventional procedure. Patients were excluded for, among others, use of thrombolytic drugs within 30 days of their CT angiography for the study, active cancer and contraindication to anticoagulant therapy. Patients with recent surgery and other high bleeding risks were not excluded.

The primary effectiveness endpoint was a reduction in core laboratory-assessed RV/LV ratio. The average RV/LV ratio decreased from 1.53 (n = 104) at baseline assessment to 1.15 (n = 101) in the 48 hours after treatment using the FlowTrieve, representing a statistically significant reduction in RV/LV ratio of 0.38 on average (25.1%; p < 0.0001).

The primary safety endpoint was measured by device-related death, major bleeding, treatment-related clinical deterioration, pulmonary vascular injury or cardiac injury in the 48 hours after treatment using the FlowTrieve. Four patients (3.8%) experienced six major adverse events in the 48 hours after treatment. All major adverse events were determined to be procedure related, with no device-related major adverse events. All four (3.8%) patients exhibited clinical deterioration. There was one major bleeding event (0.9%) and one pulmonary vascular injury. The major bleeding event experienced by one patient was also classified as a pulmonary vascular injury and as clinical deterioration. Two patients (1.9%) experienced respiratory deterioration during or immediately after the procedure that required emergent intubation. One patient (0.9%) became agitated during the procedure, requiring increased sedation, and had a ventricular fibrillation event that required cardioversion and emergent intubation. An additional 10 patients experienced serious adverse events within 30 days after treatment, none of which were determined to be procedure or device-related. In total, 14 patients (13.2%) experienced 26 serious adverse events within 30 days, with five patients (4.7%) experiencing multiple serious adverse events. One patient (0.9%) died within 30 days of treatment because of respiratory failure from undiagnosed metastatic breast cancer. The mean procedure time was 94 minutes.

The FLARE study also provided evidence supporting other potential advantages of the FlowTrieve. Only two patients (1.9%) in the study were administered thrombolytic drugs. Further, the average ICU stay of patients enrolled in the study was 1.5 days and 41.3% of patients did not go to the ICU. The average total hospital stay for patients enrolled in the study was 4.1 days.

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*St. Luke's Hospital Study*

The safety and effectiveness of treatment of PE using the FlowTrievers has been studied and documented by researchers at St. Luke's Hospital in Kansas City, Missouri, who published their early case experience results in the *Journal of Vascular and Interventional Radiology* in September 2019. This retrospective, single-center study was conducted at St. Luke's Hospital from March 2018 to March 2019 using both the first and second generation FlowTrievers. The study demonstrated a continued positive safety profile for treatment of PE using the FlowTrievers in a single-center real-world patient population with high technical and clinical success rates.

The study evaluated the treatment of 46 PE patients using the FlowTrievers. Eight patients had high risk, or massive, PE and 38 patients had intermediate risk, or submassive, PE. All patients had right heart strain and 12 patients had contraindication to therapy with thrombolytic drugs.

Technical success was determined according to Society of Interventional Radiology guidelines and was based on navigation and use of the FlowTrievers. Technical success was achieved in 100.0% of patients.

Clinical success was based on a reduction in pulmonary artery pressure, or PAP, at the end of the procedure. Clinical success was achieved in 37 of 42 evaluated patients (88.0%). The average PAP decreased from 33.9 mmHg before treatment to 27.0 mmHg after treatment using the FlowTrievers, representing a statistically significant average reduction in PAP of 6.9 mmHg on average (20.4%;  $p < 0.0001$ ). In addition, 27 of 38 patients with intermediate risk PE (71.1% of total patients with intermediate risk PE) demonstrated a reduction in supplemental oxygen requirements during the procedure.

All patients survived to hospital discharge and there were no device-related complications or deaths within 30 days after treatment. Two patients (4.6%) experienced major adverse effects. One patient (2.2%) experienced procedure-related blood loss requiring a transfusion. One patient (2.2%) developed hemoptysis that was self-limiting and required intubation, likely due to a puncture caused by the guidewire. Both of these patients recovered well. Two patients (4.6%) died within 30 days of treatment, one due to metastatic pancreatic cancer and one due to anoxic brain injury from prolonged out of hospital cardiac arrest that was triggered by PE but occurred prior to treatment.

*Toma Study*

Additional information regarding the safety and effectiveness of treatment of PE using the FlowTrievers was presented at the Transcatheter Cardiovascular Therapeutics, or TCT, symposium in September 2019. The information presented related to a retrospective, multi-center study, or the Toma Study, that was conducted at three sites across the United States from October 2017 to March 2019. The study evaluated the treatment of 27 critically-ill patients with high risk, or massive, PE, a population whose mortality rate would be up to 50%. The study evaluated the effectiveness of the FlowTrievers for the treatment of the highest risk, critically-ill PE patients, and reported mortality outcomes and hemodynamic improvements that we believe have the potential to improve the treatment of this challenging patient population.

Patients were included if they had high risk, or massive, PE, which was defined for purposes of the study as needing vasopressor support, respiratory failure due to PE or hemodynamic evidence of decreased cardiac index by right heart catheterization. Patients were at high risk for bleeding, with a number of post-trauma patients and patients having had recent surgery or strokes. Six patients previously required cardiopulmonary resuscitation, or CPR, and three patients failed systemic thrombolysis, prior to treatment with the FlowTrievers.

Procedural success, which was defined as clot removal with clinical improvement, was achieved in 25 patients (93.0%). In addition, researchers observed significant improvements in PAP, pulmonary artery saturation, cardiac output, heart rate and systolic blood pressure following treatment.

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There were no vascular complications or cardiac or pulmonary injuries reported in the study. The conditions of two patients (7.4%) deteriorated during the procedure. One of these patients (3.7%) was stabilized on extracorporeal membrane oxygenation, and one patient (3.7%) died during the procedure. Researchers involved with the Toma Study have determined that neither of these events were device- or procedure-related. Together, we believe these data show a meaningful improvement for this patient population whose mortality rate would be up to 50%.

*FLASH Registry*

We are currently enrolling patients in the FlowTrieve All-Come Registry for Patient Safety and Hemodynamics, a prospective, multi-center registry designed to evaluate real-world patient outcomes and capture several acute and longer term outcome measures. We plan to enroll up to 500 patients with intermediate and high risk PE at up to 50 sites across the United States. We believe data from the FLASH registry will generate a robust cadence of publications and, ultimately, will inform the design of future definitive clinical trials with the goal of establishing the FlowTrieve as the standard of care for treatment of PE. We expect initial interim results from the FLASH registry to be presented in the third quarter of 2020. As of December 31, 2019, we had enrolled 117 patients in the FLASH registry.

Eligible patients must meet inclusion criteria specified for the registry. Generally, patients must exhibit clinical signs and symptoms consistent with acute PE and/or CT or pulmonary angiography evidence of proximal filling defect in at least one main or lobar pulmonary artery and be scheduled for treatment for PE using the FlowTrieve at the investigator's discretion. Patients will be excluded if they are unable to receive anticoagulant therapy, have known sensitivity to radiographic contrast agents that cannot be adequately pre-treated, have a life expectancy of less than 30 days or are participating in another investigational drug or device treatment study that would interfere with participation in the registry, or if imaging evidence or other evidence suggests that the patient is not appropriate for a catheter-based thrombectomy procedure.

The primary outcome measure is the composite of patients that experience major adverse events, including device-related death, major bleeding, or device or procedure-related adverse events, in the 48 hours after treatment using the FlowTrieve. Secondary safety outcomes that are also being reported include the rate of patients with individual components of composite major adverse events in the 48 hours after treatment and the rates of death and device-related serious adverse events within 30 days of treatment. Secondary effectiveness outcomes include change in pulmonary artery pressures, changes in a range of on-table hemodynamic measurements and utility measures, such as length of stay in the ICU and hospital. In addition, there are follow-up visits for patients at up to six months from the date of treatment.

*Ongoing Studies*

There are a number of additional studies that are ongoing. For example, there are more than 10 investigator-initiated studies being conducted to evaluate, among others, clot morphology, healthcare economics and long-term implications involving VTE. Examples of additional studies include:

- OhioHealth Riverside Methodist Hospital in Columbus, Ohio and CVPath Institute are analyzing DVT and PE samples to determine the chronicity of clot, degree of collagen-transformation and resistance to fibrinolysis.
- Memorial Sloan Kettering in New York, New York is conducting a study treating DVT in a cancer center. Cancer patients have a high risk of DVT and PE due to hypercoagulability, which is the tendency to have or form clot as a result of inherited or acquired molecular defects, but there is reluctance to treat such patients due to limited life expectancies.

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**Sales and Marketing**

We currently sell our products to approximately 400 of the approximately 1,500 hospitals in the United States with a cath lab where interventional procedures can be performed. Our target physicians are interventional cardiologists, interventional radiologists and vascular surgeons. As we expand our network of hospital customers and leverage our expanding sales organization, we seek to increase awareness within these hospitals and with our target physicians, referring physicians and other stakeholders at the account level in order to drive greater adoption of our products as the preferred first-line solution for the treatment of venous diseases. This strategy enables our sales representatives to have regular and targeted communications to convey the benefits of our products to non-interventional physicians, such as emergency department physicians and pulmonologists. To accomplish this, we conduct regular national, regional and local training and educational programs for both interventional and non-interventional physicians. 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. We have 510(k) clearance in the United States for our ClotTrieve and FlowTrieve products. We are in the process of obtaining CE Marks for both FlowTrieve and ClotTrieve, which will provide us with the ability to commercialize in Europe in the future.

We recruit sales representatives who have substantial and applicable medical device and/or sales experience. Our most important relationships are between our sales representatives and physicians. Our front-line sales representatives attend over 80% of the procedures in which our products are used, which puts us at the intersection of the patient, product and physician. We have developed systems and processes to harness the information gained from these interactions and we leverage this information to rapidly iterate products, introduce and execute physician education and training programs and scale our sales organization. We are rapidly expanding our network of sales representatives. As of December 31, 2019, we had 63 sales representatives, up from 21 sales representatives as of December 31, 2018.

Our products are simple, intuitive and easy to use, and do not require significant additional training. They are designed to utilize standard endovascular skills. Our target physicians can readily learn the required additional techniques for use of our products.

**Coverage and Reimbursement**

In the United States, we sell our products to hospitals. Hospitals in turn bill various third-party payors, such as Medicare, Medicaid and private health insurance plans, for the total healthcare services required to treat the patient. Government agencies, private insurers and other payors determine whether to provide coverage for a particular procedure and to reimburse hospitals for inpatient treatment at a fixed rate based on the diagnosis-related group, or DRG, as determined by the U.S. Centers for Medicare and Medicaid Services, or CMS. The fixed rate of reimbursement is based on the procedure performed, and is unrelated to the specific medical device used in that procedure. Medicare rates for the same or similar procedures vary due to geographic location, nature of facility in which the procedure is performed (i.e., teaching or community hospital) and other factors. While private payors vary in their coverage and payment policies, most use coverage and payment by Medicare as a benchmark by which to make their own decisions.

*ClotTrieve*

Procedures using our ClotTrieve product are categorized under CPT code 37187 for venous mechanical thrombectomy procedures. The primary ICD-10-CM diagnosis code for DVT is I82.40. The MS-DRGs are 270 when the patient presents with major complications or co-morbidities, 271 when the patient presents with a complication or co-morbidity, and 272 for patients without complications or co-morbidities.

The 2020 in-hospital physician professional fee payment for CPT code 37187 is \$412. The 2020 total related value units for CPT code 37187 is 11.41. We believe physicians feel this level of payment represents a reasonable amount for these types of procedures.

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The 2020 CMS national average payment amounts for MS-DRGs 270, 271 and 272 are \$31,985, \$22,207 and \$16,281, respectively. The MS-DRG payments for procedures using ClotTriever are intended to cover all hospital costs associated with treating a patient during his or her hospital stay, with the exception of physician charges associated with performing medical procedures. We believe that facilities feel this level of payment represents a reasonable amount for these treatments.

*FlowTriever*

Procedures using our FlowTriever product are categorized under CPT code 37184 under arterial, noncoronary, mechanical thrombectomy procedures. The primary ICD-10-CM diagnosis code for PE is I26.9. The MS-DRGs are 163 when the patient presents with major complications or co-morbidities, 164 when the patient presents with a complication or co-morbidity, and 165 for patients without complications or co-morbidities.

The 2020 in-hospital physician professional fee payment for CPT code 37184 is \$456. The 2020 total related value units for CPT codes 37184 is 12.64. We believe physicians feel this level of payment represents a reasonable amount for these types of procedures.

The 2020 CMS national average procedure payment amounts for MS-DRGs 163, 164 and 165 are \$30,504, \$15,845 and \$11,574, respectively. The MS-DRG payments for FlowTriever procedures are intended to cover all hospital costs associated with treating a patient during his or her hospital stay, with the exception of physician charges associated with performing medical procedures. We believe that facilities feel this level of payment represents a reasonable amount for these treatments.

We understand that in 1983, CMS adopted a National Coverage Determination, or NCD, for Transvenous Pulmonary Embolectomy, NCD 240.6. At that time, NCD 240.6 deemed pulmonary embolectomy to be experimental and non-covered by Medicare. NCD 240.6 does not have a published effective date, does not provide any details about the covered procedure or devices, and does not cite any of the factors or evidence that was used to establish non-coverage. Since that time, technology and clinical practices related to embolectomy have changed significantly. We also understand that multiple physician societies have requested that CMS remove NCD 240.6 through an expedited process available to remove NCDs that have not been updated in at least 10 years.

While NCD 240.6 is published, CMS approved Medicare coverage for FlowTriever procedures performed in connection with our FLARE study under Medicare's Category B IDE coverage policy. Hospitals have continued to perform FlowTriever procedures, and we are not aware of any coverage concerns related to those procedures from Medicare or any private insurance carrier. See "Risk Factors—Risks Related to Our Business—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."

**Research and Development**

We are dedicated to the venous system and are committed to driving innovation for the treatment of VTE, including DVT and PE. We believe our ability to develop innovative products for the treatment of VTE is attributable to our dedicated focus on the venous system, the design philosophy and product innovation process that we have implemented, our efforts to leverage and expand our clinical evidence and the insights that we have gained from our work in developing our products to date. Our engineering team has broad mechanical and biomedical engineering, project management, materials science, design and prototyping expertise.

Our research and development effort is informed by near real-time field-based input from our sales organization, physicians and the direct field experience of our engineers. This process has allowed us to rapidly innovate and enhance our products. For example, the FLARE study was completed using the first generation FlowTriever. We are currently selling the third generation FlowTriever, which has improved clot removal, ease of use and procedure times, all of which has resulted in rapid adoption. We expect to introduce our fourth

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generation FlowTrierer in the first quarter of 2020, which is designed to further improve product performance. Likewise, we are currently selling the third generation ClotTrierer, and we expect to introduce the fourth generation in the first quarter of 2020.

We are currently focused on three key goals as we develop additional and next generation venous products for commercialization. First, we seek to continue to enhance the effectiveness, efficiency and ease of use of our current products. Second, we plan to expand the application of our thrombectomy technology to areas of the body that are not addressed by our existing products. Third, we are developing solutions beyond thrombectomy to address other unmet needs.

For the years ended December 31, 2018 and 2019, our research and development expenses were \$4.0 million and \$ \_\_\_\_\_, respectively.

**Manufacturing and Supply**

We currently manufacture and assemble our ClotTrierer and FlowTrierer products at our 38,200 square foot facility in Irvine, California. We also inspect, test, package and ship finished products from this facility. We have intentionally pursued a vertically integrated manufacturing strategy. We believe this offers important advantages, including rapid product iteration and control over our product quality. We believe our current manufacturing capacity is sufficient to meet our current expected demand for at least the next 12 months.

We are registered with the FDA as a medical device manufacturer and are licensed by the State of California to manufacture and distribute our medical devices. We are required to manufacture our products in compliance with the FDA's Quality System Regulation, or QSR. The FDA enforces the QSR through periodic inspections and may also inspect the facilities of our suppliers. We moved to our current Irvine, California facility in November 2019, which has been registered with the FDA and was approved by the State of California for the manufacture and distribution of medical devices in October 2019. The FDA conducted its most recent inspection in August 2016. This inspection was conducted at our prior facility, which was also located in Irvine, California. The FDA has not conducted an inspection at our new facility.

We have received International Standards Organization, or 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 expect the next recertification audit to take place in 2021. The most recent surveillance audit was conducted on our new facility in November 2019 and no major non-conformities were identified. There have been no surveillance audits or unannounced audits on our new facility. To date, our surveillance and unannounced audits have not identified any major non-conformities.

We use a combination of internally manufactured and externally-sourced components to produce our ClotTrierer and FlowTrierer products. Externally-sourced components include off-the-shelf materials, sub-assemblies and custom parts that are provided by approved suppliers. Almost all of these components, including the nitinol coring element of the ClotTrierer, are provided by single-source suppliers. While there are other suppliers that could make or provide any one of our externally-sourced components, we seek to manage single-source supplier risk by regularly assessing the quality and capacity of our suppliers, implementing supply and quality agreements where appropriate and actively managing lead times and inventory levels of sourced components. In addition, we are currently in the process of identifying and approving alternative suppliers to dual or multi-source certain of our components. We generally seek to maintain sufficient supply levels to help mitigate any supply interruptions and enable us to find and qualify another source of supply. For certain components, we estimate that it would take up to six months to find and qualify a second source. Order quantities and lead times for externally sourced components are based on our forecasts, which are derived from historical demand and anticipated future demand. Lead times for components may vary depending on the size of the order, time required to fabricate and test the components, specific supplier requirements and current market demand for the materials, sub-assemblies and parts.

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Our suppliers are evaluated, qualified and approved as part of our supplier quality program, which includes verification and monitoring procedures to ensure that our suppliers comply with FDA and ISO standards, as well as our own specifications and requirements. We inspect and verify externally sourced components under strict processes supported by internal policies and procedures. We maintain a rigorous change control policy to assure that no product or process changes are implemented without our prior review and approval.

Our finished products are ethylene oxide sterilized at a local, qualified supplier.

### **Competition**

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. There is growing interest in treatment of VTE with catheter-based solutions, and there are a significant number of approved thrombectomy devices available. As this interest continues to grow, we anticipate that this competition will intensify.

Many of our competitors have longer, more established operating histories, and significantly greater name recognition and financial, technical, marketing, sales, distribution and other resources. In addition, certain competitors have several competitive advantages, including established treatment patterns pursuant to which drugs are generally first-line or concurrent therapies for the treatment of VTE and established relationships with hospitals and physicians who prescribe their drugs or are familiar with existing interventional procedures for the treatment of VTE.

We compete primarily on the basis that our solutions are designed specifically for the venous system and are able to treat patients with DVT and PE safely, effectively and without the need for thrombolytic drugs and their related costs and complications. Our overall competitive position is dependent upon a number of factors, including patient outcomes and adverse event rates, patient experience and treatment time, acceptance by hospitals, physicians and referral sources, ease-of-use and reliability, patient recovery time and level of discomfort, economic benefits and cost savings, availability of reimbursement and the strength of clinical data and supporting evidence. One of the major hurdles to adoption of our products will be overcoming established treatment patterns, which will require education of referral sources and physicians and supportive clinical data.

### **Intellectual Property**

We actively seek to protect the intellectual property and proprietary technology that we believe is important to our business. We rely on a combination of trademark, copyright, patent, trade secret and other intellectual property laws, employment, confidentiality and invention assignment agreements, and protective contractual provisions with our employees, contractors, consultants, suppliers, partners and other third parties to protect our intellectual property rights.

As of December 31, 2019, we held 17 U.S. patents, which are expected to expire between November 2032 and April 2037, 14 pending U.S. patent applications, three issued foreign patents, 11 pending foreign patent applications and four pending Patent Cooperation Treaty applications, excluding our licensed and sublicensed patents. The term of individual patents depends on the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a nonprovisional patent application in the applicable country. Our patents include a number of claims related to our systems, future concepts for our products and methods for treating vascular occlusions and embolisms.

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As of December 31, 2019, we also licensed one U.S. patent and sublicensed one U.S. patent related to braiding elements of our product designs, such as the tubular braiding of our clot collection bag. The licensed U.S. patent is expected to expire in October 2037 and is licensed pursuant to an amended and restated technology agreement, dated March 2, 2018, between Inceptus Medical, LLC, or Inceptus, and us. The license is a worldwide, exclusive, royalty-free license in the field of the treatment of embolism and thrombosis in human vasculature other than carotid arteries, coronary vasculature and cerebral vasculature. The sublicensed U.S. patent is expected to expire in March 2030 and is sublicensed pursuant to a sublicense agreement, dated August 1, 2019, between Inceptus and us. Pursuant to the sublicense agreement, Inceptus granted us a non-transferable, worldwide, exclusive sublicense to its licensed intellectual property 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. Inceptus licensed this intellectual property pursuant to an intellectual property license agreement, dated May 4, 2018, between Inceptus and Drexel University.

