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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

OR

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

Commission File Number 001-39293

Inari Medical, Inc.

(Exact name of Registrant as specified in its Charter)

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.001 par value per share	NARI	The Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☒ NO ☐

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The NASDAQ Stock Market on June 30, 2020, the last business day of the Registrant's most recently completed second fiscal quarter was approximately $953.6 million.

The number of shares of Registrant's Common Stock outstanding as of March 1, 2021 was 49,500,688.

DOCUMENTS INCORPORATED BY REFERENCE

The Registrant intends to file a definitive proxy statement pursuant to Regulation 14A withing 120 days of the end of the fiscal year ended December 31, 2020. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

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Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Annual Report on Form 10-K may be forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "targets," "projects," "contemplates," "believes," "estimates," "forecasts," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this Annual Report on Form 10-K include, but are not limited to statements regarding our future results of operations and financial position, industry and business trends, stock compensation, business strategy, plans, market growth, regulatory climate, competitive landscape and our objectives for future operations.

The forward-looking statements in this Annual Report on Form 10-K are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. Forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the important factors discussed in Part I, Item 1A. "Risk Factors" in this Annual Report on Form 10-K for the year ended December 31, 2020. The forward-looking statements in this Annual Report on Form 10-K are based upon information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

You should read this Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K and have filed as exhibits to this Annual Report on Form 10-K with the understanding that our actual future results, levels of activity, performance and achievements may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained in this Annual Report on Form 10-K, whether as a result of any new information, future events or otherwise.

Summary Risk Factors

Our business is subject to numerous risks and uncertainties, including those described in Part I, Item 1A. "Risk Factors" in this Annual Report on Form 10-K. You should carefully consider these risks and uncertainties when investing in our common stock. The principal risks and uncertainties affecting our business include, but are not limited to, the following:

- We are an early-stage company with a history of significant net losses, we may incur operating losses in the future and we may not be able to sustain profitability;
- A pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide, including the outbreak of the novel strain of coronavirus disease, COVID-19, could adversely affect our business;
- Our revenue is currently generated from the sales of our two products and we are therefore highly dependent on the success of those products. 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;
- We have limited commercial sales experience regarding our products, including limited experience in training and marketing and selling our products, which makes it difficult to evaluate our current business, predict our future prospects and forecast our financial performance and growth;

- Our business is dependent upon the broad adoption of our products and catheter-based thrombectomy procedures by hospitals, physicians and patients;

- Adoption of our ClotTriever and FlowTriever products requires approval by customers, such as hospital value analysis committees, and depends upon appropriate physician training, practice and patient selection and positive clinical data;

- Our products 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 FlowTriever 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;

- 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 manufacturing facilities and 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;

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

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

PART I

Item 1. 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 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 20,000 patients at over 800 hospitals across the United States. We have experienced significant growth since we began commercializing our products, with approximately 13,200 procedures performed using our products in 2020.

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 ClotTriever and FlowTriever products, respectively. In addition, among the 668,000 DVT patients, we believe there are approximately 20,000 patients with clot in transit in the right atrium who could benefit from treatment with FlowTriever products. Taken together, this represents a potential annual addressable U.S. market opportunity for our current products of approximately $3.8 billion. 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 but 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 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.

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; and
- 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 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 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. 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: ClotTriever Outcomes, or CLOUT, for DVT and FlowTriever All-Comer Registry for Patient Safety and Hemodynamics, or FLASH, for PE. In addition, we are initiating the FlowTriever for Acute Massive Pulmonary Embolism, or FLAME, registry for high-risk PE in 2021 and there are multiple ongoing investigator-initiated studies. 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 treating 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, with our sales force covering 120 territories as of December 31, 2020. We continue to actively expand our sales organization through additional sales representatives and territories.

We have experienced significant growth since we began commercializing our products in the United States. We generated revenue of $139.7 million, with a gross margin of 90.6% and net income of $13.8 million for the year ended December 31, 2020, compared to revenue of $51.1 million, with a gross margin of 88.4% and net losses of $1.2 million for the year ended December 31, 2019. Our accumulated deficit was $27.4 million as of December 31, 2020.

Our Success Factors

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

- ***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. Our 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. In addition, we believe there are approximately 20,000 patients with clot in transit in the right atrium who could benefit from treatment with FlowTriever products. 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 $3.8 billion and that there is also a significant opportunity for our products outside the United States.

- ***Rapidly scaling commercial organization leveraging unique insights.*** Our most important relationships are between our sales representatives and physicians. Our front-line sales representatives typically attend procedures, 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 and, as of December 31, 2020, we had 120 sales territories.

- ***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 treating physicians, 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. Our products facilitate short, single-session treatments 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 over 800 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 plan to continue to grow our sales organization in order to target and expand our network 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 treating 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 economics 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 FlowTriever 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 we expect to initiate the FLAME registry for high-risk PE in 2021. In addition, there are multiple ongoing

investigator-initiated studies. We believe these studies will generate a robust cadence of publications, drive further 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. We are currently working to commercialize our solutions internationally and have received updated CE Marks for both ClotTriever and FlowTriever in Europe.

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 ClotTriever product. We believe the ClotTriever offers an innovative solution for these 242,000 patients that is safe and more effective than current treatment alternatives, and that this represents an approximately $1.6 billion per year U.S. market opportunity for DVT. In addition, among the 668,000 DVT patients, we believe there are approximately 20,000 patients with clot in transit in the right atrium who could benefit from treatment with FlowTriever products.

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. We believe the FlowTriever offers an innovative solution for these 200,000 patients that is safe and more effective than current treatment alternatives, and that this represents an approximately $2.0 billion per year U.S. market opportunity for PE.

Collectively, the potential annual addressable U.S. market for our current products is approximately $3.8 billion. We also believe there is a substantial market opportunity for DVT and PE outside the United States.

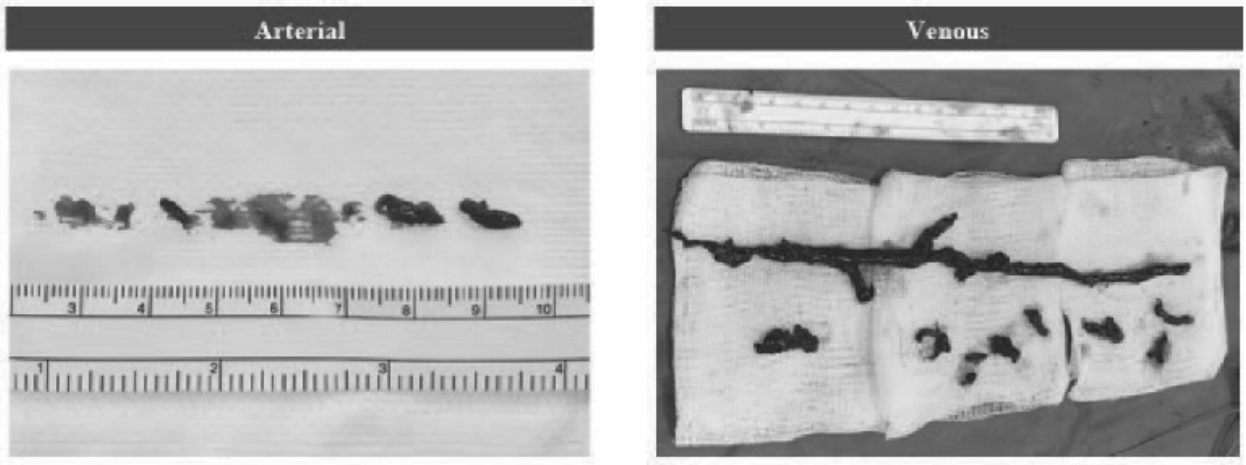
Venous and Arterial Systems and Clot Morphology

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.

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 and in smaller vessels, they are small, soft, fibrin-rich and are usually not adhered to the wall of the artery. For example, arterial clot that causes MI or stroke is generally about the size of a grain of rice.

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 quite significant in size.

The following images depict examples of arterial and venous clots:



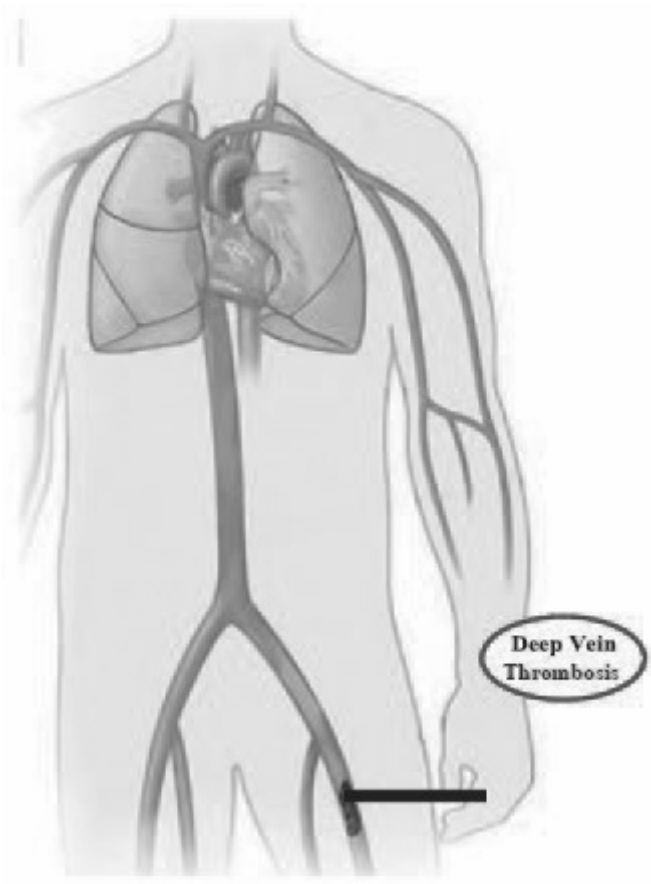
Venous Thromboembolism

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.

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.