There is no active patent litigation involving any of our patents and we have not received any notices of any patent infringement.

As of December 31, 2019, we had eight registered trademarks and two pending trademark applications worldwide, including trademark registration for “Inari Medical” in the United States and trademark registrations for “FlowTrier” and “ClotTrier” in the United States and other countries.

Our pending patent and trademark applications may not result in issued patents or trademarks, and we cannot assure you that any current or subsequently issued patents or trademarks will protect our intellectual property rights, provide us with any competitive advantage or withstand or retain its original scope after a validity or enforceability challenge from a third party. While there is no active litigation involving any of our patents or other intellectual property rights and we have not received any notices of patent or other intellectual property infringement, we may be required to enforce or defend our intellectual property rights against third parties in the future. See “Risk Factors—Risks Related to Our Intellectual Property” for additional information regarding these and other risks related to our intellectual property portfolio and their potential effect on us.

***Sublicense Agreement with Inceptus Medical, LLC***

In August 2019, we entered into a sublicense agreement with Inceptus, pursuant to which Inceptus granted us 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 sublicense is also subject to all applicable U.S. government rights, and we cannot be sure that some of our intellectual property will be free from government rights or regulations pursuant to the Bayh-Doyle Act. Furthermore, we are obligated to comply with, and to avoid acts or omissions that would reasonably be likely to cause a breach of, the Drexel License. Our sublicense from Inceptus may only be sublicensed with the prior written approval of Inceptus and Drexel University.

Pursuant to the sublicense agreement, we paid Inceptus reimbursement and milestone fees shortly after signing, and are obligated to pay an ongoing quarterly administration fee of \$18,000, which amount will increase to \$29,250 per quarter following this offering. Additionally, we are obligated to pay Inceptus on a quarterly basis an ongoing royalty calculated as the greater of a low-single digit percentage of net sales of products utilizing the licensed intellectual property and \$1,500. The sublicense agreement specifies that our obligations to pay the quarterly administration fee and low-single digit royalty will terminate, and the licensed rights under the Drexel License will become fully paid-up and royalty and payment free if, pursuant to the terms of the Drexel License,

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Drexel University fails to provide timely written consent to Inceptus to join Drexel University to any patent infringement action for which Drexel University is a legally indispensable party.

The sublicense agreement will continue until the expiration of the sublicensed patent, unless terminated earlier pursuant to the terms of the agreement. We may terminate the sublicense agreement at any time by providing prior written notice. Inceptus may terminate the sublicense agreement if we challenge the validity or enforceability of the sublicensed intellectual property, in the event of our uncured material breach, in the event of our bankruptcy or insolvency-related events, if we cease bona fide development and commercialization efforts for a specified period or if we are late in making our obligated payments under the agreement. The Drexel License includes similar term and termination provisions in respect of Inceptus and Drexel University.

***Amended and Restated Technology Agreement with Inceptus Medical, LLC***

In March 2018, we entered into an amended and restated technology agreement with Inceptus. Pursuant to this agreement, Inceptus granted us a worldwide, exclusive, royalty-free license to certain of its intellectual property related to the braiding and aspiration controller technologies underlying its patent for the treatment of embolism and thrombosis in human vasculature other than carotid arteries, coronary vasculature and cerebral vasculature, or the defined field. As consideration, we granted Inceptus a license to use our intellectual property on reciprocal terms for use outside the defined field. These cross-licenses are perpetual and irrevocable. Neither party owes any payments to each other. We have the right to assign or transfer the amended and restated technology agreement to an entity in connection with the sale of all or substantially all of our business.

**Government Regulation**

Our products and our operations are subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, and other federal and state authorities in the United States, as well as comparable authorities in foreign jurisdictions. Our products are subject to regulation as medical devices in the United States under the Federal Food, Drug, and Cosmetic Act, or FDCA, as implemented and enforced by the FDA.

***United States Regulation***

The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

***FDA Premarket Clearance and Approval Requirements***

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification, or approval of a premarket approval, or PMA, application. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents.

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While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. Some pre-amendment devices are unclassified, but are subject to FDA's premarket notification and clearance process in order to be commercially distributed. Our currently marketed products are Class II devices subject to 510(k) clearance.

*510(k) Clearance Marketing Pathway*

Our current products are subject to premarket notification and clearance under section 510(k) of the FDCA. To obtain 510(k) clearance, we must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to 12 months, but often takes longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, FDA collects user fees for certain medical device submissions and annual fees and for medical device establishments. For fiscal year 2020, the standard user fee for a 510(k) premarket notification application is \$11,594.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the "*de novo*" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval or *de novo* reclassification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k), *de novo* request or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or until PMA approval is obtained or a *de novo* request is granted. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

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,

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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.

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 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.

*PMA Approval Pathway*

Class III devices require PMA approval before they can be marketed, although some pre-amendment Class III devices for which FDA has not yet required a PMA are cleared through the 510(k) process. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities, and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, the FDA’s review often takes significantly longer, and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel’s recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the applicant or its third-party manufacturers’ or suppliers’ manufacturing facility or facilities to ensure compliance with the QSR. PMA devices are also subject to the payment of user fees, which for fiscal year 2020 includes a standard application fee of \$340,995 and an annual establishment registration fee of \$5,236.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the

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convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness. None of our products are currently marketed pursuant to a PMA.

*Clinical Trials*

Clinical trials are almost always required to support a PMA and are sometimes required to support a 510(k) submission. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's IDE regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk," to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. If the device under evaluation does not present a significant risk to human health, then the device sponsor is not required to submit an IDE application to the FDA before initiating human clinical trials, but must still comply with abbreviated IDE requirements when conducting such trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

Regardless of the degree of risk presented by the medical device, clinical studies must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA's regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

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*Post-market Regulation*

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of “off-label” uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- the FDA’s recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Our manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, we are subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our products, which would have a material adverse effect on our business. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;

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- recalls, withdrawals, or administrative detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approvals for our products; or
- criminal prosecution.

*Regulation of Medical Devices in EEA*

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, 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 European Union, or EU; and
- Strengthened 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.

*Healthcare Regulatory Laws*

Within the United States, our products and our customers are subject to extensive regulation by a wide range of federal and state agencies that govern business practices in the medical device industry. These laws include federal and state anti-kickback, fraud and abuse, false claims, transparency and anti-corruption statutes and regulations. Internationally, other governments also impose regulations in connection with their healthcare reimbursement programs and the delivery of healthcare items and services.

U.S. federal healthcare fraud and abuse laws generally apply to our activities because our products are covered under federal healthcare programs such as Medicare and Medicaid. The Anti-Kickback Statute is

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particularly relevant because of its broad applicability. Specifically, the Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in exchange for, or to induce, either the referral of an individual, or the furnishing, arranging for or recommending a good or service for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. Almost any financial interaction with a healthcare provider, patient or customer will implicate the Anti-Kickback Statute. Statutory exceptions and regulatory safe harbors protect certain interactions if specific requirements are met. However, only those interactions that represent fair market value exchanges generally are protected by a safe harbor or exception. The government can exercise enforcement discretion in taking action against unprotected activities. Further, a person or entity does not need to have actual knowledge of the Anti-Kickback Statute or specific intent in order to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties statute. Penalties for Anti-Kickback Statute violations may include both criminal penalties such as imprisonment and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid, and other federal healthcare programs. Exclusion would mean that procedures using our products would no longer be eligible for reimbursement under federal healthcare programs.

Many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any payor, not only the Medicare and Medicaid programs. Insurance companies may also bring a private cause of action for treble damages against a manufacturer for a pattern of causing false claims to be filed under the federal Racketeer Influenced and Corrupt Organizations Act, or RICO.

Another development affecting the healthcare industry is the increased use of the federal Civil False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought against healthcare providers by private individuals has increased dramatically. In addition, various states have enacted false claim laws analogous to the Civil False Claims Act, although many of these state laws apply where a claim is submitted to any third-party payor and not merely a federal healthcare program.

The federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA, among other things, created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The HIPAA healthcare fraud statute prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment and/or exclusion from government sponsored programs. The HIPAA false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines and/or imprisonment.

Laws and regulations have also been enacted by the federal government and various states to regulate the sales and marketing practices of medical device and pharmaceutical manufacturers. The laws and regulations generally limit financial interactions between manufacturers and healthcare providers; require pharmaceutical and medical device companies to comply with voluntary compliance standards issued by industry associations and the relevant compliance guidance promulgated by the U.S. federal government; and/or require disclosure to the government and/or public of financial interactions (so-called "sunshine laws"). Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation.

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Manufacturers must adopt reasonable interpretations of requirements if there is ambiguity and those interpretations could be challenged. Given the lack of clarity in laws and their implementation, our activities could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

*Coverage and Reimbursement*

Sales of our products depend, in part, on the extent to which the procedures using our products are covered by third-party payors, such as government healthcare programs, commercial insurance and managed healthcare organizations. Third-party payors are increasingly limiting coverage and reducing reimbursements for medical products and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical devices and medical services, in addition to questioning their safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net sales and results.

Moreover, the process for determining whether a third-party payor will provide coverage for a product or procedure may be separate from the process for establishing the reimbursement rate that such a payor will pay for the product or procedure. A payor's decision to provide coverage for a product or procedure does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product or procedure does not assure that other payors will also provide coverage for the product or procedure. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to ensure profitability.

*Healthcare Reform*

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the Patient Protection and Affordable Care Act, or ACA, was signed into law and substantially changed the way healthcare is financed by both governmental and private insurers in the United States. The ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the ACA imposed, among other things, a new federal excise tax on the sale of certain medical devices (which was suspended until December 31, 2019 and, absent further legislative amendments, will be reinstated effective January 1, 2020), provided incentives to programs that increase the federal government's comparative effectiveness research, and 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. 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.

Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of Medicare providers. Moreover, there has recently been heightened governmental scrutiny, including increasing legislative and enforcement interest, over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for products. Individual states in the United States have also become increasingly active in implementing regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation from other countries. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

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*Data Privacy and Security*

Medical device companies may be subject to U.S. federal and state health information privacy, security and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured PHI, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance.

In addition, certain state and foreign laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA 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. For example, California recently enacted legislation, the California Consumer Privacy Act, or CCPA, which goes into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for “protected health information” maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context. It remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted. Additionally, the EU also has laws and regulations dealing with the collection, use and processing of personal data obtained from individuals in the EU, namely the EU General Data Protection Regulation, or GDPR. These regulations are often more restrictive than those in the United States and may restrict transfers of personal data to the United States unless certain requirements are met. The GDPR provides that EU member states may make their own further laws and regulations limiting the processing of genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs to increase, and harm our business and financial condition. Failure to comply with these obligations could expose us to significant fines.

**Facilities**

Our corporate headquarters, which includes our manufacturing facility, is located in Irvine, California, where we occupy a facility totaling 38,200 square feet under a lease agreement that expires in September 2024. This facility contains dedicated research and development, training, education and manufacturing spaces. We believe this facility is sufficient to meet our current and anticipated needs in the near term and that suitable additional space is available as needed to accommodate expansion of our operations and manufacturing and distribution activities.

**Employees**

As of December 31, 2019, we had 199 employees. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

**Legal Proceedings**

We are not subject to any material legal proceedings.

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**MANAGEMENT**

**Executive Officers and Directors**

The following table sets forth information regarding our executive officers and directors as of the date of this prospectus.

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
<b>Executive Officers</b>		
William Hoffman	52	Chief Executive Officer, President and Director
Mitchell Hill	60	Chief Financial Officer
Andrew Hykes	47	Chief Commercial Officer
Thomas Tu, M.D.	47	Chief Medical Officer
<b>Non-Employee Directors</b>		
Robert Rosenbluth, Ph.D.	74	Chair of the Board
Donald Milder	65	Director
Geoff Pardo	48	Director
Jonathan Root, M.D.	60	Director
Kirk Nielsen	46	Director
Paul Lubock	64	Director
Cynthia Lucchese	59	Director
Catherine Szyman	53	Director

(1) Member of the Nominating and Corporate Governance Committee.

(2) Member of the Audit Committee.

(3) Member of the Compensation Committee.

**Executive Officers**

**William Hoffman** has served as our Chief Executive Officer and President and as a member of our board of directors since February 2015. Mr. Hoffman previously served as Chief Executive Officer at Visualase, Inc., a private company focusing on MRI-guided lasers, from May 2008 until its acquisition by Medtronic PLC, or Medtronic, in July 2014. Prior to this, Mr. Hoffman was the Chief Operating Officer of Rubicor Medical, Inc., a private company focusing on minimally invasive breast biopsy and lumpectomy technology, from April 2006 to November 2007. From July 2003 to February 2006, Mr. Hoffman served as Director of Sales and then the Vice President of Sales at FoxHollow Technologies, Inc, a private company that makes medical devices used to treat peripheral artery disease. Mr. Hoffman currently serves on the board of directors of two private companies: Monteris Medical, Inc. and 4C Medical Group. Mr. Hoffman received a B.A. from Dickinson College.

We believe Mr. Hoffman's extensive management experience in the medical device industry, and his understanding of our business, operations and strategy qualify him to serve as our Chief Executive Officer and on our board of directors.

**Mitchell Hill** has served as our Chief Financial Officer since March 2019. From June 2018 to February 2019, Mr. Hill served as the Chief Executive Officer and as a member of the board of directors of Flow Lighting Technologies, Inc., a private company specializing in cloud-based software. From August 2017 to June 2018, Mr. Hill served as a member of the board of directors of LIVMOR, Inc., a private company focusing on digital health solutions for remote patient monitoring. From September 2015 to May 2018, Mr. Hill served as a member of the board of directors and audit committee of Ominto, Inc. From March 2013 to March 2015, Mr. Hill was the Executive Vice President and Chief Financial Officer of Alphaeon Corporation, a private company serving

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healthcare providers in the self-pay medical field. Prior to 2015, Mr. Hill served as Chief Financial Officer at a number of companies, including Cameron Health, Inc., Visiogen Inc., Insight Health Services Holdings Corp., BMS Reimbursement Management, Buy.com, Inc. and Walt Disney Imagineering and Disney Development Co. Mr. Hill received his B.S. in Business Accounting from Brigham Young University and an M.B.A. from Harvard Business School.

**Andrew Hykes** has served as our Chief Commercial Officer since September 2017. From November 2012 to January 2017, Mr. Hykes was the Vice President of Commercial Operations of Sequent Medical Inc., a private company focused on catheter-based neurovascular therapies that was acquired by Terumo Corporation in July 2016. Prior to this, Mr. Hykes worked for Medtronic PLC, a public medical device company, from August 2002 to October 2012, where he held several positions including: Vice President of Marketing, Vice President of Clinical and Regulatory Affairs and Director of Investor Relations. From 1995 to 2000, Mr. Hykes worked in healthcare banking for ABN AMRO Bank. Mr. Hykes received his B.B.A. from the University of Wisconsin Madison and an M.B.A. from Harvard Business School.

**Thomas Tu, M.D.** has served as our Chief Medical Officer since July 2019. From June 2003 to June 2019, Dr. Tu was in clinical practice at Baptist Health Hospital in Louisville, Kentucky, where he also served as director of the cardiac catheterization laboratory. Since December 2010, Dr. Tu has served as the Chief Executive Officer and President of World Health Initiative, a non-profit organization that provides medical care and educational programs to hospitals in Vietnam and China. Dr. Tu is a fellow of the Society for Cardiovascular Angiography & Interventions and previously served as the chairs of the society's political action committee and Emerging Leader Mentorship program. Dr. Tu completed his training in internal medicine, cardiology, interventional cardiology, peripheral interventions at Massachusetts General Hospital and Beth Israel Deaconess Medical Center in Boston, Massachusetts. Dr. Tu is board-certified in internal medicine, cardiovascular disease, and interventional cardiology. Dr. Tu received his B.A. from the University of Virginia and his M.D. from Harvard Medical School.

**Non-Employee Directors**

**Robert Rosenbluth, Ph.D.** has served as a member of our board of directors and its Chair since September 2011 and as Chief Executive Officer and President from September 2011 until December 2014. Dr. Rosenbluth is a co-founder of our company. Prior to this, he was the co-founder and chairman of the board of directors of Sequent Medical Inc. from May 2007 until its acquisition by Terumo Medical Corporation in July 2016 and Chief Executive Officer and President from May 2007 until February 2010. Prior to this, Dr. Rosenbluth was the co-founder and chairman of the board of directors MicroVention from November 1997 until it was acquired by Terumo Medical Corporation in March 2006 and Chief Executive Officer and President from November 1997 until September 2002. Dr. Rosenbluth currently serves on the board of Inceptus Medical LLC, or Inceptus, a private medical device company incubator, and as chairman of the board of directors, Chief Executive Officer and President of Okami Medical Inc., or Okami, a private company focused on developing medical devices designed to occlude peripheral vessels. Dr. Rosenbluth received his B.S. from Columbia University and M.S. and Ph.D. from University of California, Berkeley.

We believe Dr. Rosenbluth is qualified to serve as the Chair of the board of directors due to his role as a co-founder of our company, his knowledge of the industry and his experience as the chairman of the board of other medical device companies.

**Donald Milder** has served as a member of our board of directors since September 2011. In 1999, Mr. Milder co-founded Versant Venture Management, LLC, or Versant, where he has been a Managing Director since its inception. Versant is a venture capital firm that invests in medical devices, biotechnology, life science, pharmaceuticals and healthcare sectors. Previously, Mr. Milder was a Managing Director with CPVP Management LP from August 1989 to November 1999, where he was responsible for their healthcare investments. Prior to this, Mr. Milder was the Chief Executive Officer of Infusion Systems Corporation from

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1984 to 1989. He currently serves as a board member for Eclipse Regenesys, Inc., Okami, NeoSeq Ltd. and Ceres Foundation. Mr. Milder received a B.A. from Union College and an M.B.A. from Harvard Business School.

We believe Mr. Milder is qualified to serve on our board of directors due to his extensive experience as a venture capital investor and member of the board of multiple medical device companies.

**Geoff Pardo** has served as a member of our board of directors since March 2018. Mr. Pardo has served as a partner at Gilde Healthcare since 2011. Previously, he was a partner at Spray Venture Partners from 2004 to 2011. He also served as President and Chief Executive Officer of Facet Solutions, a spinal implant company focused on treating lumbar spinal stenosis, from 2007 until the company was sold to Globus Medical in 2011. He has also worked at Cardinal Partners as an Associate leading their investing activity in the medical device sector from 2001 to 2004. He currently serves as a board member of Ablative Solutions, Inc., Vesper Medical, Inc., Vapotherm, Inc. and CVRx, Inc. Mr. Pardo received a B.A. from Brown University and an M.B.A. from The Wharton School of Business.

We believe Mr. Pardo's experience leading and managing a medical technology company, as well as his healthcare industry knowledge and his experience serving on the board of directors of other companies, qualified him to serve on our board of directors.

**Jonathan Root, M.D.** has served as a member of our board of directors since September 2011. Mr. Root has served as the Managing Member of Presidio Management Group X, LLC and several U.S. Venture Partners' funds, which are the general partners of various other venture capital funds, since 1995. Mr. Root previously served as a board member for OncoMed Pharmaceuticals, Inc., a public pharmaceutical company, from August 2004 until its merger with Mereo BioPharma Group plc in April 2019. Additionally, Mr. Root currently serves on the board of directors for several private companies in the healthcare industry. Mr. Root received an A.B. from Dartmouth College, an M.D. from University of Florida, College of Medicine and an M.B.A. from Columbia Business School.

We believe Mr. Root's medical, management and directorship experience in the healthcare industry qualified him to serve on our board of directors.

**Kirk Nielsen** has served as a member of our board of directors since September 2011. Mr. Nielsen has been a Managing Partner at Vensana Capital, a medtech-focused investment firm, since January 2019, and a Managing Director of Versant Ventures, a healthcare-focused venture capital firm, since January 2011. He currently serves as a board member for several private companies including: Metavention, Monteris Medical, Respicardia, and Veran Medical Technologies. Mr. Nielsen received an A.B. from Harvard College and an M.B.A. from Harvard Business School.

We believe Mr. Nielsen is qualified to serve on our board due to his extensive management experience serving on the board of several medical technology companies.

**Paul Lubock** first served as a member of our board of directors from September 2011 until March 2018 and then again in April 2019 to present. Mr. Lubock is a co-founder of our company. Mr. Lubock has been a Vice President of both Inceptus and Okami since July 2011 and June 2017, respectively, and he was a Vice President at our company from September 2013 until June 2017. Prior to these positions, Mr. Lubock was a co-founder, Senior Vice President and Chief Technology Officer of SenoRx, Inc., a public company which was acquired by C.R. Bard in 2010. Mr. Lubock holds over 170 issued U.S. patents. Since June 2016, Mr. Lubock has been a board member of Okami. Mr. Lubock received a B.A. from University of California, San Diego in Applied Mechanics and Engineering Science and a M.S. in Mechanical Engineering from University of California, Berkeley.

We believe Mr. Lubock is qualified to serve on our board of directors because of his role as a co-founder of our company and his extensive knowledge of our company and the medical device industry.

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**Cynthia Lucchese** has served as a member of our board of directors since November 2019. Since November 2015, Ms. Lucchese has been the Chief Administrative Officer and Chief Financial Officer of Hulman & Company, a motorsports competition and entertainment company. Prior to this she was the Senior Vice President and Chief Financial Officer of Hillenbrand, Inc., a public company with multiple brands that serve a range of industries across the globe, from January 2008 until March 2014. Ms. Lucchese has experience with medical device and life sciences companies, including Guidant, Thoratec and Eli Lilly. Ms. Lucchese currently serves on the board of two public companies. Since July 2014, she has been a board member and serves as Chair of the Audit Committee and a member of the Nominating and Corporate Governance Committee of Intersect ENT, Inc., a publicly traded medical device company. Additionally, Ms. Lucchese has been a board member of Hanger, Inc., a public company that delivers orthotic and prosthetic products and patient care, since May 2015. Ms. Lucchese became a member of Hanger's Audit Committee in November 2017 and previously was a member of the Compensation Committee. Ms. Lucchese is also a board member and Audit Committee Chair for BVI International, Inc., a privately owned global ophthalmic device company. Ms. Lucchese has a B.S. in accounting and an M.B.A. from Indiana University, Kelley School of Business.

We believe Ms. Lucchese is qualified to serve on our board of directors because of her extensive experience as a board member of public companies and experience with the medical device industry.

**Catherine Szyman** has served as a member of our board of directors since November 2019. Since January 2015, Ms. Szyman has been the Corporate Vice President of Critical Care at Edwards Lifesciences Corp., a public company specializing in artificial heart valves and hemodynamic monitoring. Prior to this, Ms. Szyman worked at Medtronic from August 1991 to December 2014, where she held a number of roles, including President of Global Diabetes, Vice President of Corporate Strategy and Business Developments, Vice President and General Manager for the endovascular business and Vice President of Finance for the vascular business. Ms. Szyman currently serves on the board of director of Endotronix, Inc., a private medical device company, Opus College of Business at the University of St. Thomas and the American Heart Association, a non-profit organization that funds cardiovascular medical research. Ms. Szyman has a B.A. from University of St. Thomas and an M.B.A. from Harvard Business School.

We believe Ms. Szyman is qualified to serve on our board of directors because of her extensive leadership experience and knowledge of medical device companies.

**Family Relationships**

There are no family relationships among any of our directors or executive officers.

**Board Composition**

Our board of directors is currently composed of nine members with no vacancies. Pursuant to our third amended and restated certificate of incorporation as in effect prior to the completion of this offering and the second amended and restated voting agreement, William Hoffman, Robert Rosenbluth, Donald Milder, Geoff Pardo, Jonathan Root, Kirk Nielsen and Paul Lubock have been designated to serve as members of our board of directors. Pursuant to our second amended and restated voting agreement, the stockholders who are party to the agreement have agreed to vote their respective shares to elect (1) one director designated by Coöperatieve Gilde Healthcare IV U.A., currently Mr. Pardo, (2) one director designated by Milder Community Property Trust, dated 11/7/91, currently Mr. Milder, (3) one director designated by U.S. Venture Partners X, L.P. and USVP X Affiliates, L.P., currently Mr. Root, (4) one director designated by Versant Venture Capital IV, L.P. and Versant Side Fund IV, L.P., currently Mr. Nielsen, and (5) three directors designated by a majority of our common stock, currently Mr. Hoffman, Dr. Rosenbluth and Mr. Lubock. Following this offering, no stockholder will have any special rights regarding the election or designation of members of our board of directors. The provisions of our third amended and restated certificate of incorporation and the second amended and restated voting agreement will no longer be in effect upon the closing of this offering and there will be no other contractual obligations

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regarding the election of our directors. Each of our current directors will continue to serve until the election and qualification of his or her successor, or his or her earlier death, resignation or removal.

In accordance with our amended and restated certificate of incorporation, which will be in effect upon the closing of this offering, our board of directors will be divided into three classes of directors. At each annual meeting of stockholders, a class of directors will be elected for a three-year term to succeed the class whose terms are then expiring, to serve from the time of election and qualification until the third annual meeting following their election or until their earlier death, resignation or removal. Upon the closing of this offering, our directors will be divided among the three classes as follows:

The Class I directors will be \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, and their terms will expire at our first annual meeting of stockholders following this offering.

The Class II directors will be \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, and their terms will expire at our second annual meeting of stockholders following this offering.

The Class III directors will be \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, and their terms will expire at our third annual meeting of stockholders following this offering.

Our amended and restated certificate of incorporation will provide that the authorized number of directors may be changed only by resolution of our board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control. See the section of this prospectus captioned “Description of Capital Stock—Anti-Takeover Provisions” for a discussion of these and other anti-takeover provisions found in our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to the closing of this offering.

#### **Director Independence**

We intend to apply to have our common stock listed on the Nasdaq Global Market. Under the rules of Nasdaq, independent directors must comprise a majority of a listed company’s board of directors within a specified period of the completion of this offering. In addition, rules require that, subject to specified exceptions, each member of a listed company’s audit, compensation, and nominating and corporate governance committees be independent. Under these rules, a director will only qualify as an “independent director” if, in the opinion of that company’s board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: (1) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries. We intend to satisfy the audit committee independence requirements of Rule 10A-3 as of the closing of this offering.

In connection with this offering, our board of directors has undertaken a review of the independence of each director and considered whether each director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. As a result of this review, our board of directors determined that \_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_, and \_\_\_\_\_ are “independent directors” as defined under the applicable rules and regulations of the SEC and the listing requirements and rules

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of Nasdaq, representing \_\_\_\_\_ of our nine directors. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director’s business and personal activities and current and prior relationships as they may relate to us and our management, including the beneficial ownership of our capital stock by each non-employee director and any transactions involving them described in the section titled “Certain Relationships and Related Party Transactions.”

**Board Committees**

Our board of directors has an audit committee, a compensation committee and a nominating and corporate governance committee, each of which has the composition and the responsibilities described below. In addition, from time to time, special committees may be established under the direction of our board of directors when necessary to address specific issues.

Each of the audit committee, the compensation committee and the nominating and corporate governance committee will operate under a written charter that will be approved by our board of directors in connection with this offering. A copy of each of the audit committee, compensation committee and nominating and corporate governance committee charters will be available on our corporate website. The reference to our website in this prospectus does not include or incorporate by reference the information on our website into this prospectus.

***Audit Committee***

Our audit committee oversees our corporate accounting and financial reporting process and assists our board of directors in monitoring our financial systems. Our audit committee will be responsible for, among other things:

- appointing, compensating, retaining, evaluating, terminating and overseeing our independent registered public accounting firm;
- discussing with our independent registered public accounting firm their independence from management;
- reviewing with our independent registered public accounting firm the scope and results of their audit;
- approving all audit and permissible non-audit services to be performed by our independent registered public accounting firm;
- overseeing the financial reporting process and discussing with management and our independent registered public accounting firm the interim and annual financial statements that we file with the SEC;
- reviewing and monitoring our accounting principles, accounting policies, financial and accounting controls and compliance with legal and regulatory requirements; and
- establishing procedures for the confidential anonymous submission of concerns regarding questionable accounting, internal controls or auditing matters.

Effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, our audit committee will consist of \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, with \_\_\_\_\_ serving as chair. Our board of directors has affirmatively determined that \_\_\_\_\_, \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_ meet the requirements for independence under the current Nasdaq listing standards and SEC rules and regulations. In addition, our board of directors has determined that \_\_\_\_\_ is an “audit committee financial expert” as defined in Item 407(d) of Regulation S-K promulgated under the Securities Act. Each member of our audit committee is financially literate.

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***Compensation Committee***

Our compensation committee oversees our compensation policies, plans and benefits programs. Our compensation committee will be responsible for, among other things:

- reviewing and approving corporate goals and objectives relevant to the compensation of our Chief Executive Officer, evaluating our Chief Executive Officer's performance in light of these goals and objectives and setting compensation;
- reviewing and setting or making recommendations to our board of directors regarding the compensation of our other executive officers;
- reviewing and approving or making recommendations to our board of directors regarding our incentive compensation and equity-based plans and arrangements; and
- appointing and overseeing any compensation consultants.

Effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, our compensation committee will consist of \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, with \_\_\_\_\_ serving as chair. The composition of our compensation committee meets the requirements for independence under the current Nasdaq listing standards and SEC rules and regulations. Each member of this committee is a non-employee director, as defined in Section 16b-3 of the Exchange Act.

***Nominating and Corporate Governance Committee***

Our nominating and corporate governance committee oversees and assists our board of directors in reviewing and recommending nominees for election as directors. Our nominating and corporate governance committee will be responsible for, among other things:

- identifying individuals qualified to become members of our board of directors, consistent with criteria approved by our board of directors;
- recommending to our board of directors the nominees for election to our board of directors at annual meetings of our stockholders;
- evaluating the overall effectiveness of our board of directors; and
- developing and recommending to our board of directors a set of corporate governance guidelines and principles.

Effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, our nominating and corporate governance committee will consist of \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, with \_\_\_\_\_ serving as chair. The composition of our nominating, governance, and corporate responsibility committee meets the requirements for independence under the current Nasdaq listing standards and SEC rules and regulations.

***Role of the Board in Risk Oversight***

Our board of directors has an active role, as a whole and also at the committee level, in overseeing the management of our risks. Our board of directors is responsible for general oversight of risks and regular review of information regarding our risks, including credit risks, liquidity risks and operational risks. The compensation committee is responsible for overseeing the management of risks relating to our executive compensation plans

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and arrangements. The audit committee is responsible for overseeing the management of risks relating to accounting matters and financial reporting. The nominating and corporate governance committee is responsible for overseeing the management of risks associated with the independence of our board of directors and potential conflicts of interest. Although each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board of directors is regularly informed through discussions from committee members about such risks. Our board of directors believes its administration of its risk oversight function has not negatively affected our board of directors' leadership structure.

**Code of Business Conduct and Ethics**

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions prior to the completion of this offering. Following this offering, a current copy of the code will be posted on the investor section of our website.

**Compensation Committee Interlocks and Insider Participation**

None of the members of our compensation committee is an officer or one of our employees. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee (or other board committee performing equivalent functions or, in the absence of any such committee, the entire board of directors) of any entity that has one or more executive officers serving on our board of directors or compensation committee.

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**EXECUTIVE AND DIRECTOR COMPENSATION**

### Executive Compensation

This section discusses the material components of the executive compensation program for our executive officers who are named in the “2019 Summary Compensation Table” below. We are an “emerging growth company” within the meaning of the JOBS Act, and have elected to comply with the reduced compensation disclosure requirements available to emerging growth companies under the JOBS Act. In 2019, our “named executive officers” and their positions were as follows:

- William Hoffman, President and Chief Executive Officer;
- Mitchell Hill, Chief Financial Officer; and
- Andrew Hykes, Chief Commercial Officer.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the completion of this offering may differ materially from the currently planned programs summarized in this discussion.

### 2019 Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officers for the year ended December 31, 2019.

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary</u> <u>(\$)</u>	<u>Bonus</u> <u>(\$)</u>	<u>Stock</u> <u>Awards</u> <u>(\$)(1)</u>	<u>Option</u> <u>Awards</u> <u>(\$)(1)</u>	<u>All Other</u> <u>Compensation</u> <u>(\$)</u>	<u>Total</u> <u>(\$)</u>
William Hoffman President and Chief Executive Officer	2019	400,000	—	163,410	—	—	563,410
Mitchell Hill Chief Financial Officer	2019	224,848	—	21,314	226,413	3,428	476,003
Andrew Hykes Chief Commercial Officer	2019	315,763	—	73,179	7,868	—	396,810

(1) Amounts reflect the full grant-date fair value of stock awards and stock options granted during 2019 computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. We provide information regarding the assumptions used to calculate the value of all stock awards and option awards made to named executive officers in Note 13 to our financial statements included in this prospectus.

### Narrative to Summary Compensation Table

#### 2019 Salaries

The named executive officers receive their respective base salaries to compensate them for services rendered to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive’s skill set, experience, role and responsibilities.

The 2019 base salaries for Messrs. Hoffman and Hill were \$400,000 and \$275,000, respectively. Mr. Hykes’ 2019 base salary was \$300,000, which was increased to \$321,000, effective April 1, 2019, to reflect significant contributions to the development of the Company.

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### **2019 Bonuses**

Our named executive officers were eligible to earn cash bonuses based on individual and corporate objectives during the year ended December 31, 2019, as determined by our board of directors in its sole discretion. For 2019, Messrs. Hoffman and Hill were eligible to receive an annual bonus of up to 50% and 30%, respectively, of their respective base salaries. For 2019, Mr. Hykes was eligible to receive an annual bonus of up to 30% of his base salary, which was increased to 40% of his base salary, effective April 1, 2019, to reflect significant contributions to the development of the Company.

Our board of directors has not yet made determinations with respect to achievement of the applicable performance goals or bonus payments with respect to 2019, but anticipates that such determinations will be made in the first quarter of 2020.

### **Equity Compensation**

We historically have used stock options as the primary incentive for long-term compensation to our named executive officers because they are able to profit from stock options only if our stock price increases relative to the stock option's exercise price, which generally is set at the fair market value of our common stock as of the applicable grant date. Generally, stock options vest as to 25% of the total number of shares underlying the option on the one-year anniversary of the grant date or the vesting commencement date and subsequently in equal monthly installments over the ensuing thirty-six months, subject to the executive's continued service with us on each applicable vesting date. Additionally, beginning in 2019, we began granting to our named executive officers restricted stock units in addition to stock options. Generally, the restricted stock units vest upon the fourth (4<sup>th</sup>) anniversary of the vesting commencement date, provided that the Company has first undertaken an initial public offering, and subject to the executive's continued service with us on the applicable vesting date. Additionally, certain of the restricted stock units subject to each award will accelerate and vest upon a termination of the executive's service due to death or by the Company without cause (as defined in the 2011 Plan), in each case following the Company's initial public offering. The restricted stock units shall also vest in full upon a sale event (as defined in the applicable award agreement). In the event of a change in control, outstanding equity awards held by our named executive officers will be treated pursuant to the terms of the governing plan.

Our named executive officers currently hold restricted stock units and stock options. Specifically, in 2019, each of Messrs. Hoffman, Hill and Hykes were granted the restricted stock units, or RSUs, and stock options set forth below, with vesting schedules substantially similar to the general vesting terms described above.

The following table sets forth the equity awards granted to our named executive officers in the 2019 fiscal year.

<u>Named Executive Officer</u>	<u>2019 Stock Options Granted</u>	<u>2019 RSUs Granted</u>
William Hoffman	—	1,372,809
Mitchell Hill	596,873	179,062
Andrew Hykes	23,875	614,780

### **Equity Compensation Plans**

#### **2011 Equity Incentive Plan**

We currently maintain the 2011 Equity Incentive Plan, as amended from time to time, or the 2011 Plan, in order to provide additional incentives for our employees, directors and consultants, and to provide incentives to attract, retain and motivate eligible persons whose present and potential contributions are important to our success.

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For additional information about the 2011 Plan, please see the section titled “2011 Equity Incentive Plan” below. As mentioned below, in connection with the completion of this offering, no further awards will be granted under the 2011 Plan.

***2020 Incentive Award Plan***

In connection with this offering, we intend to adopt a 2020 Incentive Award Plan, or the 2020 Plan, in order to facilitate the grant of cash and equity incentives to directors, employees (including our named executive officers) and consultants of our company and certain of our subsidiaries and to enable our company and certain of our subsidiaries to obtain and retain services of these individuals, which is essential to our long-term success. Upon the effectiveness of the 2020 Plan, no further grants will be made under the 2011 Plan. However, the 2011 Plan will continue to govern the terms and conditions of the outstanding awards granted under it. For additional information about the 2020 Plan, please see the section titled “2020 Incentive Award Plan” below.

***Other Elements of Compensation***

*Retirement Plans*

*401(k) Plan*

We currently maintain a 401(k) retirement savings plan for our employees, including our named executive officers, who satisfy certain eligibility requirements. Our named executive officers are eligible to participate in the 401(k) plan on the same terms as other full-time employees. The Internal Revenue Code allows eligible employees to defer a portion of their compensation, within prescribed limits, on a pre-tax basis through contributions to the 401(k) plan. We believe that providing a vehicle for tax-deferred retirement savings through our 401(k) plan adds to the overall desirability of our executive compensation package and further incentivizes our employees, including our named executive officers, in accordance with our compensation policies. We do not make matching contributions under our 401(k) plan.

*Employee Benefits and Perquisites*

*Health/Welfare Plans.* All of our full-time employees, including our named executive officers, are eligible to participate in our health and welfare plans, including:

- medical, dental and vision benefits;
- medical and dependent care flexible spending accounts;
- short-term and long-term disability insurance; and
- life insurance.

We believe the perquisites described above are necessary and appropriate to provide a competitive compensation package to our named executive officers.

*No Tax Gross-Ups*

We do not make gross-up payments to cover our named executive officers’ personal income taxes that may pertain to any of the compensation or perquisites paid or provided by our company.

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**Outstanding Equity Awards at Fiscal Year-End**

The following table summarizes the number of shares of common stock underlying outstanding equity incentive plan awards for each named executive officer as of December 31, 2019.

Name	Grant Date	Vesting Commencement Date	Option Awards				Stock Awards	
			Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)(1)
William Hoffman	02/09/2016	02/09/2016	—	—	—	—	1,942(2)	8,778
	02/09/2017	02/09/2017	—	—	—	—	41,002(3)	185,329
	12/22/2017	12/22/2017	26,307	26,308(2)	\$ 0.22	12/22/2027	—	—
	05/03/2018	03/29/2018	199,118	256,010(3)	\$ 0.30	05/03/2028	—	—
	12/13/2018	12/13/2018	134,297	402,889(3)	\$ 0.30	12/13/2028	—	—
Mitchell Hill	03/12/2019	03/12/2019	—	—	—	—	1,372,809(4)	6,205,097
	04/23/2019	03/04/2019	—	596,873(2)	\$ 0.32	04/23/2029	—	—
	03/12/2019	03/12/2019	—	—	—	—	179,062(4)	809,360
Andrew Hykes	09/26/2017	09/11/2017	—	—	—	—	120,500(3)	544,660
	09/26/2017	09/11/2017	—	—	—	—	67,782(3)	306,375
	05/03/2018	03/29/2018	138,133	177,600(3)	\$ 0.30	05/03/2028	—	—
	03/12/2019	01/01/2019	5,471	18,404(5)	\$ 0.32	03/12/2029	—	—
	03/12/2019	03/12/2019	—	—	—	—	614,780(4)	2,778,806

- (1) The market value of shares of restricted stock and RSUs that have not vested is calculated by multiplying the fair market value of a share of our common stock on December 31, 2019 (\$4.52) by the number of unvested shares of restricted stock or RSUs, as applicable, outstanding under the award.
- (2) 25% of the shares underlying the award will vest on the first anniversary of the vesting commencement date, with the remaining shares vesting in equal monthly installments on the last day of each month for the following 36 months, subject to continued service on the applicable vesting date.
- (3) 25% of the shares underlying the award will vest on the first anniversary of the vesting commencement date, with the remaining shares vesting in equal monthly installments for the following 36 months, subject to continued service on the applicable vesting date.
- (4) 100% of the RSUs will vest upon the fourth anniversary of the vesting commencement date, provided that the Company has first undertaken an initial public offering, and subject to continued service on the applicable vesting date. Additionally, the RSUs subject to each award will accelerate and vest upon a termination of the executive's service due to death or by the Company without cause (as defined in the 2011 Plan), in each case following the Company's initial public offering. The RSUs shall also vest in full upon a sale event (as defined in the applicable award agreement).
- (5) 1/48th of the shares underlying the award will vest on each monthly anniversary of the vesting commencement date, subject to continued service on the applicable vesting date.