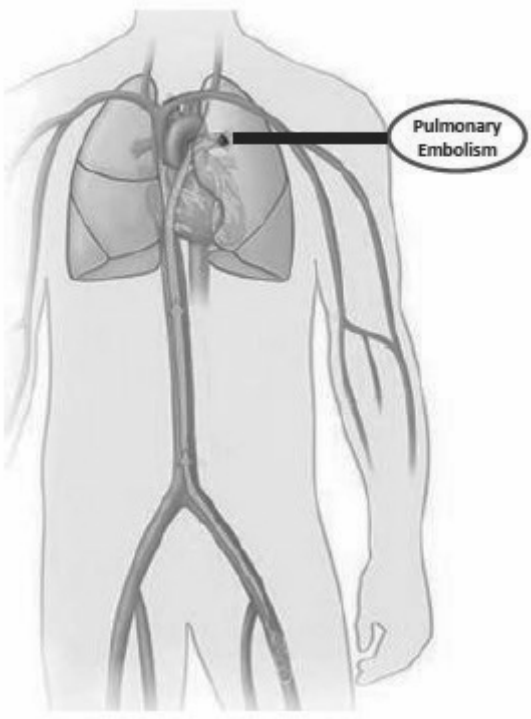
Upon presentation, DVT can be readily diagnosed via a standard ultrasound imaging assessment that is usually performed in the emergency room.

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.

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 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 intravenously on an inpatient basis and 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.

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 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. 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.
- *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, increases risk and inconvenience for the patient, and typically requires ICU stays and monitoring periods.

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.

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. 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 generally begins early and progresses quickly. 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.* 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.
- *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. 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, fewer than 250 open surgical embolectomy procedures are performed in the United States each year.

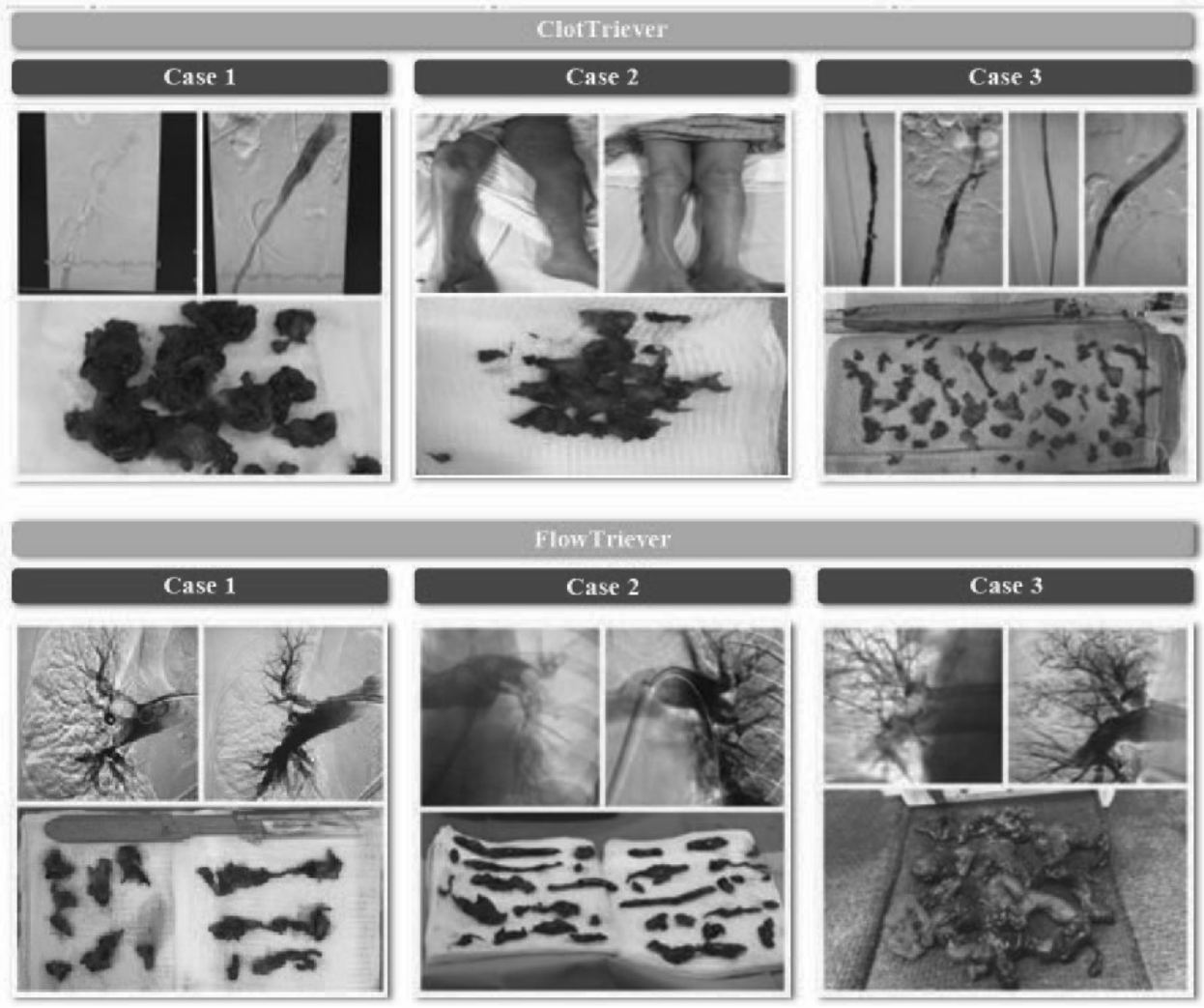
Our Solution

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.

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 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 20,000 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 treating physicians, 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, 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. 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.

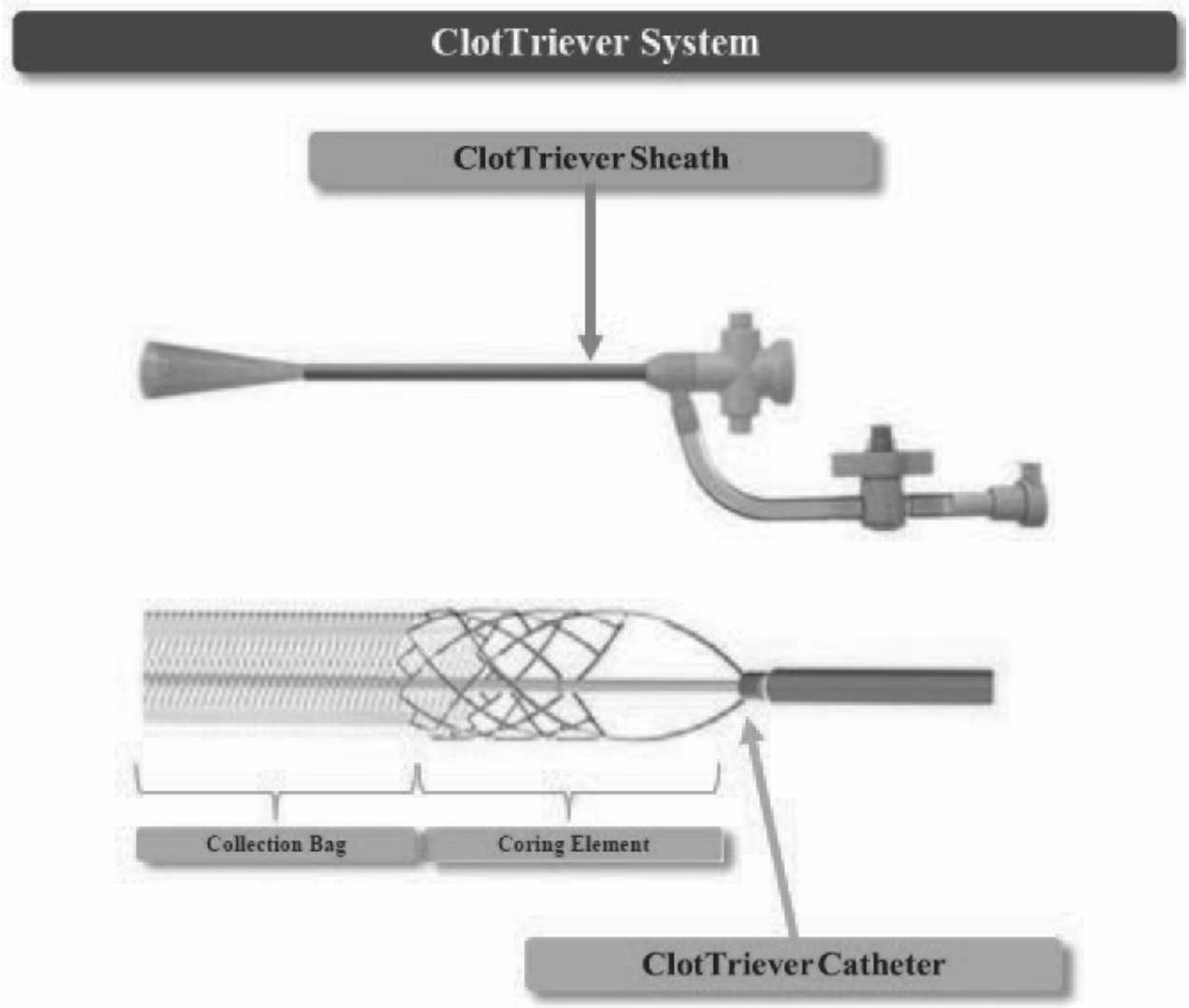
ClotTriever

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 ClotTriever is 510-(k) cleared by the FDA and CE Mark approved for the treatment of DVT.

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. The sheath is available in two sizes: 13 and 16 French. 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 core and collect clot from the vessel wall for extraction through the ClotTriever sheath. The ClotTriever catheter is a catheter 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 80 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 ClotTriever system:



Procedure

A ClotTriever 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 ClotTriever sheath 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 ClotTriever catheter 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 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 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 ClotTriever to be between 30 and 45 minutes and that the ClotTriever removes an average of 80-90% of the target clot.

Pricing

The vast majority of ClotTriever procedures use a single ClotTriever catheter and single ClotTriever sheath. Each component is priced and packaged separately.