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**Director Compensation**

**2019 Director Compensation Table**

The following table sets forth information for the year ended December 31, 2019 regarding the compensation awarded to, earned by or paid to our non-employee directors who served on our board of directors during 2019. Mr. Hoffman, who served as our President and Chief Executive Officer during the year ended December 31, 2019, and continues to serve in that capacity, does not receive additional compensation for his service as a director, and therefore is not included in the Director Compensation table below. All compensation paid to Mr. Hoffman is reported above in the “2019 Summary Compensation Table.”

<u>Name</u>	<u>Fees Earned or Paid in Cash (\$)</u>	<u>Option Awards (\$ (1))</u>	<u>All Other Compensation (\$ (2))</u>	<u>Total (\$)</u>
Brian Cox (3)	—	—	61,536	61,536
Paul Lubock (4)	—	—	30,768	30,768
Cynthia Lucchese (5)	—	163,247	—	163,247
Donald Milder	—	—	—	—
Kirk Nielsen	—	—	—	—
Geoff Pardo	—	—	—	—
Jonathan Root, M.D.	—	—	—	—
Robert Rosenbluth, Ph.D.	—	—	40,675	40,675
Catherine Szyman (5)	—	163,247	—	163,247

- (1) Amounts reflect the full grant-date fair value of stock options granted during 2019 computed in accordance with ASC Topic 718, rather than the amounts paid to or realized by the named individual. We provide information regarding the assumptions used to calculate the value of all option awards made to our directors in Note 13 to our financial statements included in this prospectus. As of December 31, 2019, each of Mses. Lucchese and Szyman held outstanding option awards covering 71,000 shares of our common stock and Mr. Lubock held 49,585 shares of restricted stock. No other members of our board of directors held outstanding awards as of December 31, 2019.
- (2) Amounts for Messrs. Rosenbluth, Lubock and Cox represent fees paid through an amended and restated services agreement with Inceptus, as described below in “Certain Relationships and Related Party Transactions—Transactions with Inceptus Medical, LLC.”
- (3) Mr. Cox resigned from our board of directors on April 12, 2019.
- (4) Mr. Lubock was appointed to our board of directors on April 12, 2019.
- (5) Mses. Lucchese and Szyman were appointed to our board of directors on November 25, 2019.

We intend to adopt a compensation program for our non-employee directors that will be in effect following the closing of this offering, and will consist of annual cash retainer fees and long-term equity awards. We are still in the process of developing our non-employee director compensation program.

**Equity Incentive Award Plans**

The following summarizes the material terms of the 2011 Plan and the 2020 Plan. We have previously made periodic grants of equity and equity-based awards to our named executive officers and other key employees under the 2011 Plan and we intend to adopt the 2020 Plan in connection with this offering, to be effective upon the closing of this offering.

**2011 Equity Incentive Plan**

Our board of directors and our stockholders approved the 2011 Plan, which became effective on August 16, 2011.

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A total of 15,738,552 shares of our common stock are reserved for issuance under the 2011 Plan. As of December 31, 2019, 716,950 shares remained available for future issuance under the 2011 Plan.

After the effective date of the 2020 Plan, no additional awards will be granted under the 2011 Plan. However, the 2011 Plan will continue to govern the terms and conditions of the outstanding awards granted under it.

*Administration.* Our board of directors administers the 2011 Plan, unless it delegates authority for administration of the plan. Subject to the terms and conditions of the 2011 Plan, the administrator has the authority to select the persons to whom awards are to be made, to determine the type or types of awards to be granted to each person, determine the number of awards to grant, determine the number of shares to be subject to such awards, and the terms and conditions of such awards, and make all other determinations and decisions and to take all other actions necessary or advisable for the administration of the 2011 Plan. The plan administrator is also authorized to establish, adopt, amend or revise rules relating to administration of the 2011 Plan, subject to certain restrictions.

*Eligibility.* Awards under the 2011 Plan may be granted to individuals who are then our employees or consultants, or employees or consultants of any parent or subsidiaries, and members of our board of directors. Only employees may be granted incentive stock options, or ISOs.

*Awards.* The 2011 Plan provides that the plan administrator may grant or issue ISOs, nonstatutory stock options, or NSOs, stock appreciation rights, or SARs, restricted stock, and restricted stock units, or RSUs, or any combination thereof. The administrator considers each award grant subjectively, considering factors such as the individual performance of the recipient and the anticipated contribution of the recipient to the attainment of our long-term goals. Each award is set forth in a separate agreement with the person receiving the award and indicates the type, terms and conditions of the award. A brief description of each award type follows.

- *Stock Options and SARs.* Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, in contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Code are satisfied. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The exercise price of a stock option or SAR may not be less than 100% of the fair market value of the underlying share on the grant date (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute awards granted in connection with a corporate transaction. The term of a stock option or SAR may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders).
- *Restricted Stock.* Restricted stock is an award of nontransferable shares of our common stock that are subject to certain vesting conditions and other restrictions.
- *RSUs.* RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met and may be accompanied by the right to receive the equivalent value of dividends paid on shares of common stock prior to the delivery of the underlying shares (i.e., dividend equivalent rights). The plan administrator may provide that the delivery of the shares underlying RSUs will be deferred on a mandatory basis or at the election of the participant. The terms and conditions applicable to RSUs will be determined by the plan administrator, subject to the conditions and limitations contained in the 2011 Plan.

*Termination of Service.* Upon a participant's termination of service, the participant may exercise his or her vested stock options within thirty days (or six months for terminations due to death or disability) of the termination date, or such longer period of time as is specified in the applicable award agreement (but in no event later than the expiration of the term of such stock option).

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*Corporate Transactions.* In the event of a merger or change in control (as defined in the 2011 Plan), fifty percent of the then-unvested portion of any outstanding awards will become fully vested immediately preceding the closing of such transaction. In addition, in the event of a merger or change in control, to the extent that the surviving entity declines to continue, substitute or assume outstanding awards, then all such awards will become fully vested in connection with the transaction, and in the case of awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at 100% percent of target levels. Any awards that are outstanding as of the consummation of a merger or change in control will terminate automatically unless the acquirer assumes such awards or such awards are otherwise continued in effect pursuant to the terms of the transaction. In the event that such awards are continued, substituted or assumed and a participant is terminated without “cause” (as defined in the 2011 Plan) within twelve months following such merger or change in control, such participant’s awards will become fully vested, and in the case of awards with performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at 100% percent of target levels.

*Adjustments.* The number of shares and class of shares that may be delivered under the plan and/or the number, class, and price of shares covered by each outstanding award may be adjusted in the event of a recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of shares or other securities of the company, or other change in the corporate structure of the Company affecting the shares.

*Dissolution or Liquidation.* In the event of the proposed dissolution or liquidation of the Company, the administrator will notify each participant as soon as practicable prior to the effective date of such proposed transaction. To the extent it has not been previously exercised, an award will terminate immediately prior to the consummation of such proposed action.

*Amendment and Termination of the 2011 Plan.* Our board of directors may at any time amend, alter, suspend or terminate the 2011 Plan. However, stockholder approval of any amendment to the 2011 Plan must be obtained to the extent necessary and desirable to comply with any applicable law, regulation or stock exchange rule. If not terminated earlier by the compensation committee or the board of directors, the 2011 Plan will continue in effect for a term of ten (10) years from the later of (a) the effective date of the 2011 Plan, or (b) the earlier of the most recent board or stockholder approval of an increase in the number of shares reserved for issuance of the 2011 Plan, which, as of December 31, 2019, is September 18, 2029.

#### **2020 Incentive Award Plan**

We intend to adopt the 2020 Incentive Award Plan, or the 2020 Plan, subject to approval by our stockholders, under which we may grant cash and equity incentive awards to eligible service providers in order to attract, motivate and retain the talent for which we compete. The material terms of the 2020 Plan, as it is currently contemplated, are summarized below. Our board of directors is still in the process of developing, approving and implementing the 2020 Plan and, accordingly, this summary is subject to change.

*Eligibility and Administration.* Our employees, consultants and directors, and employees, consultants and directors of our subsidiaries will be eligible to receive awards under the 2020 Plan. Following the completion of this offering, the 2020 Plan will be administered by our board of directors with respect to awards to non-employee directors and by our compensation committee with respect to other participants, each of which may delegate its duties and responsibilities to committees of our directors and/or officers (referred to collectively as the plan administrator below), subject to certain limitations that may be imposed under the 2020 Plan, Section 16 of the Exchange Act, and/or stock exchange rules, as applicable. The plan administrator will have the authority to make all determinations and interpretations under, prescribe all forms for use with, and adopt rules for the administration of, the 2020 Plan, subject to its express terms and conditions. The plan administrator will also set the terms and conditions of all awards under the 2020 Plan, including any vesting and vesting acceleration conditions.

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*Shares Available.* An aggregate of \_\_\_\_\_ shares of our common stock will be available for issuance under awards granted pursuant to the 2020 Plan, which shares may be authorized but unissued shares, treasury shares or shares purchased in the open market. Notwithstanding anything to the contrary in the 2020 Plan, no more than \_\_\_\_\_ shares of our common stock may be issued pursuant to the exercise of incentive stock options, or ISOs, under the 2020 Plan.

The number of shares available for issuance pursuant to the 2020 Plan will be increased by an annual amount on the first day of each calendar year beginning January 1, 2021 and ending on and including January 1, 2030, equal to the lesser of (A) \_\_\_\_\_ % of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (B) such smaller number of shares as is determined by our board of directors.

If an award under the 2020 Plan expires, lapses or is terminated, exchanged for or settled for cash, surrendered, repurchased, cancelled without having been fully exercised or forfeited any shares subject to such award may, to the extent of such forfeiture, expiration or cash settlement, be used again for new grants under the 2020 Plan. Further, shares delivered to us to satisfy the applicable exercise or purchase price of an award under the 2020 Plan and/or to satisfy any applicable tax withholding obligations (including shares retained by us from the award under the 2020 Plan being exercised or purchased and/or creating the tax obligation) will become or again be available for award grants under the 2020 Plan. The payment of dividend equivalents in cash in conjunction with any awards under the 2020 Plan will not reduce the shares available for grant under the 2020 Plan. However, the following shares may not be used again for grant under the 2020 Plan: (i) shares subject to stock appreciation rights, or SARs, that are not issued in connection with the stock settlement of the SAR on exercise, and (ii) shares purchased on the open market with the cash proceeds from the exercise of options.

Awards granted under the 2020 Plan upon the assumption of, or in substitution for, awards authorized or outstanding under a qualifying equity plan maintained by an entity with which we enter into a merger or similar corporate transaction will not reduce the shares available for grant under the 2020 Plan but will count against the maximum number of shares that may be issued upon the exercise of ISOs.

The 2020 Plan provides that the sum of any cash compensation and the aggregate grant date fair value (determined as of the date of the grant under ASC Topic 718, or any successor thereto) of all awards granted to a non-employee director as compensation for services as a non-employee director during any calendar year may not exceed the amount equal to \$ \_\_\_\_\_, increased to \$ \_\_\_\_\_, in the fiscal year of a non-employee director's initial service as a non-employee director.

*Awards.* The 2020 Plan provides for the grant of stock options, including ISOs and NSOs, SARs, restricted stock, dividend equivalents, restricted stock units, or RSUs, and other stock or cash based awards. Certain awards under the 2020 Plan may constitute or provide for a deferral of compensation, subject to Section 409A of the Code, which may impose additional requirements on the terms and conditions of such awards. All awards under the 2020 Plan will be evidenced by award agreements, which will detail all terms and conditions of the awards, including any applicable vesting and payment terms and post-termination exercise limitations. Awards other than cash awards generally will be settled in shares of our common stock, but the plan administrator may provide for cash settlement of any award. A brief description of each award type follows.

- *Stock Options and SARs.* Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, in contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Code are satisfied. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The exercise price of a stock option or SAR may not be less than 100% of the fair market value of the underlying share on the grant date (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute awards

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granted in connection with a corporate transaction. The term of a stock option or SAR may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders).

- *Restricted Stock.* Restricted stock is an award of nontransferable shares of our common stock that are subject to certain vesting conditions and other restrictions.
- *RSUs.* RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met and may be accompanied by the right to receive the equivalent value of dividends paid on shares of common stock prior to the delivery of the underlying shares (i.e., dividend equivalent rights). The plan administrator may provide that the delivery of the shares underlying RSUs will be deferred on a mandatory basis or at the election of the participant. The terms and conditions applicable to RSUs will be determined by the plan administrator, subject to the conditions and limitations contained in the 2020 Plan.
- *Other Stock or Cash Based Awards.* Other stock or cash based awards are awards of cash, fully vested shares of our common stock and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock. Other stock or cash based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of compensation to which a participant is otherwise entitled.
- *Dividend Equivalents.* Dividend equivalents represent the right to receive the equivalent value of dividends paid on shares of our common stock and may be granted alone or in tandem with awards other than stock options or SARs. Dividend equivalents are credited as of the dividend record dates during the period between the date an award is granted and the date such award vests, is exercised, is distributed or expires, as determined by the plan administrator.

*Certain Transactions.* The plan administrator has broad discretion to take action under the 2020 Plan, as well as make adjustments to the terms and conditions of existing and future awards, to prevent the dilution or enlargement of intended benefits and facilitate necessary or desirable changes in the event of certain transactions and events affecting our common stock, such as stock dividends, stock splits, mergers, acquisitions, consolidations and other corporate transactions. In addition, in the event of certain non-reciprocal transactions with our stockholders known as “equity restructurings,” the plan administrator will make equitable adjustments to the 2020 Plan and outstanding awards. In the event of a change in control of our company (as defined in the 2020 Plan), to the extent that the surviving entity declines to continue, convert, assume or replace outstanding awards, then all such awards will become fully vested and exercisable in connection with the transaction. Awards under the 2020 Plan are generally non-transferrable, except by will or the laws of descent and distribution, or, subject to the plan administrator’s consent, pursuant to a domestic relations order, and are generally exercisable only by the participant.

*Foreign Participants, Claw-Back Provisions, Transferability, and Participant Payments.* The plan administrator may modify award terms, establish subplans and/or adjust other terms and conditions of awards, subject to the share limits described above, in order to facilitate grants of awards subject to the laws and/or stock exchange rules of countries outside of the United States. All awards will be subject to the provisions of any claw-back policy implemented by our company to the extent set forth in such claw-back policy and/or in the applicable award agreement. With regard to tax withholding, exercise price and purchase price obligations arising in connection with awards under the 2020 Plan, the plan administrator may, in its discretion, accept cash or check, shares of our common stock that meet specified conditions, a “market sell order” or such other consideration as it deems suitable.

*Plan Amendment and Termination.* Our board of directors may amend or terminate the 2020 Plan at any time; however, no amendment, other than an amendment that increases the number of shares available under the

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2020 Plan, may materially and adversely affect an award outstanding under the 2020 Plan without the consent of the affected participant, and stockholder approval will be obtained for any amendment to the extent necessary to comply with applicable laws or to increase the director limit. The plan administrator will have the authority, without the approval of our stockholders, to “reprice” any stock option or SAR, or cancel any stock option or SAR in exchange for cash or another award when the option or SAR price per share exceeds the fair market value of the underlying shares. The 2020 Plan will remain in effect until the tenth anniversary of the date the board of directors adopt the 2020 Plan, unless earlier terminated.

**2020 Employee Stock Purchase Plan**

In connection with the offering, we intend to adopt the 2020 Employee Stock Purchase Plan, or the ESPP, which will become effective on the day the ESPP is adopted by our board of directors. The material terms of the ESPP, as it is currently contemplated, are summarized below. Our board of directors is still in the process of developing, approving and implementing the ESPP and, accordingly, this summary is subject to change.

*Shares Available; Administration.* We expect a total of \_\_\_\_\_ shares of our common stock to be initially reserved for issuance under our ESPP. In addition, we expect that the number of shares available for issuance under the ESPP will be annually increased on January 1 of each calendar year beginning in 2021 and ending in 2030, by an amount equal to the lesser of: (i) \_\_\_\_\_ % of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares as is determined by our board of directors. In no event will more than \_\_\_\_\_ shares of our common stock be available for issuance under the ESPP.

Our board of directors or a committee designated by our board of directors will have authority to interpret the terms of the ESPP and determine eligibility of participants. We expect that the compensation committee will be the administrator of the ESPP.

*Eligibility.* The plan administrator may designate certain of our subsidiaries as participating “designated subsidiaries” in the ESPP and may change these designations from time to time. Employees of our company and our designated subsidiaries are eligible to participate in the ESPP if they meet the eligibility requirements under the ESPP established from time to time by the plan administrator. However, an employee may not be granted rights to purchase stock under the ESPP if such employee, immediately after the grant, would own (directly or through attribution) stock possessing 5% or more of the total combined voting power or value of all classes of our common or other class of stock.

If the grant of a purchase right under the ESPP to any eligible employee who is a citizen or resident of a foreign jurisdiction would be prohibited under the laws of such foreign jurisdiction or the grant of a purchase right to such employee in compliance with the laws of such foreign jurisdiction would cause the ESPP to violate the requirements of Section 423 of the Code, as determined by the plan administrator in its sole discretion, such employee will not be permitted to participate in the ESPP.

Eligible employees become participants in the ESPP by enrolling and authorizing payroll deductions by the deadline established by the plan administrator prior to the relevant offering date. Directors who are not employees, as well as consultants, are not eligible to participate. Employees who choose not to participate, or are not eligible to participate at the start of an offering period but who become eligible thereafter, may enroll in any subsequent offering period.

*Participation in an Offering.* We intend for the ESPP to qualify under Section 423 of the Code and stock will be offered under the ESPP during offering periods. The length of offering periods under the ESPP will be determined by the plan administrator and may be up to 27 months long. Employee payroll deductions will be used to purchase shares on each purchase date during an offering period. The number of purchase periods within, and purchase dates during, each offering period will be established by the plan administrator. Offering periods

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under the ESPP will commence when determined by the plan administrator. The plan administrator may, in its discretion, modify the terms of future offering periods.

We expect that the ESPP will permit participants to purchase our common stock through payroll deductions of up to 20% of their eligible compensation, which will include a participant's gross base compensation for services to us, including overtime payments and excluding sales commissions, incentive compensation, bonuses, expense reimbursements, fringe benefits and other special payments. The plan administrator will establish a maximum number of shares that may be purchased by a participant during any offering period or purchase period, which, in the absence of a contrary designation, will be \_\_\_\_\_ shares. In addition, no employee will be permitted to accrue the right to purchase stock under the ESPP at a rate in excess of \$25,000 worth of shares during any calendar year during which such a purchase right is outstanding (based on the fair market value per share of our common stock as of the first day of the offering period).

On the first trading day of each offering period, each participant automatically will be granted an option to purchase shares of our common stock. The option will be exercised on the applicable purchase date(s) during the offering period, to the extent of the payroll deductions accumulated during the applicable purchase period. We expect that the purchase price of the shares, in the absence of a contrary determination by the plan administrator, will be 85% of the lower of the fair market value of our common stock on the first trading day of the offering period or on the applicable purchase date, which will be the final trading day of the applicable purchase period.

Participants may voluntarily end their participation in the ESPP at any time at least one week prior to the end of the applicable offering period (or such longer or shorter period specified by the plan administrator), and will be paid their accrued payroll deductions that have not yet been used to purchase shares of common stock. Participation ends automatically upon a participant's termination of employment.

*Transferability.* A participant may not transfer rights granted under the ESPP other than by will, the laws of descent and distribution or as otherwise provided in the ESPP.

*Certain Transactions.* In the event of certain transactions or events affecting our common stock, such as any stock dividend or other distribution, change in control, reorganization, merger, consolidation or other corporate transaction, the plan administrator will make equitable adjustments to the ESPP and outstanding rights. In addition, in the event of the foregoing transactions or events or certain significant transactions, including a change in control, the plan administrator may provide for (i) either the replacement of outstanding rights with other rights or property or termination of outstanding rights in exchange for cash, (ii) the assumption or substitution of outstanding rights by the successor or survivor corporation or parent or subsidiary thereof, (iii) the adjustment in the number and type of shares of stock subject to outstanding rights, (iv) the use of participants' accumulated payroll deductions to purchase stock on a new purchase date prior to the next scheduled purchase date and termination of any rights under ongoing offering periods or (v) the termination of all outstanding rights. Under the ESPP, a change in control has the same definition as given to such term in the 2020 Plan.