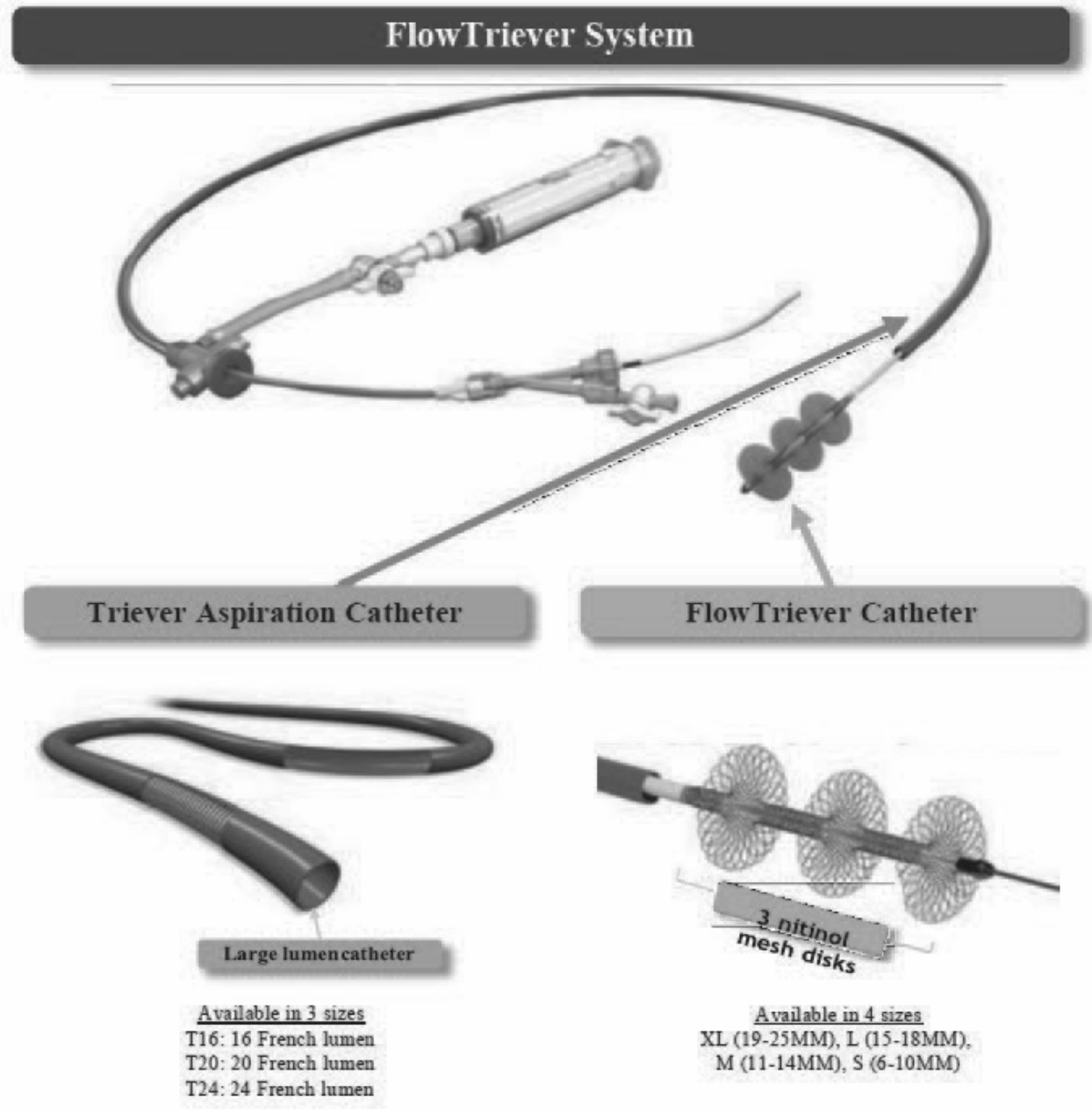
FlowTriever

The FlowTriever is a large bore catheter-based aspiration and mechanical thrombectomy system designed to remove large clots from large vessels to treat PE. The FlowTriever is a single-use, sterile system that is deployed over a wire and does not require capital equipment. The FlowTriever is 510(k)-cleared by the FDA for the treatment of PE and for clot in transit in the right atrium, and CE Mark approved for the treatment of PE.

The FlowTriever consists of two main components:

- Triever aspiration catheters – Triever aspiration catheters are highly trackable, large lumen catheters that provide a conduit for aspiration and clot removal. Triever aspiration catheters are available in three sizes, 16, 20 and 24 French. Our larger lumen Triever aspiration catheters can generate a higher rate of aspirational blood flow than small lumen catheters, as the wider catheter can carry more blood volume, at a lower resistance, than a narrower tube. Each Triever 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 Triever 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.
- FlowTriever catheter – FlowTriever catheters are designed to engage, liberate and deliver the clot to the Triever aspiration catheter for extraction. FlowTriever catheters are delivered to the clot through the Triever aspiration catheter. Each FlowTriever 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.

The image below depicts the components of the FlowTriever system:



Procedure

A FlowTriever 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 Triever aspiration catheter is then advanced over the guidewire to the target clot. Once the Triever 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 Triever aspiration catheter, creates a high flow aspiration, which we call the Whoosh, that draws clot into the Triever 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 FlowTriever to be 280 cc.

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

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 FlowTriever is between 40 and 50 minutes, the average procedure time for treatment with a FlowTriever is between 75 and 90 minutes, and that the FlowTriever removes an average of 75% of the target clot.

Pricing

The use of the FlowTriever 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 Triever aspiration catheters but does not require a FlowTriever 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 FlowTriever catheters. Due to the variability in use across procedures, we price the FlowTriever on a per procedure basis. As a result, a customer is charged the same price for each procedure that uses the FlowTriever 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.

FlowTriever 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 FlowTriever system to treat DVT, with or without the ClotTriever. For the years ended December 31, 2020 and 2019, we estimate that approximately 12% and 13%, respectively, of our DVT procedures were performed using only our FlowTriever system and approximately 7% and 8%, respectively, of our DVT procedures were performed using our ClotTriever and at least one component of the FlowTriever 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 FlowTriever Pulmonary Embolectomy Clinical Study, or FLARE study, which established the safety and effectiveness of the FlowTriever 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. In addition, we expect to initiate the FLAME registry for high-risk PE in 2021 and there are multiple ongoing investigator-initiated studies.

ClotTriever

The FDA granted 510(k) clearance of the ClotTriever in February 2017 based on a determination that the ClotTriever was substantially equivalent to a legally marketed predicate device and, in September 2020, granted 510-(k) clearance for the treatment of DVT. We were not required by the FDA to conduct clinical studies on the ClotTriever 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 ClotTriever. We are currently enrolling patients in the CLOUT registry to evaluate real-world patient outcomes using the ClotTriever in up to 500 patients.

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.

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.

Interim results from the first 105 patients enrolled in the CLOUT registry study were presented at the Annual Meeting of the American Venous Forum, or AVF, in March 2020. These interim results, as of a January 17, 2020 cutoff date, included baseline and acute procedural outcomes in 105 patients and outcomes from 30-day follow-up in 68 patients. We believe these interim results provide evidence supporting the potential for 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, as of the cutoff date, clot was removed from all but one of the patients in a single session and, based on an evaluation conducted as of February 5, 2020, 70% of 59 evaluable patients met the study's primary

effectiveness endpoint of complete or near complete (≥75%) removal of clot. Of the 65 patients for which follow-up data was collected regarding post-thrombotic syndrome, or PTS, 39 of the 61 patients that reported PTS at baseline (64%) showed no evidence of PTS at 30 days, and 60 out of all 65 patients evaluated for PTS (92%) showed improvement. No patients experienced severe disease within 30 days of treatment. Patients reported statistically significant improvements in disease severity, pain and quality of life scores within 30 days of treatment, with no device related major adverse events. Three patients (2.9%) had major adverse events within 30 days of treatment. Of these major adverse events, one patient died on day 23 after treatment because of sepsis and kidney failure associated with metastatic lung cancer (which was determined not to be procedure-related); one patient with previously documented extensive bilateral saddle PE prior to ClotTriever thrombectomy had symptomatic PE on day 2 after treatment (which was determined to be possibly procedure-related); and one patient had re-thrombosis on day 21 after treatment with incomplete thrombectomy and a Marder score reduction of 53.3% (which was determined to be procedure-related). No bleeding complications or renal injuries were reported and one wound complication, a hematoma, was reported. We believe these interim results are even more impressive given the complexity of the patient population. For example, over a quarter of the patients enrolled previously received alternative DVT treatment prior to treatment using the ClotTriever. In addition, almost two thirds 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. With the exception of one procedure, all patients were treated in a single session, with no patients receiving thrombolytic therapy, and the median thrombectomy time was 31 minutes.

Below is a summary of the outcomes information presented at the AVF Annual Meeting in March 2020:

Measure	Baseline pre-treatment	At 30 days post-treatment	P-value
Villalta score (1)	11	4	<0.01
PTS rate (2)	93.9%	35.4%	<0.001
Severe PTS rate (3)	27.7%	0%	N/A
Moderate PTS rate (4)	29.2%	13.8%	N/A
Revised Venous Clinical Severity Score (5)	6	4	<0.01
EuroQol-5 Dimension Score (6)	0.70	0.86	<0.01
Numeric Pain Rating Scale score (7)	4	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 (n=65).

(2) Percent of patients with PTS (n=65).

(3) Percent of patients with severe PTS (n=65).

(4) Percent of patients with moderate PTS (n=65).

(5) 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 (n=68).

(6) 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 (n=65).

(7) 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 (n=63).

Below is a summary of the procedural information presented at the AVF Annual Meeting in March 2020:

Procedural information	Total (median [interquartile range] or n (%))
Iliac or iliofemoral thrombus	89/105 (85%)
Single-session treatment	101/102 (99%)
Number of ClotTriever passes	3.0 [3, 5], n=102
Thrombectomy time (minutes) (1)	31.0 [22, 50], n=93
Estimated blood loss (cc)	40 [20, 75], n=92
Thrombolytics used (patients)	0/104 (0%)
Length of stay: Hospital (days)	2 [1, 4], n=95
Number of patients admitted to ICU	4/95 (4%)

(1) Amount of time ClotTriever used during procedure.

Below is a summary of the baseline characteristics presented at the AVF Annual Meeting in March 2020

Baseline Characteristics	Total (median [interquartile range] or n (%))
Age (years)	58 [45, 69], n=103
Male sex	56/103 (54%)
Prior history of DVT	29/105 (28%)
Previous treatment of current DVT (1)	27/101 (27%)
Patients with acute clot age/chronicity (less than 2 weeks)	35/101 (35%)
Patients with subacute clot age/chronicity (between 2 and 6 weeks)	37/101 (37%)
Patients with chronic age/chronicity (greater than 6 weeks)	29/101 (29%)
Thrombolytic eligibility	74/103 (72%)
Provoked DVT	45/102 (44%)
Bilateral DVT	3/105 (3%)

(1) Three patients had advanced therapy and 24 patients had thrombolytic therapy for greater than or equal to one week.

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 competed by 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 FlowTriever for use in the removal of clot from the pulmonary arteries and in the treatment of acute PE. The study supported the initial FDA 510(k) clearance for the FlowTriever. The results of the study were published in May 2019 in the *Journal of the American College of Cardiology: Cardiovascular Interventions*. We are currently enrolling patients in the FlowTriever All-Comer Registry for Patient Safety and Hemodynamics, or FLASH registry, to evaluate real-world patient outcomes using the FlowTriever in up to 500 patients.

FLASH Registry

The FLASH registry is 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 FlowTriever as the standard of care for treatment of PE.

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 FlowTriever 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 FlowTriever. 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.

In October 2020, we announced positive results from the first 230 patients enrolled in the FLASH registry. Of these patients, 98.7% (227/230) met the registry's primary endpoint of freedom from major adverse events in the 48 hours after treatment using the FlowTriever. Secondary endpoints include impact on acute hemodynamics, procedural measures, 48-hour all-cause mortality and longer-term patient outcomes. All secondary outcome measures analyzed show statistically significant and clinically meaningful improvements from baseline. In addition, there were no deaths in the 48 hours after treatment, cardiac or pulmonary injuries or procedure-related clinical deteriorations. Further, there were no instances of intracranial hemorrhage, which is a limitation of treatment with thrombolytic drugs. Hemodynamic parameters, including pulmonary artery pressure and cardiac index improved significantly after treatment. The median duration of ICU stay was zero days following intervention.

Immediate post-procedural hemodynamic improvements have not been demonstrated with thrombolytic-based approaches, which can take several hours to take effect. After treatment using the FlowTriever, patient heart rates quickly improved by an average of 23 beats per minute. The majority (77%) of patients were tachycardic (>100 bpm) pre-procedure and 25% were tachycardic immediately after treatment. In addition, the average pulmonary artery pressure dropped by 7mmHg, with several patients normalizing immediately after clot removal.

In November 2020, we announced positive follow-up results from these first 230 patients that were previously reported in October 2020 and for whom the study extended the follow-up period to 30 days after treatment with FlowTriever. At 30 days, one death (0.4%) was reported and the results showed a readmission rate of 6.7%. In contrast, the national PERT Consortium Quality Database recently showed 30-day mortality rates of 25.9% and 6.1% for high- and intermediate-risk PE patients and a readmission rate of nearly 25%. Efficacy data was also positive and showed normalization or near normalization in a battery of hemodynamic variables, such as pulmonary artery pressure, RV/LV ratio and heart rate, as well as dyspnea (shortness of breath) metrics.

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 FlowTriever. 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 the initial FDA 510(k) clearance for the FlowTriever.

All patients enrolled in the study were symptomatic for 14 days or fewer, 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 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 FlowTriever, 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 FlowTriever. 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 FlowTriever. 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.

Other Studies

There are a number of additional investigator-initiated studies being conducted to evaluate, among others, clot morphology, healthcare economics and long-term implications involving VTE.

Sales and Marketing

We currently sell our products to over 800 of the approximately 1,500 hospitals in the United States with a cath lab where interventional procedures can be performed. Our treating 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 treating 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. In 2020 we launched our online education portal and expanded our physician outreach and training with the launch of our Clot Warrior Academy, which consists of a series of live webinars.

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 and have obtained CE Marks in Europe for both our ClotTriever and FlowTriever products.

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 typically attend procedures, which puts us at the intersection of the patient, product and physician. We have developed systems and processes to harness 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 continue to expand our network of sales representatives and as of December 31, 2020, we had 120 sales territories.

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 treating 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.

ClotTriever

Procedures using our ClotTriever 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.

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.

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 non-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.

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 and hospitals have continued to perform FlowTriever procedures. 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 treatment of venous disease 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 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.

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, 2020, 2019 and 2018, our research and development expenses were $18.4 million, $7.2 million and $4.0 million, respectively.

Manufacturing and Supply

We currently manufacture and assemble our ClotTriever and FlowTriever products at our approximately 40,000 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. Although we believe our current manufacturing capacity is sufficient to meet our current expected demand for at least the next 12 months, we have entered into a lease agreement for a larger facility in Irvine, California to accommodate our growth plans.

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 current facility.

We have received International Organization for Standardization, 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. The most recent recertification audit was conducted in November 2020. One major non-conformity was identified that has been addressed to the satisfaction of the notified body in January 2021. There have been no surveillance audits or unannounced audits on our new facility.

We use a combination of internally manufactured and externally-sourced components to produce our ClotTriever and FlowTriever 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 ClotTriever, 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.

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 appropriate, 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, 2020, we held 19 U.S. patents, which are expected to expire between November 2032 and April 2037, 17 pending U.S. patent applications, four issued foreign patents, 16 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.

As of December 31, 2020, we also licensed two U.S. patents 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, 2020, we had eight registered trademarks and seven pending trademark applications worldwide, including trademark registration for "Inari Medical" in the United States and trademark registrations for "FlowTriever" and "ClotTriever" 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 $29,250 per quarter. 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, 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.

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 may take 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 2021, the standard user fee for a 510(k) premarket notification application is $12,432.

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) 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* classification. 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 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 steps that the FDA intended 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. These proposals have not yet been finalized or adopted, although the FDA may work with Congress to implement such proposals through legislation.

More recently, in September 2019, the FDA issued revised final 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 has developed and maintains a list device types appropriate for the "safety and performance based" pathway and continues 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 applications are also subject to the payment of user fees, which for fiscal year 2021 includes a standard application fee of $365,657.

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 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 investigational device exemption, or 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.

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.

Manufacturing processes for medical devices 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. Failure to maintain compliance with the QSR requirements could result in the shut- down of, or restrictions on, manufacturing operations and the recall or seizure of marketed 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 a manufacturer has 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;
- 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 the European Union

The European Union has adopted specific directives regulating the design, manufacture, clinical investigations, conformity assessment, labeling and adverse event reporting for medical devices. EU directives must be implemented into the national laws of the EU member states and national laws may vary from one member state to another.

In the EU, there is currently no premarket government review of medical devices. However, the EU requires that all medical devices placed on the market in the EU must meet the relevant essential requirements laid down in Annex I of Council Directive 93/42/EEC, or the EU Medical Devices Directive. The most fundamental essential requirement is that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter. Compliance with a standard developed to implement an essential requirement also creates a rebuttable presumption that the device satisfies that essential requirement.

To demonstrate compliance with the essential requirements laid down in Annex I to the EU Medical Devices Directive, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product, and post-market experience in respect of similar products already marketed. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can self-declare the conformity of its products with the essential requirements (except for any parts which relate to sterility or metrology), a conformity assessment procedure requires the intervention of a Notified Body. Notified Bodies are often separate entities and are authorized or licensed to perform such assessments by government authorities. The Notified Body would typically audit and examine a product's technical dossiers and the manufacturers' quality system. If satisfied that the relevant product conforms to the relevant essential requirements, the Notified Body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE Mark to the device, which allows the device to be placed on the market throughout the EU.

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. All manufacturers placing medical devices into the market in the EU must comply with the EU Medical Device Vigilance System. Under this system, incidents must be reported to the relevant authorities of the EU member states, and manufacturers are required to take Field Safety Corrective Actions, or FSCAs, to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or of other persons or to a serious deterioration in their state of health. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices.

On May 25, 2017, the EU Medical Devices Regulation (Regulation 2017/745) entered into force, which repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EU member states, regulations are directly applicable, without the need for adoption of EU member state laws implementing them, in all EU member states and are intended to eliminate current differences in the regulation of medical devices among EU member states. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensure a high level of safety and health while supporting innovation.

The Medical Devices Regulation was originally intended to become effective three years after publication, but in April 2020, the transition period was extended by the European Parliament and the Council of the EU by an additional year – until May 26, 2021. Devices lawfully placed on the market pursuant to the EU Medical Devices Directive prior to May 26, 2021 may generally continue to be made available on the market or put into service until May 26, 2025. 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
- 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 design and manufacture products and how we conduct our business in the EEAEU.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Following the end of the "Brexit" Transition Period, from 1 January 2021 onwards, the Medicines and Healthcare Products Regulatory Agency ("MHRA") will be responsible for the UK medical device market. The new regulations will require medical devices to be registered with the MHRA (but manufacturers will be given a grace period of four to 12 months to comply with the new registration process). Manufacturers based outside the UK will need to appoint a UK Responsible Person to register devices with the MHRA in line with the grace periods. By July 1, 2023, in the UK (England, Scotland, and Wales), all medical devices will require a UKCA (UK Conformity Assessed) mark but CE marks issued by EU Notified Bodies will remain valid until this time. However, UKCA marking alone will not be recognized in the EU. The rules for placing medical devices on the Northern Ireland market will differ from those in the UK.

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 particularly relevant because of its broad applicability. Specifically, the Anti-Kickback Statute prohibits persons or entities 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. 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. The term remuneration has been interpreted broadly to include anything of value. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing, or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances.

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, 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. Various states have also 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. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent in order to violate them.

Additionally, the federal Physician Payments Sunshine Act and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) annually report information related to certain payments or other transfers of value made or distributed to physicians (as defined by statute), certain other healthcare providers beginning in 2022 and teaching hospitals, certain ownership and investment interests held by physicians and their immediate family members.

Additional 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.

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. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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 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 which has been suspended from May 1, 2020 through March 31, 2021, 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.

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 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 went 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. Further, the California Privacy Rights Act, or the CPRA, recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required.

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 and European Economic Area, or EEA, 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.