*Plan Amendment; Termination.* The plan administrator may amend, suspend or terminate the ESPP at any time. However, stockholder approval of any amendment to the ESPP must be obtained for any amendment which increases the aggregate number or changes the type of shares that may be sold pursuant to rights under the ESPP, changes the corporations or classes of corporations whose employees are eligible to participate in the ESPP, or changes the ESPP in any manner that would cause the ESPP to no longer be an employee stock purchase plan within the meaning of Section 423(b) of the Code. The ESPP will terminate on the tenth anniversary of the date it is initially approved by our board of directors.

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**CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS**

In addition to the equity and other compensation, termination, change in control and other arrangements discussed in the section titled “Executive and Director Compensation,” the following is a description of each transaction since January 1, 2017 and each currently proposed transaction which:

- we have been or are to be a participant;
- the amount involved exceeded or will exceed \$120,000; and
- any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest.

**Series C Preferred Stock Financing**

In March 2018, we completed the sale of an aggregate of 20,928,610 shares of our Series C convertible preferred stock at a purchase price of \$1.2901 per share for an aggregate purchase price of approximately \$27.0 million. Each share of our Series C convertible preferred stock will automatically convert into shares of our common stock immediately prior to the closing of this offering in accordance with our certificate of incorporation, including adjustments in connection with the 1-for- reverse stock split of our common stock effected on , 2020.

The following table summarizes the Series C convertible preferred stock purchased by holders of more than 5% of our capital stock, our executive officers, our board of directors and any entities affiliated with our executive officers or a member of our board of directors.

<u>Participant (1)</u>	<u>Total Shares of Series C Convertible Preferred Stock Purchased</u>	<u>Aggregate Purchase Price (in thousands)</u>
Coöperatieve Gilde Healthcare IV U.A. (2)	10,851,872	\$ 14,000
Entities affiliated with U.S. Venture Partners (3)	3,357,542	4,331
Entities affiliated with Versant Venture Capital (4)	1,395,241	1,800
Donald Milder (5)	2,059,799	2,657
CVF, LLC	1,495,897	1,930
Robert Rosenbluth (6)	775,133	1,000
Paul Lubock (7)	116,270	150
William Hoffman	85,264	110
Andrew Hykes	19,378	25

(1) Additional details regarding these stockholders and their equity holdings are provided in this prospectus under the caption “Principal Stockholders.”

(2) Geoff Pardo, a member of our board of directors, is a partner of Coöperatieve Gilde Healthcare IV U.A., an entity affiliated with Gilde Healthcare Partners.

(3) Consists of (i) 3,253,458 shares of Series C convertible preferred stock purchased by U.S. Venture Partners X, L.P. and (ii) 104,084 shares of Series C convertible preferred stock purchased by USVP X Affiliates, L.P. Jonathan Root, a member of our board of directors, is a managing member of Presidio Management Group X, L.L.C., which is the general partner of each of U.S. Venture Partners X, L.P. and USVP X Affiliates, L.P.

(4) Consists of (i) 1,386,506 shares of Series C convertible preferred stock purchased by Versant Venture Capital IV, L.P. and (ii) 8,735 shares of Series C convertible preferred stock purchased by Versant Side Fund IV, L.P. Kirk Nielsen, a member of our board of directors, is a managing member of Versant Ventures IV, LLC, which is the general partner of each of Versant Venture Capital IV, L.P. and Versant Side Fund IV, L.P.

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- (5) Consists of 2,059,799 shares of Series C convertible preferred stock purchased by Milder Community Property Trust DTD 11/7/91, amended and restated 11/20/98, amended 3/20/01 for the benefit of Donald B. Milder, or the Milder Community Property Trust. Donald Milder, a member of our board of directors, is a trustee of the Milder Community Property Trust.
- (6) Consists of (i) 581,350 shares of Series C convertible preferred stock purchased by Robert Rosenbluth Trust Under the Robert Rosenbluth Family Trust and (ii) 193,783 shares of Series C convertible preferred stock purchased by Marital QTIP Trust Under the Robert Rosenbluth Family Trust. Robert Rosenbluth, a member of our board of directors, is a trustee of each of the Robert Rosenbluth Trust Under the Robert Rosenbluth Family Trust and the Marital QTIP Trust Under the Robert Rosenbluth Family Trust.
- (7) Consists of 116,270 shares of Series C convertible preferred stock purchased by Paul Lubock Living Trust U/A DTD 02/04/2009. Paul Lubock, a member of our board of directors, is a trustee of the Paul Lubock Living Trust U/A DTD 02/04/2009.

**Second Amended and Restated Investors' Rights Agreement**

We are party to a second amended and restated investors' rights agreement with certain holders of our convertible preferred stock and common stock, entities affiliated with certain of our executive officers and directors, as well as certain of our executive officers and directors. The second amended and restated investors' rights agreement grants rights to certain holders, including certain registration rights with respect to the registrable securities held by them, and also imposes certain affirmative obligations on us, including with respect to the furnishing of financial statements and information to the holders. See "Description of Capital Stock—Registration Rights" for additional information.

As a result of this offering, most of the covenants and restrictions set forth in the second amended and restated investors' rights agreement that apply to us will terminate and we will remain obligated to comply with reporting requirements under the Exchange Act.

**Second Amended and Restated Voting Agreement**

We are party to a second amended and restated voting agreement with certain holders of our convertible preferred stock and common stock, entities affiliated with certain of our executive officers and directors, as well as certain of our executive officers and directors. Pursuant to the second amended and restated voting agreement, these holders have agreed to vote in a certain way on certain matters, including with respect to the election of directors. The parties to the second amended and restated voting agreement have agreed to vote their respective shares to elect (1) one director designated by Coöperatieve Gilde Healthcare IV U.A., (2) one director designated by Milder Community Property Trust DTD 11/7/91, amended and restated 11/20/98, amended 3/20/01 for the benefit of Donald B. Milder, (3) one director designated by U.S. Venture Partners X, L.P. and USVP X Affiliates, L.P., (4) one director designated by Versant Venture Capital IV, L.P. and Versant Side Fund IV, L.P., and (5) three directors designated by a majority of our common stock.

The second amended and restated voting agreement will terminate by its terms in connection with the completion of this offering and none of our stockholders will have any continuing voting rights, including special rights regarding the election or designation of members of our board of directors, following this offering.

**Second Amended and Restated Right of First Refusal and Co-Sale Agreement**

We are party to a second amended and restated first refusal and co-sale agreement with certain holders of our convertible preferred stock and common stock, entities affiliated with certain of our executive officers and directors, as well as certain of our executive officers and directors, pursuant to which we have a right of first refusal and holders of our common stock that are party to the second amended and restated first refusal and co-sale agreement have a right of first refusal and a co-sale right.

The second amended and restated first refusal and co-sale agreement will terminate in connection with the completion of this offering.

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**Transactions with Inceptus Medical, LLC**

Robert Rosenbluth and Paul Lubock, each of which are current members of our board of directors and are stockholders, are principals and co-founders of Inceptus Medical, LLC, or Inceptus. In addition, Brian Cox, a former member of our board of directors and current stockholder, is a principal and co-founder of Inceptus.

In August 2019, we entered into a sublicense agreement with Inceptus, pursuant to which Inceptus granted us a sublicense to its licensed intellectual property rights related to tubular braiding technology; such rights were originally granted to Inceptus pursuant to an intellectual property license agreement with Drexel University, or Drexel License. See “Business—Intellectual Property—Sublicense Agreement with Inceptus Medical, LLC.”

In March 2018, we entered into an amended and restated technology agreement with Inceptus, pursuant to which Inceptus granted us a license to certain of its intellectual property related to braiding and aspiration controller technologies. See “Business—Intellectual Property—Amended and Restated Technology Agreement with Inceptus Medical, LLC.”

In March 2018, we also entered into an amendment to a license and assignment agreement, dated October 15, 2014, between us and Inceptus, pursuant to which the parties agreed to collaborate in the use and sharing of certain specified equipment.

In February 2018, we entered into an amended and restated services agreement with Inceptus, pursuant to which Inceptus agreed to conduct certain research and development services on our behalf. Any such services are to be set out and delivered pursuant to specified work plans and the terms of and conditions of the amended and restated services agreement. Pursuant to the amended and restated services agreement, we are obligated to pay amounts and fees to Inceptus set forth in any specified work plan, reimburse reasonable expenses of Inceptus incurred in connection with any specified work plan and pay all taxes, including interest and penalties, arising in connection with any specified work plan. The ownership and control of any intellectual property resulting from any specified work plan is determined in accordance with the amended and restated technology agreement. Inceptus has the right to terminate the amended and restated services agreement upon a change of control, upon our public offering, or upon written notice to us. Pursuant to an amended and restated work order under this amended and restated services agreement, Inceptus has agreed to provide a number of product development, manufacturing development, intellectual property preparation and prosecution, strategic planning, board participation and other services. Pursuant to this work order, from January 1, 2017 through December 31, 2019 we have paid Dr. Rosenbluth, Mr. Lubock and Mr. Cox a total of \$213,541, \$203,800 and \$244,533, respectively, for their participation on our board.

In connection with the amended and restated services agreement with Inceptus, we paid Inceptus a non-interest-bearing retainer to be applied to future amounts owed under the agreement. As of December 31, 2018, the retainer was \$275,553. In December 2019, Inceptus repaid the outstanding amount of the retainer in full.

**Executive Loan**

In March 2016 and April 2017, we loaned Mr. Hoffman, our Chief Executive Officer and President and a member of our board of directors, \$95,229 and \$173,419, respectively, in connection with his exercise of options to purchase shares of our common stock. These loans were evidenced by secured full-recourse promissory notes, which accrued interest at the rate of 2.00% per year and were secured by a first-priority security interest in the exercised shares. In November 2019, Mr. Hoffman repaid the March 2016 and April 2017 secured full-recourse promissory notes in full.

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**Director and Officer Indemnification and Insurance**

We have entered into indemnification agreements with each of our directors and executive officers and have purchased directors' and officers' liability insurance. See "Description of Capital Stock—Limitations on Liability and Indemnification Matters."

**Stock Option Grants to Executive Officers and Directors**

We have granted options to our executive officers and certain of our directors as more fully described in the section entitled "Executive and Director Compensation."

**Reserved Share Program**

At our request, the underwriters have reserved for sale, at the initial public offering price, up to % of the shares offered by this prospectus for sale to some of our directors, officers, employees, distributors, dealers, business associates and related persons. See "Underwriting—Reserved Shares."

**Policies and Procedures for Related Party Transactions**

Our board of directors has adopted a written related person transaction policy, to be effective upon the closing of this offering, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds \$120,000 in any fiscal year and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

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**PRINCIPAL STOCKHOLDERS**

The following table sets forth information with respect to the beneficial ownership of our common stock, as of December 31, 2019, and as adjusted to reflect our sale of common stock in this offering, by:

- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, a person is deemed to be a “beneficial” owner of a security if that person has or shares voting power or investment power, which includes the power to dispose of or to direct the disposition of such security. Except as indicated in the footnotes below, we believe, based on the information furnished to us, that the individuals and entities named in the table below have sole voting and investment power with respect to all shares of common stock beneficially owned by them, subject to any applicable community property laws.

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Percentage ownership of our common stock before this offering is based on 55,248,527 shares of our common stock outstanding as of December 31, 2019, after giving effect to the automatic conversion of 45,651,216 shares of our convertible preferred stock into shares of our common stock immediately prior to the closing of this offering. Percentage ownership of our common stock after this offering is based on \_\_\_\_\_ shares of our common stock outstanding as of December 31, 2019, after giving effect to the automatic conversion of 45,651,216 shares of our convertible preferred stock and our issuance of shares of our common stock in this offering. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights held by such person that are currently exercisable or that will become exercisable within 60 days of December 31, 2019 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. The table below excludes any shares of our common stock that may be purchased in this offering pursuant to the reserved share program. See “Underwriting—Reserved Shares.” Unless noted otherwise, the address of all listed stockholders is 9 Parker, Suite 100, Irvine, CA 92618.

<u>Name of Beneficial Owner</u>	<u>Total Shares Beneficially Owned</u>	<u>Percentage of Shares Beneficially Owned</u>	
		<u>Before the Offering</u>	<u>After the Offering</u>
<b>5% Stockholders</b>			
Entities affiliated with U.S. Venture Partners (1)	11,031,045	20.0%	
Coöperatieve Gilde Healthcare IV U.A. (2)	10,851,872	19.6%	
Entities affiliated with Versant Venture Capital (3)	8,204,642	14.9%	
Milder Community Property Trust (4)	7,188,004	13.0%	
CVF, LLC(5)	4,914,700	8.9%	
<b>Named Executive Officers and Directors</b>			
William Hoffman (6)	2,272,260	4.1%	
Mitchell Hill	—	*	
Andrew Hykes (7)	607,492	1.1%	
Robert Rosenbluth (8)	2,477,868	4.5%	
Jonathan Root (1)	11,031,045	20.0%	
Geoff Pardo (2)	10,851,872	19.6%	
Kirk Nielsen (3)	8,204,642	14.9%	
Donald Milder (4)	7,188,004	13.0%	
Paul Lubock (9)	1,998,900	3.6%	
Cynthia Lucchese	—	*	
Catherine Szyman	—	*	
<b>All Executive Officers and Directors as a Group (12 individuals) (10)</b>	<b>44,666,900</b>	<b>80.8%</b>	

\* Less than 1%.

- (1) Consists of (i) 10,689,083 shares of common stock held of record by U.S. Venture Partners X, L.P. and (ii) 341,962 shares of common stock held of record by USVP X Affiliates, L.P. Presidio Management Group X, L.L.C., or PMG X, is the general partner of each of U.S. Venture Partners X, L.P. and USVP X Affiliates, L.P., and has voting and dispositive power over the shares held by each of U.S. Venture Partners X, L.P. and USVP X Affiliates, L.P. Jonathan Root, a member of our board of directors, Irwin Federman, Steven Krausz, Richard Lewis, Paul Matteucci, and Casey M. Tansey are the managing members of PMG X and, as a result, may be deemed to share voting and dispositive power over the shares held by each of U.S. Venture Partners X, L.P. and USVP X Affiliates, L.P. Each of the managing members of PMG X disclaims beneficial ownership of such holdings. The mailing address for each of these entities is 1460 El Camino Real, Suite 100, Menlo Park, California 94025.
- (2) Geoff Pardo, a member of our board of directors, is a partner of Coöperatieve Gilde Healthcare IV U.A. and, as a result, may be deemed to have shared voting and dispositive power over the shares held by Coöperatieve Gilde Healthcare IV U.A. The mailing address of Coöperatieve Gilde Healthcare IV U.A. Newtonlaan 91 – 3508 AB Utrecht, The Netherlands, c/o Gilde Healthcare Partners.
- (3) Consists of (i) 8,153,280 shares of common stock held of record by Versant Venture Capital IV, L.P. and (ii) 51,362 shares of common stock held of record by Versant Side Fund IV, L.P. Versant Ventures IV, LLC, is the general partner of each of Versant Venture

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Capital IV, L.P. and Versant Side Fund IV, L.P. Kirk Nielsen, a member of our board of directors, Thomas Woiwode, Bradley Bolzon, Robin Praeger, William Link, Samuel Colella, Rebecca Robertson, Brian Atwood, Ross Jaffe and Charles Warden are the managing members of Versant Ventures IV, LLC and, as a result, may be deemed to share voting and dispositive power over the shares held by each of Versant Venture Capital IV, L.P. and Versant Side Fund IV, L.P. The mailing address for each of these entities is One Sansome, Suite 3630, San Francisco, CA 94104.

- (4) Consists of 7,188,004 shares of common stock held of record by Milder Community Property Trust DTD 11/7/91, amended and restated 11/20/98, amended 3/20/01 for the benefit of Donald B. Milder, or the Milder Community Property Trust. Donald Milder, a member of our board of directors, is a trustee and beneficiary of the Milder Community Property Trust.
- (5) Richard H. Robb, manager of CVF, LLC, exercises voting and investment power with respect to the shares held by CVF, LLC. The address of CVF, LLC is 222 N. LaSalle Street, Suite 2000, Chicago, IL 60601.
- (6) Includes 403,260 shares of common stock underlying options exercisable within 60 days of December 31, 2019.
- (7) Includes 157,755 shares of common stock underlying options exercisable within 60 days of December 31, 2019.
- (8) Consists of (i) 2,209,085 shares of common stock held of record by Robert Rosenbluth Family Trust, (ii) 193,783 shares of common stock held of record by Martial QTIP Trust under Robert Rosenbluth Family Trust and (iii) 75,000 shares of common stock held directly.
- (9) Consists of (i) 1,517,638 shares of common stock held of record by Paul Lubock Living Trust U/A DTD 02/04/2009 and (ii) 481,262 shares of common stock held directly.
- (10) Includes 561,015 shares of common stock underlying options exercisable within 60 days of December 31, 2019.

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**DESCRIPTION OF CAPITAL STOCK**

The following description of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the amended and restated bylaws that will be in effect upon the closing of this offering. Copies of these documents will be filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of our common stock and preferred stock reflect changes to our capital structure that will occur upon the closing of this offering.

**General**

Upon the closing of this offering, our authorized capital stock will consist of \_\_\_\_\_ shares, all with a par value of \$0.001 per share, of which:

- \_\_\_\_\_ shares are designated as common stock; and
- \_\_\_\_\_ shares are designated as preferred stock.

**Common Stock**

As of December 31, 2019, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 45,651,216 shares of our common stock immediately prior to the closing of this offering, we had outstanding 55,248,527 shares of common stock held by 69 stockholders of record.

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that we may designate and issue in the future.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. Our outstanding shares of common stock are, and the shares offered by us in this offering will be, when issued and paid for, validly issued, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

**Preferred Stock**

As of December 31, 2019, there were 45,651,216 shares of our convertible preferred stock outstanding. Immediately prior to the closing of this offering, all outstanding shares of our convertible preferred stock will convert into 45,651,216 shares of our common stock.

Under the terms of our amended and restated certificate of incorporation that will become effective immediately prior to the closing of this offering, our board of directors is authorized to direct us to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

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The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from seeking to acquire, a majority of our outstanding voting stock. Upon the closing of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

**Common Stock Warrant**

As of December 31, 2019, we had a warrant to purchase an aggregate of 39,713 shares of our common stock, with an exercise price of \$0.10 per share. Unless exercised earlier, the warrant will expire in February 2025. The warrant contains provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the warrant in the event of certain stock dividends, stock splits, reorganizations, reclassifications and consolidations. The warrant has a net exercise provision under which its holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of the shares at the time of exercise of the warrant after deduction of the aggregate exercise price.

**Preferred Stock Warrants**

As of December 31, 2019, we had warrants to purchase an aggregate of 366,410 shares of our convertible preferred stock outstanding with a weighted average exercise price of \$1.12 per share, including warrants to purchase an aggregate of 110,000 shares of our Series A convertible preferred stock and 256,410 shares of our Series B convertible preferred stock. Immediately prior to the closing of this offering, these warrants will convert into warrants to purchase 366,410 shares of our common stock with a weighted average exercise price of \$1.12 per share. Unless exercised earlier, the warrant to purchase 110,000 shares will expire in December 2021 and the warrant to purchase 256,410 shares will expire in April 2026.

The warrants contain provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the applicable warrant in the event of certain stock dividends, stock splits, reorganizations, reclassifications and consolidations. The warrants have a net exercise provision under which its holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of the shares at the time of exercise of the warrant after deduction of the aggregate exercise price.

**Options**

As of December 31, 2019, 5,829,739 options were outstanding under our 2011 Equity Incentive Plan, of which 1,488,440 were vested as of that date.

**RSUs**

As of December 31, 2019, we had 4,094,552 shares of our common stock subject to RSUs under our 2011 Equity Incentive Plan. Our outstanding RSUs vest upon the satisfaction of a time-based condition and a service-based condition and the completion of an initial public offering or sale event. The time-based condition is satisfied on the fourth anniversary of the date of grant of the RSU, subject to continued service through the vesting date. This offering will satisfy the requirement for an initial public offering or sale event. On the vesting date of the RSUs, the recipient is entitled to receive one share of common stock for every RSU that vests.

**Registration Rights**

The second amended and restated investors' rights agreement grants the parties thereto certain registration rights in respect of the "registrable securities" held by them, which securities include (1) the shares of

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our common stock issued upon the conversion of shares of our convertible preferred stock or (2) any common stock issued as a dividend or other distribution to or in exchange for or in replacement of the shares referenced in clause (1). The registration of shares of our common stock pursuant to the exercise of these registration rights would enable the holders thereof to sell such shares without restriction under the Securities Act when the applicable registration statement is declared effective. Under the second amended and restated investors' rights agreement, we will pay expenses relating to such registrations, including up to \$35,000 of the reasonable fees of one special counsel for the participating holders, and the holders will pay all underwriting discounts and commissions relating to the sale of their shares. The second amended and restated investors' rights agreement also includes customary indemnification and procedural terms.