Human Capital Resources and Employees

We employ a growing and highly-skilled employee base across all employee functions and promote a culture focused on patient care in the treatment of VTE. Our key purpose is to serve and improve the quality of life of these patients, our patients. We believe that removing clot can have a profound impact on the lives of our patients over the short and long term, and that 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 human capital objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and future employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

As of December 31, 2020, we had 456 employees. None of our employees are subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

Available Information

We make our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports, available free of charge at our website as soon as reasonably practicable after they have been filed with the SEC. Our website address is www.inarimedical.com. Information on our website is not part of this report. The SEC maintains a website that contains the materials we file with the SEC at www.sec.gov.

Item 1A. Risk Factors.

RISK FACTORS

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

A Risks Related to Our Business

We are an early-stage company with a history of significant net losses, we may incur operating losses in the future and we may not be able to sustain profitability.

We have incurred significant net losses since our original formation as Inceptus Newco1 Inc. in July 2011 and may incur operating losses in future years. For the years ended December 31, 2020, 2019 and 2018, we had a net income of $13.8 million and net losses of $1.2 million and $10.2 million, respectively. We expect to incur additional losses in the future. As of December 31, 2020, we had an accumulated deficit of $27.4 million. To date, we have financed our operations primarily through equity and debt financings and from sales of our two products, the ClotTriever, for treatment of deep vein thrombosis, or DVT, and the FlowTriever, for treatment of pulmonary embolism, or PE. The losses and accumulated deficit have primarily been due to the substantial investments we have made to develop our products, costs related to our sales and marketing efforts, general research and development expenses, including costs related to clinical and regulatory initiatives to obtain marketing approval, and infrastructure improvements.

In addition, as a public company, we incur significant legal, accounting and other expenses. Accordingly, we expect to continue to incur operating losses for the foreseeable future and we cannot assure you that we will be able to sustain profitability in the future. Our failure to 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.

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

If a pandemic, epidemic or outbreak of an infectious disease occurs in the United States or worldwide, our business may be adversely affected. In December 2019, a novel strain of coronavirus, SARS-CoV-2, was identified in Wuhan, China. Since then, SARS-CoV-2, and the resulting disease, COVID-19, has spread to most countries, including all 50 states in the United States. In response to the pandemic, governmental authorities recommended, and in certain cases required, that elective, specialty and other procedures and appointments be suspended or canceled to avoid non-essential patient exposure to medical environments and potential infection with COVID-19 and to focus limited resources and personnel capacity toward the treatment of COVID-19 patients. In addition, since March 2020 numerous state and local governments have issued "stay at home" orders, some with tiered restrictions based on a region's ICU availability. Such orders or restrictions resulted in reduced operations at our headquarters (including our manufacturing facility), work stoppages, slowdowns and delays, travel restrictions and cancellation of events. These orders and restrictions significantly decreased the number of procedures performed using our products during restricted periods, including March and April 2020 and early 2021, and otherwise negatively impacted our business, financial condition and results of operations, including new customer procurement and onboarding. We believe the COVID-19 pandemic has also negatively impacted the number of DVT and PE diagnoses as hospitals focus on COVID-19 and as patients postpone healthcare visits and treatments.

Decreases in procedures have been most prevalent in regions experiencing significant outbreaks. These measures and challenges will likely continue for the duration of the pandemic, which is uncertain, and will continue to significantly reduce our revenue and negatively impact our business, financial condition and results of operations while the pandemic continues. Further, once the pandemic subsides, we anticipate there will be a substantial backlog of patients seeking appointments with physicians and surgeries to be performed at hospitals and ambulatory surgery centers relating to a variety of medical conditions, and as a result, patients seeking procedures performed using our products, particularly the ClotTriever, will have to navigate limited provider capacity. We believe this limited provider, hospital and ambulatory surgery center capacity could have a significant adverse effect on our business, financial condition and results of operations following the end of the pandemic.

Other disruptions or potential disruptions include restrictions on the ability of our sales representatives and other personnel to travel and access customers for training and case support; inability of our suppliers to manufacture components and parts and to deliver these to us on a timely basis, or at all; disruptions in our production schedule and ability to manufacture and assemble products; inventory shortages or obsolescence; delays in actions of regulatory bodies; delays in clinical trials and studies; diversion of or limitations on employee resources that would otherwise be focused on the operations of our business, including because of sickness of employees or their families or the desire of employees to avoid contact with groups of people; delays in growing or reductions in

our sales organization, including through delays in hiring, lay-offs, furloughs or other losses of sales representatives; restrictions in our ability to ship our products to customers; business adjustments or disruptions of certain third parties, including suppliers, medical institutions and clinical investigators with whom we conduct business; negative impact on our customers' credit profiles, which may adversely impact our future collection experience; and additional government requirements or other incremental mitigation efforts that may further impact our or our suppliers' capacity to manufacture our products. The extent to which the COVID-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity and spread of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

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

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

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

To date, all of our revenue has been derived, and we expect it to continue to be substantially derived, from sales of our ClotTriever and FlowTriever. We believe these products 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 relative novelty of our products, together with our limited commercialization experience, makes it difficult to evaluate our current business and predict our future prospects. A number of factors, including some outside of our control, may contribute to fluctuations in our financial results, including:

- Physician and hospital demand for our products and adoption of our products and catheter-based thrombectomy procedures;
- Changes in reimbursement rates by government or commercial payors;
- Positive or negative media coverage, or public, patient and/or physician perception, of our products or competing products and treatments;
- Any safety or effectiveness concerns that arise regarding our products or other catheter-based thrombectomy procedures;

- The effectiveness of our marketing and sales efforts, including our ability to have a sufficient number of talented sales representatives to sell our products;
- Unanticipated delays in product development or product launches;
- Our ability to raise additional capital on acceptable terms, or at all, if needed to support the commercialization of our products;
- Our ability to achieve and maintain compliance with all regulatory requirements applicable to our products;
- Our ability to obtain, maintain and enforce our intellectual property rights;
- Our third-party suppliers' ability to supply the components of our products in a timely manner, in accordance with our specifications, and in compliance with applicable regulatory requirements; and
- Introduction of new products or alternative treatments for VTE that compete with our products.

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

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

Our business is dependent upon the broad adoption of our products and catheter-based thrombectomy procedures by hospitals, physicians and patients.

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

- Lack of experience with our products and concerns that we are relatively new to market;
- Perceived liability risk generally associated with the use of new products and treatment options;
- Lack or perceived lack of sufficient clinical evidence, including long-term data, supporting clinical benefits or the cost-effectiveness of our products over existing treatments;
- The failure of key opinion leaders to provide recommendations regarding our products, or to assure physicians, patients and healthcare payors of the benefits of our products as an attractive alternative to other treatment options;
- Perception that our products are unproven;
- Long-standing relationships with companies and distributors that sell other products or treatment options for VTE, such as repurposed arterial devices and thrombolytic drugs;
- Lack of availability of adequate third-party payor coverage or reimbursement;
- Competitive response and negative selling efforts from providers of alternative treatments; and
- Perception regarding the time commitment and skill development that may be required to gain familiarity and proficiency with our products.

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

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

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

Adoption of our ClotTriever and FlowTriever products depends upon appropriate physician training, practice and patient selection.

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

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

The rate of adoption and sales of our products is heavily influenced by clinical data. Currently, the primary clinical data regarding the safety and effectiveness of our products is limited to our FlowTriever Pulmonary Embolectomy Clinical Study, or FLARE study, which was a prospective, multicenter, single-arm study to evaluate

the safety and effectiveness of our first-generation FlowTriever for use in the removal of clot from the pulmonary arteries in the treatment of 106 patients with acute intermediate-risk PE. Other studies 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. We are currently enrolling our ClotTriever Outcomes, or CLOUT, and FlowTriever All-Comer Registry for Patient Safety and Hemodynamics, or FLASH, registries, each of which is intended to evaluate and assess real-world patient outcomes in up to 500 patients. We plan to conduct additional clinical trials to help drive increased awareness and adoption of our products with existing and new customers. Historical clinical results are not necessarily predictive of future clinical results, and we cannot assure you that the results reported in these registries will be consistent with, or better than, currently available clinical data. Moreover, the outcomes and updates resulting from these registries, including interim results, may be compared to the results of other products and treatments for DVT or PE, and if the comparisons are not favorable, it may limit the adoption of our products. In addition, our competitors and other third parties may also conduct clinical trials of our products without our participation. Unfavorable or inconsistent clinical data from existing or future clinical trials conducted by us, our competitors or other third parties, the interpretation of our clinical data or findings of new or more frequent adverse events, could subject us to mandatory or voluntary product recalls, suspension or withdrawal of FDA or other governmental clearance or approval, significant legal liability or harm to our business reputation and could have a material adverse effect on our business, financial condition and results of operations.

Our products will be adopted and compete, in part, based on long-term data regarding patient outcomes and the risk of our products relative to other treatment options. The long-term clinical outcomes of catheter-based thrombectomy procedures with our products are not known and, due to the novelty of our products, there is no long-term data regarding patient outcomes beyond our current clinical trials. The results of short-term clinical experience of our products do not necessarily predict long-term clinical outcomes. We believe that physicians will compare the rates of long-term clinical outcomes for procedures using our products against alternative procedures and treatment options. If the long-term data do not meet physicians' expectations, or if long-term data indicate that our products are not as safe or effective as other treatment options, or as current short-term data would suggest, our products may not become widely adopted, physicians may recommend alternative treatments for their patients, which will negatively affect our business, financial condition and results of operations.

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

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

In order to generate future growth, we plan to continue to significantly expand and leverage our commercial infrastructure to increase our customer base and increase awareness and adoption by existing customers to drive our growth. Identifying and recruiting qualified sales and marketing professionals and training them on our products and catheter-based thrombectomy procedures in the venous system, on applicable federal and state laws and regulations and on our internal policies and procedures requires significant time, expense and attention. It can take several months or more before a sales representative is fully trained and productive. Our sales force may subject us to higher fixed costs than those of companies with competing products or treatments, such as thrombolytic drugs, that can utilize independent third parties, placing us at a competitive disadvantage. Our business may be harmed if our efforts to expand and train our sales force do not generate a corresponding increase in product sales and revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our products. Any failure to hire, develop and retain talented sales personnel, to achieve desired productivity levels in a reasonable period of time or timely reduce fixed costs, could have material adverse effect on our business, financial condition and results of operations.