Holders of 53,047,866 of our outstanding shares of common and preferred stock, which represents approximately 96% of our outstanding shares, are entitled to registration rights pursuant to the second amended and restated investors' rights agreement. These registration rights will expire on the fifth anniversary of this offering.

***Demand Registration Rights***

The second amended and restated investors' rights agreement provides that, at any time beginning on the 180<sup>th</sup> day after the closing of this offering, holders of not less than two-thirds of the registrable securities then outstanding may, on not more than two occasions, request that we prepare, file and maintain a registration statement to register their registrable securities if the aggregate offering price to the public would exceed \$10 million. Following such a request, we will as soon as practicable, but in any event no more than 90 days, use our best efforts to effect such registration. Once we are eligible to use a registration statement on Form S-3, the stockholders party to the second amended and restated investors' rights agreement may request that we prepare, file and maintain a registration statement on Form S-3 covering the sale of their registrable securities, but only if the anticipated offering price would exceed \$1 million.

***Piggyback Registration Rights***

In the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the stockholders party to the second amended and restated investors' rights agreement will be entitled to certain "piggyback" registration rights allowing them to include their registrable securities in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act other than with respect to (1) a demand registration, (2) a registration relating solely to the employee benefits plans, (3) a registration relating to the offer and sale of debt securities, (4) a registration relating to a corporate reorganization transaction on Form S-4 or (5) a registration on any registration form that does not permit secondary sales, the stockholders party to the second amended and restated investors' rights agreement will be entitled to notice of the registration and will have the right to include their registrable securities in the registration subject to certain limitations.

***Anti-Takeover Provisions***

***Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws***

Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the voting power of our shares of common stock outstanding will be able to elect all of our directors. Our amended and restated certificate of incorporation and amended and restated bylaws, which will be in effect upon the closing of this offering, will provide that all stockholder actions must be effected at a duly called meeting of stockholders and not by consent in writing. A special meeting of stockholders may be called only by a majority of our board of directors, the chair of our board of directors, or our chief executive officer.

Our amended and restated certificate of incorporation will further provide that, immediately after this offering, the affirmative vote of holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power

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of all of the then outstanding shares of voting stock, voting as a single class, will be required to amend certain provisions of our certificate of incorporation, including provisions relating to the size of the board, removal of directors, special meetings, actions by written consent and cumulative voting. The affirmative vote of holders of at least sixty-six and two-thirds percent (66-2/3%) of the voting power of all of the then outstanding shares of voting stock, voting as a single class, will be required to amend or repeal our bylaws, although our bylaws may be amended by a simple majority vote of our board of directors.

Our amended and restated certificate of incorporation will further provide that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms, and will give our board of directors 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.

Finally, our amended and restated certificate of incorporation will provide 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: (i) any derivative action or proceeding brought on behalf of us; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees or agents to us or our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our amended and restated certificate of incorporation or amended and restated bylaws; or (iv) any action asserting a claim against us governed by the internal affairs doctrine; 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 will also provide 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, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. 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. 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 action, a court could find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in such action.

The foregoing provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of our Company by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change the control of our Company.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of our Company. These provisions are also designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy rights. However, these provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in control of our Company or our management. As a consequence, these provisions also may inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

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***Section 203 of the Delaware General Corporation Law***

We are subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon closing of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned by (1) persons who are directors and also officers and (2) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by our board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an “interested stockholder” as an entity or person who, together with the person’s affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

**Limitations on Liability and Indemnification Matters**

Our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to the closing of this offering, will provide that we will indemnify each of our directors and executive officers to the fullest extent permitted by the DGCL. We have entered into indemnification agreements with each of our directors and executive officers that may, in some cases, be broader than the specific indemnification provisions contained under Delaware law. Further, pursuant to our indemnification agreements and directors’ and officers’ liability insurance, our directors and executive officers are indemnified and insured against the cost of defense, settlement or payment of a judgment under certain

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circumstances. In addition, as permitted by Delaware law, our amended and restated certificate of incorporation will include provisions that eliminate the personal liability of our directors for monetary damages resulting from breaches of certain fiduciary duties as a director. The effect of this provision is to restrict our rights and the rights of our stockholders in derivative suits to recover monetary damages against a director for breach of fiduciary duties as a director.

These provisions may be held not to be enforceable for violations of the federal securities laws of the United States.

**Listing**

We intend to apply to list our common stock on the Nasdaq Global Market under the symbol “NARI.”

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is \_\_\_\_\_.

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**SHARES ELIGIBLE FOR FUTURE SALE**

Immediately prior to this offering, there was no public market for our common stock, and no predictions can be made about the effect, if any, that market sales of our common stock or the availability of such shares for sale will have on the market price prevailing from time to time. Nevertheless, future sales of our common stock in the public market, or the perception that such sales may occur, could adversely affect the market price of our common stock and could impair our ability to raise capital through future sales of our securities. See “Risk Factors—Risks Related to this Offering—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.” Furthermore, although we intend to apply to have our common stock listed on the Nasdaq Global Market, we cannot assure you that there will be an active public trading market for our common stock.

Upon the closing of this offering, based on the number of shares of our common stock outstanding as of December 31, 2019 and after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into shares of our common stock immediately prior to the closing of this offering, we will have an aggregate of \_\_\_\_\_ shares of our common stock outstanding (or \_\_\_\_\_ shares of our common stock if the underwriters exercise in full their option to purchase additional shares). Of these shares of our common stock, all of the \_\_\_\_\_ shares sold in this offering (or \_\_\_\_\_ shares if the underwriters exercise in full their option to purchase additional shares) will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our “affiliates,” as that term is defined in Rule 144 under the Securities Act, whose sales would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining \_\_\_\_\_ shares of our common stock will be “restricted securities,” as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. We expect that substantially all of these shares will be subject to the 180-day lock-up period under the lock-up agreements described below. Upon expiration of the lock-up period, we estimate that approximately \_\_\_\_\_ shares of our common stock will be available for sale in the public market, subject in some cases to applicable volume limitations under Rule 144.

**Lock-Up Agreements**

We and each of our directors and executive officers and holders of substantially all of our outstanding capital stock, who will collectively own \_\_\_\_\_ shares of our common stock upon the closing of this offering (based on our shares outstanding as of December 31, 2019 and after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into shares of our common stock immediately prior to the closing of this offering), have agreed, subject to certain exceptions, not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of BofA Securities, Inc. and Morgan Stanley & Co. LLC.

Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above. For a further description of these lock-up agreements, please see “Underwriting.”

**Rule 144**

***Affiliate Resales of Restricted Securities***

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days

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before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell in “broker’s transactions” or certain “riskless principal transactions” or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately \_\_\_\_\_ shares of our common stock immediately after this offering (or \_\_\_\_\_ shares if the underwriters exercise their option to purchase additional shares in full); or
- the average weekly trading volume in shares of our common stock on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of \$50,000, the seller must file a notice on Form 144 with the Securities and Exchange Commission and Nasdaq concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

***Non-Affiliate Resales of Restricted Securities***

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

**Rule 701**

In general, under Rule 701, any of an issuer’s employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

The Securities and Exchange Commission has indicated that Rule 701 will apply to typical options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

**Equity Plans**

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of our common stock subject to outstanding options under our 2011 Equity Incentive Plan and shares of our common stock issued or issuable under our 2020 Incentive Plan. We expect to file the registration statement covering shares offered pursuant to our 2020 Incentive Plan shortly after the date of this prospectus, permitting the resale of such shares by nonaffiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144.

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**Registration Rights**

Upon the closing of this offering, the holders of \_\_\_\_\_ shares of our common stock (including shares of our common stock issuable upon the conversion of all outstanding shares of our convertible preferred stock immediately prior to the closing of this offering) or their transferees will be entitled to various rights with respect to the registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. See “Description of Capital Stock—Registration Rights” for additional information. Shares covered by a registration statement will be eligible for sale in the public market upon the expiration or release from the terms of the lock-up agreement.

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**MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS**

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder’s particular circumstances, including the impact of the alternative minimum tax or the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- “controlled foreign corporations,” “passive foreign investment companies,” and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans; and
- “qualified foreign pension funds” as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

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**THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT TAX OR LEGAL ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.**

**Definition of a Non-U.S. Holder**

For purposes of this discussion, a “Non-U.S. Holder” is any beneficial owner of our common stock that is neither a “U.S. person” nor an entity or arrangement treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more “United States persons” (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

**Distributions**

As described in the section entitled “Dividend Policy,” we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder’s adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under “—Sale or Other Taxable Disposition.”

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder of our common stock will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). If a Non-U.S. Holder holds the stock through a financial institution or other intermediary, the Non-U.S. Holder will be required to provide appropriate documentation to the intermediary, which then will be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the

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Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

**Sale or Other Taxable Disposition**

A Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

Gain described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty), which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period. Non-U.S. Holders are encouraged to consult their tax advisors regarding the possible consequences to them if we are, or were to become, a USRPHC.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

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**Information Reporting and Backup Withholding**

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to the Non-U.S. Holder, regardless of whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting, if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

**Additional Withholding Tax on Payments Made to Foreign Accounts**

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act, or FATCA) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, recently proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

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**UNDERWRITING**

BofA Securities, Inc. and Morgan Stanley & Co. LLC are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

<u>Underwriter</u>	<u>Number of Shares</u>
BofA Securities, Inc.	
Morgan Stanley & Co. LLC	
Canaccord Genuity LLC	
Wells Fargo Securities, LLC	
Total	

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

#### **Commissions and Discounts**

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$ \_\_\_\_\_ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discounts and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	<u>Per Share</u>	<u>Without Option</u>	<u>With Option</u>
Public offering price	\$	\$	\$
Underwriting discounts	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

The expenses of the offering, not including the underwriting discounts, are estimated at \$ \_\_\_\_\_ and are payable by us. We have also agreed to reimburse the underwriters for their expenses relating to clearance of this offering with the Financial Industry Regulatory Authority in an amount up to \$ \_\_\_\_\_.

**Confidential Treatment Requested by Inari Medical, Inc.  
Pursuant to 17 C.F.R. Section 200.83**

**Option to Purchase Additional Shares**

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to additional shares at the public offering price, less the underwriting discounts. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

**Reserved Shares**

At our request, the underwriters have reserved for sale, at the initial public offering price, up to % of the shares offered by this prospectus for sale to some of our directors, officers, employees, distributors, dealers, business associates and related persons. If these persons purchase reserved shares, this will reduce the number of shares available for sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus. We have agreed to reimburse the underwriters for certain fees and expenses in connection with this reserved share program, including the fees and disbursements of counsel to the underwriters, up to an amount not to exceed \$ .

**No Sales of Similar Securities**

We, our executive officers and directors and our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus without first obtaining the written consent of BofA Securities, Inc. and Morgan Stanley & Co. LLC. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly

- offer, pledge, sell or contract to sell any common stock,
- sell any option or contract to purchase any common stock,
- purchase any option or contract to sell any common stock,
- grant any option, right or warrant for the sale of any common stock,
- transfer or otherwise dispose of any common stock,
- request or demand that we file or make a confidential submission of a registration statement related to the common stock,
- enter into any swap or other agreement that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise, or
- publicly disclose the intention to do any of the foregoing.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock. It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition. BofA Securities, Inc. and Morgan Stanley & Co. LLC, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time with or without notice.

**Confidential Treatment Requested by Inari Medical, Inc.  
Pursuant to 17 C.F.R. Section 200.83**

**Nasdaq Global Market Listing**

We expect the shares to be approved for listing on the Nasdaq Global Market, subject to notice of issuance, under the symbol “NARI.”

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are:

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us,
- our financial information,
- the history of, and the prospects for, our company and the industry in which we compete,
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,
- the present state of our development, and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

**Price Stabilization, Short Positions and Penalty Bids**

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. “Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. “Naked” short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

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Pursuant to 17 C.F.R. Section 200.83**

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discounts received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on the Nasdaq Global Market, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

**Electronic Distribution**

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

**Other Relationships**

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

**Notice to Prospective Investors in the European Economic Area**

In relation to each Member State of the European Economic Area (each a "Member State"), no shares have been offered or will be offered pursuant to this offering to the public in that Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Member State or, where appropriate, approved in another Member State and notified to the competent authority in that Member State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Member State at any time under the following exemptions under the Prospectus Regulation:

- (a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

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Pursuant to 17 C.F.R. Section 200.83**

provided that no such offer of shares shall require us or any representative to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Member State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with us and the representatives that it is a qualified investor within the meaning of the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in a Relevant Member State to qualified investors, in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

We, the representatives and their respective affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgments and agreements.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares in any Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129 (as amended) and includes any relevant implementing measure in each Member State.

The above selling restriction is in addition to any other selling restrictions set out below.

**Notice to Prospective Investors in the United Kingdom**

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are “qualified investors” (as defined in the Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19 (5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or Order, and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”). This document must not be acted on or relied on in the United Kingdom by persons who are not relevant persons. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons.

**Notice to Prospective Investors in Switzerland**

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, us or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory

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Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

**Notice to Prospective Investors in the Dubai International Financial Centre**

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

**Notice to Prospective Investors in Australia**

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, or ASIC, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons, or Exempt Investors, who are “sophisticated investors” (within the meaning of section 708(8) of the Corporations Act), “professional investors” (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

**Notice to Prospective Investors in Hong Kong**

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are

**Confidential Treatment Requested by Inari Medical, Inc.  
Pursuant to 17 C.F.R. Section 200.83**

likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

**Notice to Prospective Investors in Japan**

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, “Japanese Person” shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

**Notice to Prospective Investors in Singapore**

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the shares were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or SFA) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor.

Securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries’ rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

- (a) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- (b) where no consideration is or will be given for the transfer;
- (c) where the transfer is by operation of law; or
- (d) as specified in Section 276(7) of the SFA.

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Pursuant to 17 C.F.R. Section 200.83**

**Notice to Prospective Investors in Canada**

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

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**LEGAL MATTERS**

The validity of the shares of our common stock offered hereby will be passed upon for us by Latham & Watkins LLP. Certain legal matters will be passed upon for the underwriters by Shearman & Sterling LLP, New York, New York.

**EXPERTS**

The financial statements as of and for the year ended December 31, 2018 included in this prospectus and in the registration statement have been so included in reliance on the report of BDO USA, LLP, an independent registered public accounting firm (the report on the financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern), appearing elsewhere herein and in the registration statement, given on the authority of said firm as experts in auditing and accounting.

**WHERE YOU CAN FIND MORE INFORMATION**

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the shares of common stock offered hereby, reference is made to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and in each instance, such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. You can read our SEC filings, including the registration statement, at the SEC's website which contains reports, proxy and information statements and other information regarding registrants, like us, that file electronically with the SEC. The address of the website is [www.sec.gov](http://www.sec.gov).

As a result of this offering, we will become subject to the information and reporting requirements of the Exchange Act and, in accordance with this law, will file periodic reports, proxy and information statements and other information with the SEC. These periodic reports, proxy and information statements and other information will be available for inspection at the website of the SEC referred to above. We also maintain a website at [www.inarimedical.com](http://www.inarimedical.com). Upon completion of this offering, you may access these materials free of charge as soon as reasonably practicable after they are filed electronically with, or furnished to, the SEC. The inclusion of our website address in this prospectus is an inactive textual reference only. The information contained on, or that can be accessed through, our website is not incorporated by reference into, and is not a part of, this prospectus or the registration statement of which this prospectus forms a part. Investors should not rely on any such information in deciding whether to purchase our common stock.

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**INARI MEDICAL, INC.  
INDEX TO FINANCIAL STATEMENTS**

**As of and  
for the Year Ended December 31, 2018**

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**Confidential Treatment Requested by Inari Medical, Inc.  
Pursuant to 17 C.F.R. Section 200.83**

**Report of Independent Registered Public Accounting Firm**

Shareholders and Board of Directors  
Inari Medical, Inc.  
Irvine, California

**Opinion on the Financial Statements**

We have audited the accompanying balance sheet of Inari Medical, Inc. (the “Company”) as of December 31, 2018, the related statement of operations, mezzanine equity and stockholders’ deficit, and cash flows for the year then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

**Going Concern Uncertainty**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Basis for Opinion**

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company’s auditor since 2019.

Costa Mesa, California  
December 19, 2019

**Confidential Treatment Requested by Inari Medical, Inc.  
Pursuant to 17 C.F.R. Section 200.83**

**INARI MEDICAL, INC.**

**BALANCE SHEET**

	<b>December 31, 2018</b>
<b>Assets</b>	
<b>Current assets</b>	
Cash and cash equivalents	\$ 21,833,743
Restricted cash	50,000
Accounts receivable	2,229,498
Inventories, net	1,093,335
Prepaid expenses and other current assets	757,860
Total current assets	25,964,436
Property and equipment, net	919,962
Deposits and other assets	17,083
<b>Total assets</b>	<b><u>\$ 26,901,481</u></b>
<b>Liabilities, Mezzanine Equity, and Stockholders' Deficit</b>	
<b>Current liabilities</b>	
Accounts payable	\$ 714,090
Payroll-related accruals	1,286,245
Accrued expenses and other current liabilities	127,515
Total current liabilities	2,127,850
Notes payable	9,836,410
Warrant liabilities	212,528
<b>Total liabilities</b>	<b><u>12,176,788</u></b>
<b>Commitments and Contingencies (Note 6)</b>	
<b>Mezzanine equity</b>	
Redeemable convertible preferred stock, \$0.001 par value, 46,017,626 shares authorized as of December 31, 2018, 45,651,216 shares issued and outstanding as of December 31, 2018; aggregate liquidation preference of \$54,414,999 as of December 31, 2018	54,170,233
<b>Stockholders' deficit</b>	
Common stock, \$0.001 par value, 60,000,000 shares authorized, 9,011,923 shares issued and outstanding as of December 31, 2018	9,012
Additional paid in capital	1,426,949
Subscription receivable	(757,975)
Accumulated deficit	(40,123,526)
<b>Total stockholders' deficit</b>	<b><u>(39,445,540)</u></b>
<b>Total liabilities, mezzanine equity and stockholders' deficit</b>	<b><u>\$ 26,901,481</u></b>

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

**Confidential Treatment Requested by Inari Medical, Inc.  
Pursuant to 17 C.F.R. Section 200.83**

**INARI MEDICAL, INC.**

**STATEMENT OF OPERATIONS**

	<b>Year Ended December 31, 2018</b>
Revenues	\$ 6,828,773
Cost of goods sold	1,280,488
Gross profit	5,548,285
Operating expenses	
Research and development	3,989,752
Selling, general and administrative	10,697,914
Total operating expenses	14,687,666
Loss from operations	(9,139,381)
Other income (expense)	
Interest income	92,075
Interest expense	(887,173)
Other expenses	(218,209)
Total other expenses, net	(1,013,307)
Net loss and comprehensive loss	\$ (10,152,688)
Net loss per share, basic and diluted	\$ (1.41)
Weighted average common shares used to compute net loss per share, basic and diluted	7,221,036

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

**Confidential Treatment Requested by Inari Medical, Inc.  
Pursuant to 17 C.F.R. Section 200.83**

**INARI MEDICAL, INC.**

**STATEMENT OF MEZZANINE EQUITY AND STOCKHOLDERS' DEFICIT**

	<b>Redeemable Convertible Preferred Stock</b>		<b>Common Stock</b>		<b>Subscription Receivable</b>	<b>Additional Paid In Capital</b>	<b>Accumulated Deficit</b>	<b>Total Stockholders' Deficit</b>
	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>	<b>Amount</b>				
<b>Balance, December 31, 2017</b>	24,722,606	\$ 27,251,389	7,819,016	\$ 7,819	\$ (500,877)	\$ 921,407	\$ (29,970,838)	\$ (29,542,489)
Issuance of Series C redeemable preferred stock at \$1.2901 per share for cash, net of offering costs of \$81,156	20,928,610	\$ 26,918,844	—	—	—	—	—	—
Options exercised for common stock	—	—	1,192,907	1,193	(245,101)	257,796	—	13,888
Interest earned on subscription receivable	—	—	—	—	(11,997)	—	—	(11,997)
Share based compensation expense	—	—	—	—	—	247,746	—	247,746
Net loss	—	—	—	—	—	—	(10,152,688)	(10,152,688)
<b>Balance, December 31, 2018</b>	<u>45,651,216</u>	<u>\$ 54,170,233</u>	<u>9,011,923</u>	<u>\$ 9,012</u>	<u>\$ (757,975)</u>	<u>\$ 1,426,949</u>	<u>\$ (40,123,526)</u>	<u>\$ (39,445,540)</u>

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

**Confidential Treatment Requested by Inari Medical, Inc.  
Pursuant to 17 C.F.R. Section 200.83**

**INARI MEDICAL, INC.**

**STATEMENT OF CASH FLOWS**

	<b>Year Ended December 31, 2018</b>
<b>Cash flows from operating activities</b>	
Net loss	\$ (10,152,688)
Adjustments to reconcile net loss to net cash used in operating activities:	
Depreciation	283,048
Amortization of deferred financing costs	106,023
Share based compensation expense	247,746
Amortization of fair value of warrants issued with debt	29,192
Loss on disposal of fixed assets	29,446
Loss on change in fair value of warrant liability	85,477
Changes in:	
Accounts receivable	(2,165,367)
Inventories	(558,037)
Prepaid expenses and other assets	40,874
Accounts payable	372,056
Payroll-related accruals, accrued liabilities and other liabilities	790,115
Net cash used in operating activities	(10,892,115)
<b>Cash flows from investing activities</b>	
Purchase of property and equipment	(752,700)
Net cash used in investing activities	(752,700)
<b>Cash flows from financing activities</b>	
Gross proceeds from issuance of redeemable convertible preferred stock	27,000,000
Preferred stock offering costs	(81,156)
Debt financing costs	(175,000)
Proceeds from exercise of stock options	13,888
Net cash provided by financing activities	26,757,732
<b>Net increase in cash</b>	15,112,917
<b>Cash, cash equivalents and restricted cash, beginning of year</b>	6,770,826
<b>Cash, cash equivalents and restricted cash, end of year</b>	<u>\$ 21,883,743</u>
<b>Supplemental disclosures of cash flow information</b>	
Cash paid for taxes	\$ 15,668
Cash paid for interest	\$ 747,222
<b>Noncash investing and financing</b>	
Write-off of fully-depreciated fixed assets	\$ 47,906
Promissory notes issued for exercises of stock options	\$ 245,101
Accrual of deferred interest obligation associated with debt	\$ 140,000

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

**Confidential Treatment Requested by Inari Medical, Inc.  
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**INARI MEDICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS**

**1. Description of Business and Basis of Presentation**

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 vascular thrombi and emboli. The Company received 510(k) clearance from the U.S. Food and Drug Administration (FDA) in February 2016 for its FlowTrier system, used to treat pulmonary emboli, and in February 2017 for its ClotTrier system, used for the treatment of deep vein thrombosis.

The accompanying financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

***Liquidity and Going Concern***

The Company has incurred significant net losses and negative cash flows from operations since inception and has an accumulated deficit of \$40,123,526 as of December 31, 2018. As of December 31, 2018, the Company has cash and cash equivalents of \$21,833,743. The Company has funded its operations through debt and equity financing and revenues from sales of its products.

Management's plans include increasing revenues through continued commercialization of current and future products, as well as continuing to seek external sources of liquidity. However, there can be no assurance that the Company will be successful in increasing revenues or that any additional financing will be available, either on acceptable terms or at all. These factors raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**2. Summary of Significant Accounting Policies**

***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 revenues 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.

***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. A compensating and restricted balance is held by the Company to secure corporate purchasing cards, the balance of which was \$50,000 as of December 31, 2018.

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**INARI MEDICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS**

***Accounts Receivable***

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. There was no allowance for doubtful accounts recorded and no accounts receivable write-offs recognized as of and for the year ended December 31, 2018.

***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 (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 statement of operations and comprehensive 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 accompany statement of operations.

***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 term loan 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 December 31, 2018.

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**INARI MEDICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS**

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 interest and other expense in the statements of operations. The carrying value of the warrants will continue to be adjusted until such time as these instruments are exercised, expire or convert into warrants to purchase shares of the Company's stock. At that time, the liabilities will be adjusted to fair value and reclassified to additional paid-in capital, a component of stockholders' deficit.

***Revenue Recognition***

Product sales of the FlowTrier and ClotTrier systems are made to hospitals in the United States utilizing the Company's direct sales force. Generally, the Company provides training to the hospital staff prior to the first purchase of product by the hospital, and this training can include several cases utilizing free of charge product. The cost of training products provided at no charge is included in cost of sales. The Company provides a 30-day right of return period.

The Company recognizes revenue under Accounting Standards Codification (ASC) 605, *Revenue Recognition*, when all the following criteria are met, which is generally when the goods are delivered to the customer:

- Appropriate evidence of a binding arrangement exists with the customer;
- The sales price is established with the customer;
- The shipment of the product has been received by the customer; and
- Collection of the corresponding receivable from the customer is reasonably assured at the time of sale.

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**INARI MEDICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS**

***Shipping Costs***

Shipping costs billed to customers are reported as a reduction of cost of goods sold, with the corresponding costs reported within costs of goods sold.

***Advertising Costs***

Advertising costs are charged to operations as incurred. Advertising costs were \$98,799 for the year ended December 31, 2018. 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. 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 comprised of 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 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.

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**INARI MEDICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS**

***Comprehensive Income (Loss)***

The Company's net loss equaled comprehensive loss for the year ended December 31, 2018.

***Net Loss per Share of Common Stock***

Basic net loss per share is computed by dividing the net 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 loss per share is computed by dividing the net 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 loss per share calculation, redeemable convertible preferred stock and warrants, and common stock options are considered to be potentially dilutive securities. Since the Company was in a loss position for the period presented, basic net loss per share is the same as diluted net loss per share as the inclusion of all potential dilutive common shares would have been anti-dilutive.

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.

***Recently Adopted Accounting Pronouncements***

In July 2016, the FASB issued ASC 2016-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*. Topic 330 currently requires an entity to measure inventory at the lower of cost or market, where market could be replacement cost, net realizable value, or net realizable value less an approximately normal profit margin. This ASU limits the scope to inventory that is measured using first-in, first-out (FIFO) or average cost and requires inventory be measured at the lower of cost or net realizable value. The Company adopted this guidance as of January 1, 2018. Adoption of this guidance did not have a material impact on the Company's financial statements.

***Recent Accounting Pronouncements***

The Company will adopt ASC 606, *Revenue from Contracts with Customers*, effective January 1, 2019 using the modified retrospective method. Results for reporting periods beginning after January 1, 2019 will be presented under ASC 606, while prior period amounts will not be adjusted and continue to be reported in accordance with our historic accounting under ASC 605. ASC 606 supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of the new standard is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASC 606 defines a five-step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP. The Company has substantially completed its evaluation of the adoption of this ASU and believes it will not have a material impact on the amount or timing of revenue on its financial statements.

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**NOTES TO FINANCIAL STATEMENTS**

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. This guidance is effective for annual periods beginning after December 15, 2019, with early adoption permitted. The guidance should be applied to new awards granted after the date of adoption. Management is evaluating the impact that adopting this guidance will have on the financial statements.

In February 2017, the FASB issued ASU 2017-02, *Leases*, 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. The ASU 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 guidance will be effective for the Company in 2021 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.

### 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:

	<b>December 31, 2018</b>			<b>Total</b>
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	
<b>Liabilities</b>				
Convertible preferred stock warrant liability	\$ —	\$ —	\$212,528	\$212,528
<b>Total liabilities</b>	<u>\$ —</u>	<u>\$ —</u>	<u>\$212,528</u>	<u>\$212,528</u>

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

	<b>Year Ended December 31, 2018</b>
Beginning balance	\$ 127,051
Change in fair value of warrant liability	85,477
Ending balance	<u>\$ 212,528</u>

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

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**INARI MEDICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS**

#### 4. Inventories, net

Inventories are net of reserves totaling \$180,388 as of December 31, 2018, and consist of the following:

	<u>December 31, 2018</u>
Raw materials	\$ 365,577
Work in process	196,747
Finished goods	531,011
	<u>\$ 1,093,335</u>

#### 5. Property and Equipment

Property and equipment consist of the following:

	<u>December 31, 2018</u>
Manufacturing equipment	\$ 970,626
Leasehold improvements	399,148
Computer software	292,655
Furniture and fixtures	100,539
Computer hardware	165,919
Assets in progress	51,946
	<u>1,980,833</u>
Accumulated depreciation	<u>(1,060,871)</u>
	<u>\$ 919,962</u>

Depreciation expense of \$208,278 was included in operating expenses and \$74,770 was included in cost of goods sold for the year ended December 31, 2018. A loss on retirement of assets no longer in service of \$29,446 was included in operating expenses for the year ended December 31, 2018.

#### 6. Commitments and Contingencies

##### *Operating Leases*

The Company leases its manufacturing and office facility under a lease agreement beginning on August 27, 2014. In October 2017, the Company amended this lease agreement to extend the term until December 2020 and lease an adjacent suite starting in January 2018. Rent expense under the lease agreement for the year ended December 31, 2018 was \$202,501. The lease, as amended, provides for escalations and expires in December 2020. In March 2019, a new lease was executed. See Note 17 for more details. Future minimum commitments under the lease agreement are as follows:

<u>Years ending December 31,</u>	<u>Amount</u>
2019	\$216,447
2020	224,399
	<u>\$440,846</u>

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**NOTES TO FINANCIAL STATEMENTS**

***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 revenues are derived from the sale of catheter-based therapeutic devices in the United States. For the year ended December 31, 2018, 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 December 31, 2018.

No vendor accounted for more than 10% of the Company's purchases for the year ended December 31, 2018. Three vendors each made up 13% to 14% of accounts payable as of December 31, 2018.

**8. Purchased Development Services, Related Party**

Certain shareholders of the Company are shareholders of Inceptus Medical, Inc. (Inceptus). Beginning in September 2011, the Company engaged Inceptus to develop the technology that has led to the Company's products, the FlowTriever and the ClotTriever systems. Inceptus charges the Company monthly for the cost of its employees engaged in development activities for the Company. 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 braiding and braiding devices.

Included in prepaid expenses and other current assets is a non-interest-bearing retainer paid by the Company to Inceptus of \$275,553 as of December 31, 2018. The retainer will be applied to amounts owed by the Company to Inceptus at a time mutually agreed to by both parties. For the year ended December 31, 2018, the Company incurred development expenses with Inceptus of \$16,436 included in research and development expense. The Company did not make any payments to Inceptus during the year ended December 31, 2018 (See Note 17).

**9. Debt**

The Company had the following outstanding debt, net deferred financing costs and discounts, as of December 31, 2018:

	<u>Amount</u>
Term loan	\$ 10,000,000
Final payment fee	140,000
Total notes payables	<u>10,140,000</u>
Unamortized discount and deferred financing costs	(303,590)
Notes payable	<u>\$ 9,836,410</u>

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**INARI MEDICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS**

**Term Loan**

In April 2016, the Company entered into a term loan agreement with East West Bank (EWB Loan). The EWB Loan was available in two tranches of \$5 million each, both of which have been drawn down by the Company. The original term was 48 months and interest were payable monthly at the Prime Rate plus 2.50%. Principal repayment was to begin on April 1, 2018. A facility fee of \$100,000 was paid in April 2017 and a 1.5% final payment fee was payable at maturity. The EWB Loan was secured by substantially all the assets of the Company. The EWB Loan called for Series B Preferred Stock warrants to be issued in the amount of \$300,000 with a strike price of \$1.17 per share. The warrants expire in ten years. The fair value of the warrants of \$158,167 was determined using the Black Scholes model at the time of their issuance and was recorded as a debt discount, amortized to interest expense over the life of the loan.

In March 2018, The Company refinanced its EWB Loan into a new term loan (the "Term Loan") with East West Bank. The outstanding principal balance of the Term Loan remained unchanged at \$10 million, however, the maturity date was extended to March 2022 and the interest only period was extended an additional 24 months to March 2020. The Term Loan provides for two additional six-month interest only periods beyond the initial interest only period, earned based on the achievement of certain revenue milestones, for a total potential interest only period of 36 months. The total loan term is 48 months, with principal repayable monthly when the interest only period ends. Interest is payable monthly at the Prime Rate plus 2.50% (8.00% as of December 31, 2018). In conjunction with the refinance, the Company paid a facility fee of \$100,000 and a 1.4% final payment fee is payable at maturity. The Company also paid East West Bank half of the original 1.5% final payment fee due under the EWB Loan or \$75,000. The remaining half of the original final payment due under the EWB Loan was forgiven by East West Bank. The Term Loan is secured by substantially all the assets of the Company, including intellectual property under certain conditions, and subject to certain reporting and financial covenants. As of December 31, 2018, the Company was in compliance with or received waivers for all debt covenants.

The Company accounted for the refinance of the EWB Loan to the Term Loan as a modification of debt. Accordingly, no gains or losses were recorded on the refinance and the Company capitalized additional debt finance costs of \$165,000 and expensed \$132,731 of fees paid by the Company to third parties (see Note 17).

Maturities of the Term Loan, including the 1.4% final payment fee, are as follows:

<u>Years ending December 31,</u>	<u>Amount</u>
2019	\$ —
2020	3,750,000
2021	5,000,000
2022	1,390,000
Total future payments	10,140,000
Unamortized discount and deferred financing costs	(303,590)
Note payable	<u>\$ 9,836,410</u>

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**INARI MEDICAL, INC.**

**NOTES TO FINANCIAL STATEMENTS**

***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 and were as follows as of December 31, 2018:

	<u>Amount</u>
Deferred financing costs	\$320,555
Accumulated amortization	(68,690)
Unamortized deferred financing costs	251,865
Unamortized discount	51,725
Unamortized discount and deferred financing costs	<u>\$303,590</u>

**10. Redeemable Convertible Preferred Stock**

Redeemable convertible preferred stock (“convertible preferred stock”) consists of the following as of December 31, 2018:

	<u>Shares Authorized</u>	<u>Shares Issued and Outstanding</u>	<u>Net Carrying Value</u>	<u>Liquidation Value</u>
Series A	8,995,000	8,885,000	\$ 8,777,570	\$ 8,885,000
Series B	16,094,016	15,837,606	18,473,819	18,529,999
Series C	20,928,610	20,928,610	26,918,844	27,000,000
Total	<u>46,017,626</u>	<u>45,651,216</u>	<u>\$ 54,170,233</u>	<u>\$ 54,414,999</u>

In March 2018, the Company issued 20,928,610 shares of Series C Preferred Stock at a price of \$1.2901 per share for total gross proceeds of \$27 million.

The Company records convertible preferred stock at fair value on the dates of issuance, net of issuance costs. As of December 31, 2018, 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 are not within the Company’s control and in the event of certain “liquidation events” that are 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, 2018, the Company has 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. Subsequent adjustments to increase or decrease the carrying values to the ultimate liquidation values will be made if and when it becomes probable that such a liquidation event will occur.

***Voting Rights***

Each share of convertible preferred stock has a number of votes equal to the number of shares of common stock into which it is convertible. The holders of the Series A preferred stock, voting as a separate class, have the right to elect two directors to the Company’s board of directors (the “Board”) so long as at least 500,000 shares of Series A preferred stock are outstanding. The holders of the Series B, voting as separate a class, have the right to elect one director to the Company’s Board, so long as at least 500,000 shares of Series B preferred stock are outstanding. The holders of the Series C, voting as separate a class, have the right to elect one director

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**NOTES TO FINANCIAL STATEMENTS**

to the Company's Board, so long as at least 500,000 shares of Series C preferred stock are outstanding. The holders of the common stock, voting as a separate class, have the right to elect three members to the Board. Any other members of the Company's Board shall be elected by both (i) the holders of convertible preferred stock, voting as a separate class and on an as-converted basis, and (ii) the holders of common stock, voting as a separate class.

***Dividend Rights***

The convertible preferred stockholders are entitled to receive dividends at an annual rate of \$0.08 per share of Series A, \$0.0936 per share of Series B, and \$0.1032 per share of Series C (each adjusted to reflect subsequent recapitalizations). Such dividends are payable out of funds legally available, are payable only when and if declared by the Company's Board and are noncumulative. No dividends may be paid on the common stock during any fiscal year unless any declared dividends on convertible preferred stock have been paid. After the payment of these dividends, any dividends declared by the Company's Board out of funds legally available shall be shared equally among all outstanding shares on an as-converted basis. As of December 31, 2018, no dividends have been declared or paid to date.

***Liquidation Rights***

In the event of any liquidation, dissolution or winding-up of the Company, the liquidation preference is first to Series C preferred stock holders, the amount of their original issue price of \$1.2901 per share, plus declared but unpaid dividends, next to Series B Preferred Stock holders and Series A Preferred Stock holders, *pari passu*, the amount of their respective original issue price of \$1.17 and \$1.00, plus declared but unpaid dividends. The preferred shareholders have a participation right of \$3.00 per share for the Series A and Series B Preferred Stock, and \$3.8703 per share for the Series C Preferred Stock. The preferred shareholders are entitled to the greater of this participation right or the proceeds distributed *pro rata* as if the preferred stock had converted to common stock at the inception of any liquidation payouts.

***Optional Conversion Rights***

Each share of Series A, Series B and Series C convertible preferred stock is convertible at the option of the holder into the number of shares of common stock determined by dividing the original issue price by the applicable conversion price. The original issue price per share and initial conversion price per share is \$1.00 for Series A, \$1.17 for Series B and \$1.2901 for Series C convertible preferred stock. The conversion price per share for the convertible preferred stock shall be adjusted for certain recapitalizations, splits, combinations, common stock dividends or as set forth in the Company's amended and restated certificate of incorporation. At December 31, 2018, none of the preferred stock has been converted to common stock.

***Automatic Conversion Rights***

Each share of convertible preferred stock shall automatically be converted into shares of common stock at the then effective conversion rate for such share upon the earlier of (i) immediately prior to the closing of a firm commitment underwritten initial public offering pursuant to an effective registration statement filed under the Securities Act of 1933, as amended (the "Securities Act"), covering the offer and sale of the Company's common stock, provided that the offering price per share is not less than \$3.8703 (as adjusted for recapitalizations) and the aggregate gross proceeds to the Company are not less than \$40.0 million, or (ii) upon the receipt by the Company of a written request for such conversion from a) with respect to the Series C preferred stock, a majority of the holders and b) with respect to the Series A and Series B preferred stock, at least

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**NOTES TO FINANCIAL STATEMENTS**

two third of the holders voting as a single class, or, if later, the effective date for conversion specified in such requests. The conversion prices and rates for each series of convertible preferred stock are the same in the event of an automatic conversion as they would be in the event of an optional conversion.

***Redemption Rights***

The holders of at least two-thirds of the then outstanding shares of Series A convertible preferred stock, Series B convertible preferred stock, and Series C convertible preferred stock (voting together as a single class and on an as-converted basis) may request, in writing, and any time after five years from the date of first issuance of the Series C preferred stock (i.e., five years from March 28, 2018), the redemption of all outstanding shares of convertible preferred stock. The Company shall, upon such written request, redeem all outstanding shares in three equal annual installments beginning on the date specified in the redemption request, which date may not be less than 90 days after the Company's receipt of such request. The redemption price shall be the original issue price of the convertible preferred stock plus an amount for all declared and unpaid dividends thereon.

**11. Stockholder's Deficit**

***Common Authorized Stock***

In March 2018, the Company's authorized capital was amended to issue 106,017,626 shares of stock, consisting of 60,000,000 shares of common stock, par value \$0.001 per share, and 46,017,626 shares of Preferred Stock, par value \$0.001 per share, 8,995,000 of which are designated Series A Preferred Stock, 16,094,016 of which are designated Series B Preferred Stock and 20,928,610 of which are designated Series C Preferred Stock.

***Warrants***

The Company has issued common stock warrants to a placement agent in connection with equity fundraising and redeemable convertible preferred stock warrants to banks in connection with debt.

Warrants issued and outstanding as of December 31, 2018:

	<u>Number of warrants</u>	<u>Warrants Outstanding Exercise Price</u>	<u>Expiration</u>
Common stock warrants	39,713	\$ 0.10	10/19/2025
Series A redeemable convertible preferred stock warrants	110,000	\$ 1.00	12/10/2021
Series B redeemable convertible preferred stock warrants	256,410	\$ 1.17	4/28/2026 - 3/30/2027
Total redeemable convertible preferred stock warrants	366,410		
Total outstanding warrants	<u>406,123</u>		

The Series A and Series B redeemable convertible preferred stock warrants allow the holders to obtain shares of redeemable convertible preferred stock that contain a liquidation preference. Because this liquidation preference may be payable in cash upon a change in control of the Company or upon exercise of redemption rights and because such a transaction is considered to be outside of the control of the Company, these warrants have been classified as liabilities on the accompanying balance sheets and are presented at their estimated fair values at each reporting date.