Our ability to increase our customer base and achieve broader market acceptance of our products will depend, to a significant extent, on our ability to expand our sales and marketing and educational efforts. We plan to dedicate significant resources to our sales and marketing and educational programs. Our business may be harmed if these efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our brand in a cost effective manner is critical to achieving broad acceptance of our products and reaching new physicians, hospitals and patients. Brand promotion activities may not generate hospital or physician awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the market acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad adoption of our products.

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

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

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

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

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

We understand that various medical societies, including the Society for Cardiovascular Angiography and Interventions, the Society for Interventional Radiology, and the Society for Vascular Medicine, as well as the American College of Cardiology, have requested that CMS remove NCD 240.6. We can give no assurance that NCD 240.6 will be removed or if so, what the timing will be. Further, CMS may elect to retain NCD 240.6 and Medicate Administrative Contractors, or MACs, could begin to deny coverage for procedures using our FlowTriever product for the treatment of PE, which could result in claim denials and overpayments for our customers and significantly impact demand for the FlowTriever, which would have a material adverse effect on our business, financial condition and results of operations.

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

We derive our revenue from sales of our ClotTriever and FlowTriever products to hospitals and other medical centers, which typically bill all or a portion of the costs and fees associated with our products to various third-party payors, including Medicare, Medicaid, private commercial insurance companies, health maintenance organizations and other healthcare-related organizations, and then bill patients for any applicable deductibles or co-payments. For example, we sell our products to hospitals that purchase our products for use in catheter-based thrombectomy procedures and do not sell our products to commercial payors. As a result, access to adequate coverage and reimbursement for our products by third-party payors is essential to the acceptance and adoption of our products.

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

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

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

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

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

Further, we believe that future coverage and reimbursement may be subject to increased restrictions, such as additional prior authorization requirements, both in the United States and in international markets. If Medicare no longer covers any of our products, there would be a material adverse effect on our business, financial condition and

results of operations. In addition, Medicare Administrative Contractors could issue a local coverage determination decision that could restrict the patients eligible for the treatment with our products or in another manner unfavorable to our business. Third-party coverage and reimbursement for procedures using our products or any of our products in development for which we may receive regulatory clearance or approval may not be available or adequate in either the United States or international markets. Further, other VTE treatments, such as thrombolytic drugs, may be more widely covered or subject to different co-pay policies and requirements, which could impact demand for our products. If hospital, physician and/or patient demand for our products is adversely affected by third-party reimbursement policies and decisions, it could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

- Established treatment patterns pursuant to which drugs are generally first-line or concurrent therapies for the treatment of VTE;
- Established relationships with hospitals and physicians who prescribe their drugs or are familiar with existing interventional procedures for the treatment of VTE;
- Established relationships with key stakeholders, including interventional cardiologists, interventional radiologists and vascular surgeons, referring physicians, vascular surgeons, pulmonologists, radiologists, general practitioners and administrators;
- Greater financial and human capital resources;
- Significantly greater name recognition;
- Additional lines of products, and the ability to offer rebates or bundle products to offer greater discounts or incentives to gain a competitive advantage; and
- Established sales, marketing and worldwide distribution networks.

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

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

Our business strategy depends on our ability to manufacture our current and future products in sufficient quantities and on a timely basis to meet customer demand, while adhering to product quality standards, complying with regulatory quality system requirements and managing manufacturing costs. We have a facility located in Irvine, California, where we manufacture, assemble, inspect, test, package and ship our products. We currently produce our ClotTriever and FlowTriever products at this facility, and we do not have additional facilities. If this facility suffers damage, or a force majeure event, this could materially impact our ability to operate.

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

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

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

We depend on a limited number of single source suppliers to manufacture our components, sub-assemblies and materials, which makes us vulnerable to supply shortages and price fluctuations.

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

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

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

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

Although we require our third-party suppliers and providers to supply us with components and services that meet our specifications and other applicable legal and regulatory requirements in our agreements and contracts, and we perform incoming inspection, testing or other acceptance activities to ensure the components meet our requirements, there is a risk that these third parties will not always act consistent with our best interests, and may not always supply components or provide services that meet our requirements or in a timely manner.

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

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

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

If we fail to comply with the terms and obligations of our intellectual property licenses, including the payment obligations described above, our rights may be reduced or terminated, in which event we may not be able to develop and market any product that is covered by our intellectual property licenses. In addition, Inceptus may terminate the sublicense agreement if we cease bona fide development and commercialization of all licensed products for a period of six consecutive months. The sublicense agreement with Inceptus automatically terminates upon the termination of the intellectual property license agreement with Drexel University, and we cannot guarantee Inceptus' compliance with the terms of such intellectual property license agreement. In the event of termination of the intellectual property license agreement with Drexel University, Drexel University will, in good faith, grant to us a direct license on terms no less favorable than those given to Inceptus by Drexel University by Inceptus. Termination of this license for failure to comply with such obligations or for other reasons, or reduction or elimination of our licensed rights under it or any other license, may result in our having to negotiate new or reinstated licenses on less favorable terms or our not having sufficient intellectual property rights to operate our business or cause us to enter into a new license for a similar intellectual property or braiding technology. The occurrence of such events could materially harm our business and financial condition.

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

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

Risks of catheter-based thrombectomy procedures with our products include the risks that are common to endovascular procedures, including perforation, dissection, embolization, bleeding, infection and nerve injury. DVT procedures also include the additional risks of causing PE. We are aware of certain characteristics and features of catheter-based thrombectomy procedures that may prevent widespread market adoption, including the fact that physicians would need to adopt and learn a new procedure, and that a degree of training for physicians will be required to enable them to effectively operate our products.

Our current products are contraindicated, and therefore should not be used, in certain circumstances for certain patients. Our ClotTriever is contraindicated for use without anticoagulation; use in the cerebral, carotid or coronary vasculature; use in the pulmonary arteries; use in endarterectomy procedures or vessel dilation; removal of fibrous, adherent or calcified material; use in vessels less than six millimeters in diameter; and use with power injectors. Our FlowTriever is contraindicated for use in the cerebral, carotid or coronary vasculature; use in endarterectomy procedures or vessel dilation; removal of fibrous, adherent or calcified material; use with power injectors; and use in vessels less than six millimeters in diameter, with the largest 24 French catheter contraindicated for use in vessels less than eight millimeters in diameter.

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

We seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions, but keep limited components, sub-assemblies, materials and finished products on hand. To ensure adequate inventory supply and manage our operations with our third-party suppliers, we forecast anticipated materials requirements and demand for our products in order to predict inventory needs and then place orders with our suppliers based on these

predictions. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including our limited historical commercial experience, rapid growth, failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our products, our failure to accurately forecast customer acceptance and adoption of new products, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions.

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

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

Our quarterly and annual results of operations, including our revenue, profitability and cash flow, may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Fluctuations in quarterly and annual results may decrease the value of our common stock. Because our quarterly results may fluctuate, period-to-period comparisons may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

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

- the timing of customer orders or medical procedures using our products and the number of available selling days in any quarterly period, which can be impacted by holidays, the mix of products sold and the geographic mix of where products are sold;
- the timing and cost of, and level of investment in, research, development, licenses, regulatory approval, commercialization activities, acquisitions and other strategic transactions, or other significant events relating to our products, which may change from time to time;
- the cost of manufacturing our products, which may vary depending on the quantity of production and the terms of our agreements with third-party suppliers; and
- future accounting pronouncements or changes in our accounting policies.

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

The market for our products is highly competitive, dynamic, and marked by rapid and substantial technological development and product innovation. New entrants or existing competitors could attempt to develop products that compete directly with ours. Demand for our products and future related products could be diminished by equivalent or superior products and technologies offered by competitors. If we are unable to innovate successfully, our existing products could become obsolete and our revenue would decline as our customers purchase our competitors' products. Developing our current and new products is expensive and time-consuming and could divert management's attention away from our core business. The success of any new product offering or product enhancements to our solution will depend on several factors, including our ability to:

- assemble sufficient resources to acquire or discover additional products;
- properly identify and anticipate physician and patient needs;
- develop and introduce new products and product enhancements in a timely manner;
- avoid infringing upon the intellectual property rights of third-parties;
- demonstrate, if required, the safety and efficacy of new products with data from preclinical studies and clinical trials;
- obtain the necessary regulatory clearances or approvals for expanded indications, new products or product modifications;
- be fully FDA-compliant with marketing of new devices or modified products;
- produce new products in commercial quantities at an acceptable cost;
- provide adequate training to potential users of our products;
- receive adequate coverage and reimbursement for procedures performed with our products; and
- develop an effective and dedicated sales and marketing team.

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

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

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

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

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

Cost-containment efforts of our customers, purchasing groups and governmental organizations could have a material adverse effect on our sales and profitability. Consolidation in the healthcare industry or group purchasing organizations could lead to demands for price concessions, which may affect our ability to sell our products at prices necessary to support our current business strategies.

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

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

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

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

Manufacturers of medical devices have a history of price competition, and we can give no assurance that we will be able to achieve satisfactory prices for our current or any new products or maintain prices at the levels we have historically achieved. Any decline in the amount that payors reimburse our customers for our products could make it difficult for customers to continue using, or to adopt, our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, or if we add more components to our systems, our gross margins will decrease, which will adversely affect our ability to invest in and grow our business. If we are unable to maintain our prices, including during any international expansion, 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, and may generally be disruptive to our business. 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. Our goal is to expand our manufacturing operations to include additional facilities, however, we do not currently have additional operational 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. To the extent any additional facilities are available and operational at the time of such events, transitioning manufacturing capacity to offset the loss of our manufacturing facility in Irvine may not be possible or may not be cost effective. 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, state and non-U.S. regulatory requirements, we may not be able to resume production on a timely basis even if we are able to replace production capacity in the event that we lose our manufacturing capacity. While we maintain property and business interruption insurance, such insurance has limits and would only cover the cost of rebuilding and relocating and lost revenue, but not general damage or losses caused by earthquakes or losses we may suffer due to our products being replaced by competitors' products. The inability to perform our research, development and manufacturing activities, combined with our limited 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, 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.