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The fair value of the redeemable convertible preferred stock warrants was determined using the Black Scholes option pricing model with the following assumptions:

	December 31, 2018	
	Series A	Series B
Expected volatility	63.20%	60.60%
Preferred stock fair value (per share)	\$ 1.01	\$ 1.09
Dividend yield	—	—
Risk free interest rates	2.46%	2.59%
Expected remaining term in years	2.95	7.33 - 8.25

### 12. Subscription Receivable

As of December 31, 2018, the Company issued secured full recourse promissory notes with outstanding principal balances totaling \$734,578 to certain employees to finance their exercise of common stock options. The notes bear interest at 2% per year. Principal and interest are payable at the earlier of seven years from the issuance date, at the time of the employee's termination of service or at the time the Company sells its shares. These notes are accounted for as recourse notes, resulting in a subscription receivable being recorded as a reduction of stockholders' equity at the time of issuance of the common stock and exercise of the options. Recourse note holders early exercised unvested options. A restricted stock purchase agreement was entered into concurrently with the recourse note agreement to allow the Company to repurchase common stock pertaining to any unvested shares at the time employment is terminated for any reason. The Company's repurchase right expires within 90 days of the employee's termination date. The recourse notes have all been subsequently repaid in full. For additional information see Note 17—*Subsequent Events*.

### 13. Equity Incentive Plan

In 2011, the Company adopted the 2011 Equity Incentive Plan (the 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. Awards granted under the Plan have a term of 10 years and generally vest over a four-year period with a straight-line vesting and a 25% one-year cliff. In March 2018, the Company's Board authorized the expansion of the Plan by 3,400,000 shares, increasing the authorized shares of the Company's common stock to 9,130,000 as reserved for issuance under the Plan, of which 778,737 were available for issuance as of December 31, 2018.

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A summary of stock option activity for the year ended December 31, 2018 is as follows:

	Number of Awards	Weighted Average Exercise Price	Weighted Average Fair Value	Weighted Average Remaining Contractual Life (in years)
<b>Outstanding</b> , December 31, 2017	2,402,868	\$ 0.19	\$ 0.15	8.22
Granted	2,754,379	0.30	0.25	
Exercised	(1,192,907)	0.18	0.14	
Cancelled	(125,000)	0.22	0.18	
<b>Outstanding</b> , December 31, 2018	<u>3,839,340</u>	<u>\$ 0.23</u>	<u>\$ 0.19</u>	<u>8.04</u>
Vested and exercisable at December 31, 2018	<u>662,441</u>	<u>\$ 0.18</u>	<u>\$ 0.14</u>	<u>6.74</u>
Vested and expected to vest at December 31, 2018	<u>3,839,340</u>	<u>\$ 0.23</u>	<u>\$ 0.19</u>	<u>8.04</u>

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 year ended December 31, 2018:

	2018
Expected volatility	109.10%
Common stock fair value (per share)	\$ 0.30
Dividend yield	—
Risk free interest rates	2.84%
Expected remaining term in years	6.04

*Expected volatility*—Since the Company does not have sufficient stock price history to estimate the expected volatility of its shares, the expected volatility is calculated based on the average volatility for a peer group in the industry in which the Company does business.

*Dividend yield of zero*—The Company has not declared or paid dividends.

*Risk-free interest rates*—The Company applies the risk-free interest rate based on the US Treasury yield for the expected term of the option.

*Expected term*—The Company calculated the expected term as the average of the contractual term of the option and the vesting period for its employee stock options.

The Company uses its historical rate of cancelled or expired unvested shares since inception of the plan as the expected forfeiture rate.

Total compensation cost for share-based payment arrangements recognized in operating expenses for the year ended December 31, 2018 was \$247,746. Total compensation costs as of December 31, 2018 related to non-vested awards to be recognized in future periods was \$811,318, expected to be recognized over the weighted average period of 3.1 years.

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**14. Income Taxes**

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards.

The tax effects of significant items comprising the Company's deferred taxes as of are as follows:

	<u>Year Ended December 31, 2018</u>
<b>Deferred tax assets</b>	
Inventory	\$ 49,022
Fixed asset basis	—
Intangible asset basis	2,099,784
Accrued vacation	74,358
NOLs and capital loss carryforwards	8,193,534
Credit carryforwards	1,876,886
Other	23,229
<b>Total deferred tax assets</b>	<u>\$ 12,316,813</u>
<b>Deferred tax liabilities</b>	
Fixed asset basis	\$ (19,879)
Other liabilities	(4,448)
<b>Total deferred tax liabilities</b>	<u>\$ (24,327)</u>
Valuation allowance	<u>\$ (12,292,486)</u>
Net deferred taxes losses and tax credit carryforwards	<u>—</u>

ASC 740 requires that the tax benefit of net operating losses ("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 carryforward period. Management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits from operating loss carryforwards is currently not likely to be realized and, accordingly, has provided a valuation allowance. The valuation allowance increased by \$3,715,088 during 2018.

NOLs and tax credit carryforwards as of December 31, 2018 are as follows:

	<u>Amount</u>	<u>Expiration Years</u>
NOLs, federal	\$ 30,250,594	See Notes below
NOLs, state	29,871,415	See Notes below
Tax credits, federal	515,073	See Notes below
Tax credits, state	773,492	See Notes below

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The effective tax rate of the Company's provision (benefit) for income taxes differs from the federal statutory rate as follows:

	<u>Year Ended December 31, 2018</u>
Statutory rate	21.00%
Permanent adjustments	(1.57%)
General business credits	3.83%
Change in valuation allowance	(23.26%)
Total	<u>— %</u>

As a result of losses incurred in the past, the Company has NOLs carrying forward and are available for use in years in which the Company has taxable income (subject to expiration rules and to Internal Revenue Code of 1986, as amended ("IRC") §382). As of December 31, 2018, the Company has approximately \$30,194,788 and \$29,815,619 of Federal and California NOLs respectively, being carried over from 2011 to 2018. The NOLs begin expiring in the calendar year 2031 for Federal and California purposes. However, under the new Tax Cuts and Jobs Act, all NOLs incurred after December 31, 2017 are carried forward indefinitely for Federal tax purposes. California has not conformed to the indefinite carry forward period.

In the ordinary course of its business the Company incurs costs that, for tax purposes, are determined to be qualified research expenditures within the meaning of IRC §41(b)(1) and are therefore subject to the Increasing Research Activities credit under IRC §41. The R&D credit carryforward as of December 31, 2018 is \$858,455 and \$1,289,153 for Federal and California, respectively. The R&D credit carryforwards begin expiring in the calendar year 2031 for Federal purposes. However, for California purposes, the R&D credits carryforward indefinitely.

The usability of the R&D credits and NOLs is limited by the provisions of IRC §382 whereby the amount of pre-ownership change NOLs available for use in a post-ownership change tax year is limited to the value of the Company as of the date of the ownership change multiplied by the long term AFR rate. As of December 31, 2018, no testing has been performed.

On December 22, 2017, the Tax Cuts and Jobs Act was enacted into law. Among numerous provisions included in the new law was the reduction of the corporate federal income tax rate from 35% to 21% effective January 1, 2018. We continue to analyze and assess the impact of the Tax Cuts and Jobs Act and believe that its impact on the Company may not be fully known for some time. During the year ended December 31, 2018, we applied the newly enacted corporate federal income tax rate to the remeasurement of U.S. deferred tax assets and liabilities resulting in a tax benefit of approximately \$3.75 million. The decrease in net deferred tax liabilities was reasonably estimated and based on the tax rates at which they are expected to reverse in the future. The final impact may differ, possibly materially, due to, among other things, changes in interpretations, assumptions made by us, the issuance of Federal tax regulations and guidance, and actions we may take as a result of the Tax Cuts and Jobs Act.

Included in prepaid expenses and other current assets on the Company's balance sheet is \$340,165 at December 31, 2018 of research and development tax credit carryforwards that are expected to be utilized as a credit to offset payroll taxes. The remaining amount of research and development tax credit carryforwards are included in net deferred tax assets. State minimum franchise tax expense for the year ended December 31, 2018 were \$15,668 and are included in general and administrative expenses in the Company's statement of operations.

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**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 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 period presented due to their anti-dilutive effect:

	<b>Year Ended December 31, 2018</b>
Redeemable convertible preferred stock	45,651,216
Common stock options	3,839,340
Restricted stock subject to future vesting	1,149,968
Convertible preferred stock warrants	366,410
Common stock warrants	39,713
	<u>51,046,647</u>

**17. Subsequent Events**

Management has evaluated subsequent events through December 19, 2019, the date the financial statements were available to be issued.

***New Facility Lease***

In March 2019, the Company executed a five-year lease for a facility in Irvine, California, where all operations of the Company will be moved in September 2019. The lease contains two optional extension periods of five years each. In connection with the lease, the Company maintains a letter of credit for the benefit of the landlord in the amount of \$337,920, which is secured by cash. The future minimum lease payments over the initial five-year term total \$3,126,000. The Company took possession of this facility during September 2019.

Concurrently, a termination agreement was executed that releases the Company from its current facility lease obligation within 90 days of occupying the new facility.

***Amendment to Term Loan with East West Bank***

In June 2019, East West Bank agreed to extend the due date of the 2018 audited financial statements from May 30, 2019 to September 30, 2019.

***Equity Incentive Plan***

In March 2019, the Company's Board approved the grant of 4,094,552 Restricted Stock Units (RSUs) under the Plan described in note 13. Each RSU represents the right to be issued, upon satisfaction of applicable conditions, one share of Common Stock of the Company.

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The RSUs will vest in March 2023 provided the Company completes an initial public offering (IPO) by that time. Earlier vesting of the RSUs could occur in the event of a sale of the Company prior to March 2023. The number of RSUs earned will be based on: (a) if IPO, the trailing 3-month average stock trading value or (b) if sale, the valuation of the Company upon sale.

No RSUs will be earned in the event the Company completes neither an IPO nor a sale prior to March 2023. The RSUs expire on December 31, 2023.

In April 2019, the Company's Board authorized the expansion of the Plan described in note 13 by 2,252,000 shares. Together with the approval of the 4,094,552 RSU mentioned above, the number of shares of common stock reserved for issuance under the Plan was increased to 15,476,552.

To accommodate the increase in common stock reserved for issuance under the Plan, in July 2019, the Company's authorized capital was amended to 116,017,626 shares of stock, consisting of 70,000,000 shares of common stock, par value \$0.001 per share, and 46,017,626 shares of Preferred Stock, par value \$0.001 per share, 8,995,000 of which are designated Series A Preferred Stock, 16,094,016 of which are designated Series B Preferred Stock and 20,928,610 of which are designated Series C Preferred Stock.

***Repayment of Recourse Promissory notes***

As described in Note 12, the Company had issued recourse promissory notes to certain employees. During November 2019, all outstanding principal and accrued interest in the aggregate amount of \$772,687 were repaid to the Company by the employees.

***New Credit Facility***

In December 2019, the Company entered into a \$40 million credit facility with Signature Bank (the "SB Credit Facility") and concurrently extinguished the 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.

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, 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 maturity date of the revolving line of credit is in December 2022 and can be extended to December 2024 if the Company is able to raise at least \$75 million in

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gross proceeds from an initial public offering. 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. 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 twelve month revenues of \$40 million at December 31, 2019 with incremental monthly increases to \$60 million at 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.

***Purchased Development Services, Related Party***

In December 2019, the outstanding non-interest-bearing retainer held by Inceptus was repaid to the Company in full (see Note 8).

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Through and including \_\_\_\_\_, 2020, (the 25th day after the date of this prospectus), all dealers effecting transactions in the Common Stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

**Shares**



**Common Stock**

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**PROSPECTUS**

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**BofA Securities**

**Morgan Stanley**

**Canaccord Genuity**

**Wells Fargo Securities**

, 2020

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**PART II**

**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 13. Other Expenses of Issuance and Distribution.**

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and the Global Market listing fee.

	<u>Amount</u>
Securities and Exchange Commission registration fee	\$ *
FINRA filing fee	*
Initial Global Market listing fee	*
Accountants' fees and expenses	*
Legal fees and expenses	*
Blue Sky fees and expenses	*
Transfer Agent's fees and expenses	*
Printing and engraving expenses	*
Miscellaneous	*
Total expenses	<u>\$ *</u>

\* To be filed by amendment.

**Item 14. Indemnification of Directors and Officers.**

The Registrant is governed by the Delaware General Corporation Law, or DGCL. Section 145 of the DGCL provides that a corporation may indemnify any person, including an officer or director, who was or is, or is threatened to be made, a party to any threatened, pending or completed legal action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person was or is an officer, director, employee or agent of such corporation or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided such officer, director, employee or agent acted in good faith and in a manner such person reasonably believed to be in, or not opposed to, the corporation's best interest and, for criminal proceedings, had no reasonable cause to believe that such person's conduct was unlawful. A Delaware corporation may indemnify any person, including an officer or director, who was or is, or is threatened to be made, a party to any threatened, pending or contemplated action or suit by or in the right of such corporation, under the same conditions, except that such indemnification is limited to expenses (including attorneys' fees) actually and reasonably incurred by such person, and except that no indemnification is permitted without judicial approval if such person is adjudged to be liable to such corporation. Where an officer or director of a corporation is successful, on the merits or otherwise, in the defense of any action, suit or proceeding referred to above, or any claim, issue or matter therein, the corporation must indemnify that person against the expenses (including attorneys' fees) which such officer or director actually and reasonably incurred in connection therewith.

The Registrant's amended and restated certificate of incorporation will authorize the indemnification of its officers and directors, consistent with Section 145 of the DGCL.

Reference is made to Section 102(b)(7) of the DGCL, which enables a corporation in its original certificate of incorporation or an amendment thereto to eliminate or limit the personal liability of a director for

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violations of the director's fiduciary duty, except (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) pursuant to Section 174 of the DGCL, which provides for liability of directors for unlawful payments of dividends of unlawful stock purchase or redemptions or (iv) for any transaction from which a director derived an improper personal benefit.

We have entered into indemnification agreements with each of our directors and officers. These indemnification agreements may require us, among other things, to indemnify our directors and officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of his or her service as one of our directors or officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request.

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act against certain liabilities.

**Item 15. Recent Sales of Unregistered Securities.**

Since January 1, 2016, we have issued and sold the following securities:

1. In March 2018, we completed the sale of an aggregate of 20,928,610 shares of our Series C convertible preferred stock to certain investors at a purchase price of \$1.2901 per share, for an aggregate purchase price of approximately \$27.0 million. All of our shares of Series C convertible preferred stock will convert into shares of our common stock immediately prior to the closing of our initial public offering.
2. In April 2016, we issued a warrant to purchase 128,205 shares of our Series B convertible preferred stock to East West Bank at an exercise price of \$1.17 per share. Pursuant to the terms of the warrant, on March 31, 2017, the number of shares for which this warrant can be exercised was automatically increased to 256,410 shares upon the extension of credit under a loan and security agreement with East West Bank.
3. Since January 1, 2016, we have granted stock options to employees, directors and consultants, covering an aggregate of 8,317,483 shares of our common stock under our 2011 Equity Incentive Plan, at exercise prices ranging from \$0.22 to \$4.01 per share, and have issued 5,018,561 shares of common stock upon exercise of stock options under our 2011 Equity Incentive Plan with an aggregate exercise price of \$927,386
4. In March 2019, we issued restricted stock units, or RSUs, to employees representing an aggregate of 4,094,552 shares of common stock under our 2011 Equity Incentive Plan. Our outstanding RSUs vest upon the satisfaction of a time-based condition and a service-based condition and the completion of an initial public offering or sale event. The time-based condition is satisfied on the fourth anniversary of the date of grant of the RSU, subject to continued service through the vesting date. This offering will satisfy the requirement for an initial public offering or sale event. On the vesting date of the RSUs, the recipient is entitled to receive one share of common stock for every RSU that vests.

Unless otherwise stated, the issuances of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Regulation D

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promulgated thereunder, or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. Individuals who purchased securities as described above represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the share certificates issued in such transactions.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions or any public offering.

**Item 16. Exhibits and Financial Statement Schedules.**

(a) Exhibits.

The following documents are filed as exhibits to this registration statement.

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
1.1*	Form of Underwriting Agreement
3.1**	Third Amended and Restated Certificate of Incorporation, as amended to date and as currently in effect
3.1.1**	Corrected Certificate of Amendment of Third Amended and Restated Certificate of Incorporation, dated July 18, 2019
3.2*	Form of Amended and Restated Certificate of Incorporation, to be effective upon the completion of this offering
3.3**	Bylaws, as currently in effect
3.4*	Form of Amended and Restated Bylaws, to be effective upon the completion of this offering
4.1*	Form of Certificate of Common Stock
4.2**	Second Amended and Restated Investors' Rights Agreement by and between Inari Medical, Inc. and certain investors, dated March 29, 2018
4.3**	Warrant to purchase common stock, issued by Inari Medical, Inc. to Croton Partners, LLC, dated February 19, 2015
4.4**	Warrant to purchase Series A preferred stock, issued by Inari Medical, Inc. to Silicon Valley Bank, dated December 10, 2014
4.5**	Warrant to purchase Series B preferred stock, issued by Inari Medical, Inc. to East West Bank dated April 29, 2016
5.1*	Opinion of Latham & Watkins LLP
10.1**	Form of Indemnification Agreement between Inari Medical, Inc. and its directors and officers
10.2**	Lease between Inari Medical, Inc. and Bake Technology Park LLC, dated March 6, 2019
10.3#**	2011 Equity Incentive Plan
10.4#**	Form of Stock Option Agreement pursuant to 2011 Equity Incentive Plan
10.5#**	Form of Restricted Stock Unit Agreement pursuant to 2011 Equity Incentive Plan
10.6#*	2020 Incentive Award Plan and related form agreements
10.7#*	2020 Employee Stock Purchase Plan and related form agreements
10.8**	Loan and Security Agreement, dated as of December 11, 2019, by and between Inari Medical, Inc. and Signature Bank

**Confidential Treatment Requested by Inari Medical, Inc.  
Pursuant to 17 C.F.R. Section 200.83**

<u>Exhibit Number</u>	<u>Description of Exhibit</u>
10.9**	Sublicense Agreement, dated as of August 1, 2019, by and between Inari Medical, Inc. and Inceptus Medical, LLC
10.10#**	Amended and Restated Services Agreement, dated as of February 1, 2018, by and between Inari Medical, Inc. and Inceptus Medical, LLC
10.11**	Amended and Restated Technology Agreement, dated as of March 2, 2018, by and between Inari Medical, Inc. and Inceptus Medical, LLC
10.12*	Form of Executive Employment Agreement
23.1*	Consent of Independent Registered Public Accounting Firm
23.2*	Consent of Latham & Watkins LLP (included in Exhibit 5.1)
24.1*	Power of Attorney (included on signature page)

\* To be filed by amendment.

\*\* Previously filed.

# Indicates management contract or compensatory plan.

(b) Financial Statement Schedules. Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

**Item 17. Undertakings.**

The undersigned registrant hereby undertakes to provide to the underwriter, at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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**SIGNATURES**

Pursuant to the requirements of the Securities Act, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Irvine, State of California, on this      day of      , 2020.

**INARI MEDICAL, INC.**

By: \_\_\_\_\_  
William Hoffman  
Chief Executive Officer and President

**SIGNATURES AND POWER OF ATTORNEY**

We, the undersigned officers and directors of Inari Medical, Inc., hereby severally constitute and appoint William Hoffman and Mitchell Hill, and each of them singly (with full power to each of them to act alone), our true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution in each of them for him and in his name, place and stead, and in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement (or any other registration statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as full to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities held on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
_____ William Hoffman	Chief Executive Officer (principal executive officer), President and Director	, 2020
_____ Mitchell Hill	Chief Financial Officer (principal financial and accounting officer)	, 2020
_____ Robert Rosenbluth, Ph.D.	Chair of the Board of Directors	, 2020
_____ Paul Lubock	Director	, 2020
_____ Cynthia Lucchese	Director	, 2020
_____ Donald Milder	Director	, 2020

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<u>Signature</u>	<u>Title</u>	<u>Date</u>
_____ Kirk Nielsen	Director	, 2020
_____ Geoff Pardo	Director	, 2020
_____ Jonathan Root, M.D.	Director	, 2020
_____ Catherine Szyman	Director	, 2020