We may experience disruptions to our business as a result of the relocation of our headquarters and general expansion of our operations.

We may experience disruptions as we continue to expand our operations and facilities and execute on our growth strategy. In October 2020, we entered into a lease agreement to move our headquarters to a larger space in Irvine, California. The process of moving our business, opening new facilities and bringing operations online at new sites, including our research and development and manufacturing operations, is inherently complex and is not part of our day-to-day operations. The relocation and expansion of our headquarters and the opening of any additional new facilities cause significant disruption to our operations, divert management attention and resources and involve significant costs, all of which could have a material adverse effect on our business, financial condition and results of operations. The relocation of our headquarters and the opening of any new additional facilities with manufacturing operations will require the movement and/or installation of key manufacturing equipment and certification or recertification with applicable regulatory bodies, including the FDA. We can give no assurance that the relocation of our headquarters will be completed as planned or within the anticipated timeframe, or that we will fully realize the expected benefits of the relocation or any additional facilities that we seek to open.

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

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

Our products may become obsolete in the future.

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

We provide a limited warranty for our products.

We provide a limited warranty that our products are free of material defects and conform to specifications, and offer to repair, replace or refund the purchase price of defective products. As a result, we bear the risk of potential

warranty claims on our products. In the event that we attempt to recover some or all of the expenses associated with a warranty claim against us from our suppliers or vendors, we may not be successful in claiming recovery under any warranty or indemnity provided to us by such suppliers or vendors and any recovery from such vendor or supplier may not be adequate. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in costs to us.

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

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

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

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

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

Our future success depends in part upon patients having an experience with our products that meets their expectations in order to increase physician demand for our products as a result of positive feedback, social media and word-of-mouth. Patients may be dissatisfied if their expectations of the procedure and results, among other things, are not met. Despite what we believe to be the safety profile of our products, patients may experience adverse events such as venous dissection or puncture, embolization of clot, stroke, heart attack and death. If the

results of catheter-based thrombectomy procedures with our products do not meet the expectations of the patients, or the patient experiences adverse events, it could discourage the patient and treating physician from referring our products to others. Dissatisfied patients may express negative opinions through social media. Any failure to meet patient expectations and any resulting negative publicity could harm our reputation and future sales.

We depend on our senior management team and the loss of one or more key employees or an inability to attract and retain highly skilled employees will negatively affect our business, financial condition and results of operations.

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

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

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

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

Our products have been cleared by the FDA for specific indications and meet certain treatment parameters. If physicians expand the patient population in which they elect to use our products such that it is outside of the intended use that has been cleared by the FDA, then such use, misuse or off-label use of our products may result in outcomes and adverse events including death, potentially leading to product liability claims. Our products are not indicated for use in all patients with VTE and therefore cannot be marketed or advertised in the United States for certain uses without additional clearances from the FDA. However, we cannot prevent a physician from using our products for off-label applications or using components or products that are not our products when performing procedures with our products. There may be increased risk of injury to patients if physicians attempt to use our devices off-label. In addition, we cannot guarantee that physicians are trained by us or their peers prior to utilizing our products. Complications resulting from the use of our products off-label or use by physicians who have not been trained appropriately, or at all, may not effectively treat the applicable conditions and may expose us to product liability claims or litigation by our customers or their patients and may harm our reputation.

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

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

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

Since inception, we have incurred significant net losses and may continue to incur net losses for the foreseeable future. To date, our primary sources of capital have been the net proceeds we received through private placements of preferred stock, debt financing agreements, the sale of our common stock in our IPO and revenue from the sale of our products. As of December 31, 2020, we had $164.2 million in cash and cash equivalents and short-term investments, no long-term debt and an accumulated deficit of $27.4 million. Based on our current planned operations, we expect that our cash and cash equivalents and available borrowings will enable us to fund our operating expenses for at least 12 months from the date hereof. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

We expect to continue to invest in clinical trials and registries that are designed to provide clinical evidence of the safety and efficacy of our products, expanding our sales and marketing organization, and research and development of product improvements and future products. Moreover, we expect to incur additional expenses associated with operating as a public company, including legal, accounting, insurance, exchange listing and SEC compliance, investor relations and other expenses. Because of these and other factors, we expect to continue to incur net losses and negative cash flows from operations for the foreseeable future. Our future funding requirements will depend on many factors, including:

- The degree and rate of market acceptance of our products and catheter-based thrombectomy procedures;
- Whether we acquire third-party companies, products or technologies;
- Repayment of debt;
- The scope and timing of investment in our sales force and expansion of our commercial organization;
- The impact on our business from the ongoing and global COVID-19 pandemic, or any other pandemic, epidemic or outbreak of an infectious disease;
- The scope, rate of progress and cost of our current or future clinical trials and registries;
- The cost of our research and development activities;

- The cost and timing of additional regulatory clearances or approvals;
- The costs associated with any product recall that may occur;
- The costs of attaining, defending and enforcing our intellectual property rights;
- The terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- The emergence of competing technologies or other adverse market developments; and
- The rate at which we expand internationally.

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

In addition, the terms of debt securities issued or borrowings could impose significant restrictions on our operations including restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to pay dividends, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms, such as relinquishment or licensing of certain technologies or products that we otherwise would seek to develop or commercialize ourselves, or reserve for future potential arrangements when we might otherwise be able to achieve more favorable terms. In addition, we may be forced to work with a partner on one or more of our products or market development programs, which could lower the economic value of those programs to us.

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

We entered into a new credit facility, which may affect our ability to operate our business and secure additional financing in the future.

In August 2020, we repaid in full and terminated our credit facility with Signature Bank, or the SB Credit Facility. In September 2020, we entered into a senior secured revolving credit facility with Bank of America, or the Credit Agreement, under which we may borrow loans up to a maximum principal amount of $30.0 million. Advances under the Credit Agreement bear interest at an annual rate equal to the greater of the prime rate, the federal funds rate plus 0.50%, or the LIBOR rate, or successor rate, based upon an interest period of 30 days plus 1.00%, plus an applicable margin. Margin will be 1.25% until March 31, 2021 and then will range from 1.00% to 1.50% based on the Company's applicable fixed charge coverage ratio. As of December 31, 2020, there were no amounts outstanding under the Credit Agreement. In addition, we are required to pay an unused line fee at an annual rate ranging from 0.25% to 0.375% of the average daily unused portion of the amounts available under the Credit Agreement. We are required to make monthly interest payments on any borrowed amounts outstanding under the Credit Agreement, which may divert resources from other activities.

Our obligations under the Credit Agreement 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, dispose of assets, undergo a change in control, merge or consolidate, incur debt, make distributions, grant liens and make investments, in each case subject to certain exceptions. The covenants related to the Credit Agreement, as well as any future financing agreements into which we may enter, may restrict our ability to finance our operations and engage in, expand or otherwise pursue our business activities and strategies.

While we have not previously breached and are not currently in breach of these or any other covenants contained in our Credit Agreement 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 Credit Agreement. If not waived, future defaults could cause all of the outstanding indebtedness under the Credit Agreement 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 indebtedness, we need to generate cash from our operating activities. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory and other factors beyond our control. We cannot assure you that our business will be able to generate sufficient cash flow from operations or that future borrowings or other financings will be available to us in an amount sufficient to enable us to service our indebtedness and fund our other liquidity needs. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness instead of funding working capital, capital expenditures or other general corporate purposes, we will be less able to plan for, or react to, changes in our business, industry and in the economy generally. This may place us at a competitive disadvantage compared to our competitors that have less indebtedness.

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

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

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

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

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

liabilities for past sales, create significant administrative burdens for us, discourage users from purchasing our products, or otherwise harm our business, results of operations and financial condition.

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

As of December 31, 2020 we had U.S. federal, state, and foreign net operating loss carryforwards, or NOLs, of $30.1 million, $25.0 million, and $0.8 million, respectively, and U.S. federal and state research and development credit carryforwards of $2.3 million and $1.7 million, respectively. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change," generally defined as a greater than 50 percentage point change by value in its equity ownership over a rolling three-year period, is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, and its research and development credit carryforwards to offset future taxable income. Our existing NOLs and research and development credit carryforwards have been, and may in the future be, subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs and research and development credit carryforwards could be further limited by Sections 382 and 383 of the Code. In addition, our ability to deduct net interest expense may be limited if we have insufficient taxable income for the year during which the interest is incurred, and any carryovers of such disallowed interest would be subject to the limitation rules similar to those applicable to NOLs and other attributes. Future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Code. For these reasons, in the event we experience a future change of control, we may not be able to utilize a material portion of the NOLs, research and development credit carryforwards or disallowed interest expense carryovers, even if we attain profitability.

In addition, the tax benefit of NOLs, temporary differences and credit carryforwards are required to be recorded as an asset to the extent that we assess that realization is more likely than not. We believe that recognition of the deferred tax asset arising from these future tax benefits is not likely to be realized and, accordingly, have provided a valuation allowance of $11.9 million and $11.8 million for the years ended December 31, 2020 and 2019, respectively.

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

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

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

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

Our long-term strategy is to increase our international presence, including securing regulatory approvals in targeted countries outside the United States. We have received CE Mark approval for our ClotTriever and FlowTriever products, allowing us to commercialize in Europe. 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 pricing, market and financial pressures on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- Restrictions on the site-of-service for use of our products and the economics related thereto for physicians, providers and payors;
- Natural disasters, political and economic instability, including wars, terrorism, political unrest, outbreak of disease, boycotts, curtailment of trade and other market restrictions; and
- Regulatory and compliance risks that relate to maintaining accurate information and control over activities subject to regulation under the United States Foreign Corrupt Practices Act of 1977, or FCPA, U.K. Bribery Act of 2010 and comparable laws and regulations in other countries.

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

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

Following a national referendum and enactment of legislation by the government of the United Kingdom, the United Kingdom formally withdrew from the European Union and ratified a trade and cooperation agreement governing its future relationship with the European Union. The agreement, which is being applied provisionally from January 1, 2021 until it is ratified by the European Parliament and the Council of the European Union, addresses trade, economic arrangements, law enforcement, judicial cooperation and a governance framework including procedures for dispute resolution, among other things. Because the agreement merely sets forth a framework in many respects and will require complex additional bilateral negotiations between the United Kingdom and the European Union as both parties continue to work on the rules for implementation, significant political and economic uncertainty remains about how the precise terms of the relationship between the parties will differ from the terms before withdrawal.

These developments, or the perception that any of them could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may

significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these factors could depress economic activity and restrict our access to capital, which could have a material adverse effect on our business, financial condition and results of operations and reduce the price of our common stock.

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

In the ordinary course of our business, we may become exposed to, or collect and store, sensitive data, including procedure-based information and legally-protected health information, credit card, and other financial information, insurance information, and other potentially personally identifiable information. We also store sensitive intellectual property and other proprietary business information. We are taking measures to implement policies and procedures designed to ensure compliance with applicable data security and privacy-related laws and regulations and protect sensitive information from unauthorized access or disclosure. However, our information technology, or IT, and infrastructure, and that of our third-party billing and collections provider and other technology partners and providers, may be vulnerable to cyber attacks by hackers or viruses or breaches due to employee error, malfeasance or other disruptions. We rely extensively on IT systems, networks and services, including internet sites, data hosting and processing facilities and tools, physical security systems and other hardware, software and technical applications and platforms, some of which are managed, hosted, provided and/or used by third-parties or their vendors, to assist in conducting our business. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems or infrastructure, by our workforce, others with authorized access to our systems or unauthorized persons could negatively impact operations. The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our or our third-party providers' systems, portable media or storage devices. For example, companies have experienced an increase in phishing and social engineering attacks from third-parties in connection with the COVID-19 global pandemic. We could also experience a business interruption, theft of confidential information or reputational damage from industrial espionage attacks, malware or other cyber-attacks, which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature and expect them to continue as cybersecurity threats have been rapidly evolving in sophistication and becoming more prevalent in the industry. We are investing in protections and monitoring practices of our data and IT to reduce these risks and continue to monitor our systems on an ongoing basis for any current or potential threats. There can be no assurance, however, that our efforts will prevent breakdowns or breaches to our or our third-party providers' databases or systems, and such breakdowns or breaches could adversely affect our business, our financial condition and our reputation.

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

The FCPA and similar worldwide anti-bribery laws prohibit companies and their intermediaries from corruptly providing any benefits to government officials for the purpose of obtaining or retaining business. The U.S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, the U.S. Foreign Corrupt Practices Act, or the FCPA, and other federal statutes and regulations, including those established by the Office of Foreign Assets Control, or OFAC. In addition, the U.K. Bribery Act of 2010, or the Bribery Act, prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that fails to prevent bribery by anyone associated with the organization can be charged under the Bribery Act unless the organization can establish the defense of

having implemented adequate procedures to prevent bribery. Under these laws and regulations, as well as other anti-corruption laws, anti-money laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties and other sanctions.

We are in the process of further enhancing policies designed to ensure compliance by us and our directors, officers, employees, representatives, consultants and agents with the FCPA, OFAC restrictions, the Bribery Act and other export control, anti-corruption, anti-money-laundering and anti-terrorism laws and regulations. In the future, we may operate in parts of the world that have experienced governmental corruption to some degree. Moreover, because of the significant role government entities play in the regulation of many foreign healthcare markets, we may be exposed to heightened FCPA and similar risks arising from our efforts to seek regulatory approval of and reimbursement for our products in such countries. We cannot assure you that our internal control policies and procedures will protect us from improper acts committed by our employees or agents, nor can we assure you that our business partners have not engaged and will not engage in conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct. Violations of these laws, or allegations of such violations, would significantly disrupt our business and have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

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

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

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

We rely on a combination of contractual provisions, confidentiality procedures and patent, copyright, trademark, trade secret and other intellectual property laws to protect the proprietary aspects of our products, brands, technologies and data. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Our success will depend, in part, on preserving our trade secrets, maintaining the security of our data and know-how and obtaining and maintaining other intellectual property rights. We may not be able to obtain or maintain intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage.

In addition, despite our efforts to enter into confidentiality agreements with our employees, consultants, clients and other vendors who have access to such information, our trade secrets, data and know-how could be subject to

unauthorized use, misappropriation, or disclosure to unauthorized parties, and could otherwise become known or be independently discovered by third parties. Our intellectual property, including trademarks, could be challenged, invalidated, infringed, and circumvented by third parties, and our trademarks could also be diluted, declared generic or found to be infringing on other marks. If any of the foregoing occurs, we could be forced to re-brand our products, resulting in loss of brand recognition and requiring us to devote resources to advertising and marketing new brands, and suffer other competitive harm. Third parties may also adopt trademarks similar to ours, which could harm our brand identity and lead to market confusion.

Failure to obtain and maintain intellectual property rights necessary to our business and failure to protect, monitor and control the use of our intellectual property rights could negatively impact our ability to compete and cause us to incur significant expenses. The intellectual property laws and other statutory and contractual arrangements in the United States and other jurisdictions we depend upon may not provide sufficient protection in the future to prevent the infringement, use, violation or misappropriation of our trademarks, data, technology and other intellectual property and services, and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated or otherwise violated.

We rely, in part, on our ability to obtain, maintain, expand, enforce, and defend the scope of our intellectual property portfolio or other proprietary rights, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights. The process of applying for and obtaining a patent is expensive, time consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions where protection may be commercially advantageous, or we may not be able to protect our proprietary rights at all. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary.

We own numerous issued patents and pending patent applications. As of December 31, 2020, we held 19 U.S. patents, which are expected to expire between November 2032 and April 2037, 17 pending U.S. patent applications, four issued foreign patents, 16 pending foreign patent applications and four pending Patent Cooperation Treaty applications, excluding our licensed and sublicensed patents. We also licensed two U.S. patents and sublicensed one U.S. patent. The patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and therefore, the scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty.

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

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

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

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

Even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. Issued patents may be challenged, narrowed, invalidated or circumvented. Decisions by courts and governmental patent agencies may introduce uncertainty in the enforceability or scope of patents owned by or licensed to us. Furthermore, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own products and practicing our own technology. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid, unenforceable or not infringed; competitors may then be able to market products and use manufacturing and analytical processes that are substantially similar to ours. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

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

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

The U.S. Patent and Trademark Office, or USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and

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

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

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

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

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

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

matters can be time consuming, costly to defend in litigation, divert management's attention and resources, damage our reputation and brand and cause us to incur significant expenses or make substantial payments. Vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third-party's patent or trademark or of misappropriating a third-party's trade secret.

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

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

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

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

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

Any litigation or claim against us, even those without merit and even those where we prevail, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages (which may be increased up to three times of awarded damages) and/or substantial royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way

that would not infringe the intellectual property rights of others. We could encounter delays in product introductions while we attempt to develop alternative methods or products. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products.

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

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

Additionally, we may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent or other intellectual property infringement proceeding, a court may decide that a patent or other intellectual property of ours is invalid or unenforceable, in whole or in part, construe the patent's claims or other intellectual property narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents or other intellectual property do not cover the technology in question. Furthermore, even if our patents or other intellectual property are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. An adverse result in any litigation proceeding could put one or more of our patents or other intellectual property at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business position, financial condition and results of operations.

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

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect and some courts are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, collaborators and others upon the commencement of their relationship with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection for our trade secrets, know-how, or other proprietary information in the event the unwanted use is outside the scope of the provisions of the contracts or in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how, or other proprietary information. There can be no assurance that such third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. Despite the protections we do place on our intellectual property or other proprietary rights, monitoring unauthorized use and disclosure of our intellectual

property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology. To the extent our intellectual property or other proprietary information protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or otherwise obtain and use our products or technology, or develop similar technology. Our competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our products, brand and business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of our products and harm our business, the value of our investment in development or business acquisitions could be reduced and third parties might make claims against us related to losses of their confidential or proprietary information. Any of the foregoing could materially and adversely affect our business, financial condition and results of operations.

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

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach.

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

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trademarks and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents and trademarks or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent and trademarks rights in foreign

jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and trademarks in those jurisdictions, as well as elsewhere at risk of being invalidated or interpreted narrowly and our patent or trademark applications at risk, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Certain countries in Europe and certain developing countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

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

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

Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property we regard as our own, based on claims that our employees or consultants have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against any other claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies or features that are important or essential to our products could have a material adverse effect on our business, financial condition and results of operations, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have an adverse effect on our business, financial condition and results of operations.

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, certifications or approvals for our future products or modifications to our current products, and failure to timely obtain necessary clearances, certifications or approvals for our future products or modifications to our current products would adversely affect our ability to grow our business.

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

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

In the United States, we have obtained clearance of our ClotTriever and FlowTriever products through the 510(k) clearance process. Any modification to these systems that has not been previously cleared may require us to submit a new 510(k) premarket notification and obtain clearance, or submit a PMA and obtain FDA approval prior to implementing the change. Specifically, any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have made modifications to 510(k)-cleared products in the past and have determined based on our review of the applicable FDA regulations and guidance that in certain instances new 510(k) clearances or PMA approvals were not required. We may make modifications or add additional features in the future that we believe do not require a new 510(k) clearance or approval of a PMA. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMA applications for modifications to our previously cleared products for which we have concluded that new

clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.

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

- Our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;
- The disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of our clinical trials or the interpretation of data from preclinical studies or clinical trials;
- Serious and unexpected adverse device effects experienced by participants in our clinical trials;
- The data from our preclinical studies and clinical trials may be insufficient to support clearance or approval, where required;
- Our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- The manufacturing process or facilities we use may not meet applicable requirements; and
- The potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

In order to sell our products in member countries of the European Union, or the EU, our products must comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93/42/EEC). Compliance with these requirements is a prerequisite to be able to affix the CE mark to our products, without which they cannot be sold or marketed in the EU. 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 (risk) classification. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can self-declare 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 or licensed by a member state of the EU 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 and national member states laws, we would be unable to continue to affix the CE mark to our products, which would prevent us from selling them within the EU.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Following the end of the "Brexit" Transition Period, from 1 January 2021 onwards, the Medicines and Healthcare Products Regulatory Agency ("MHRA") will be responsible for the UK medical device market. The new

regulations will require medical devices to be registered with the MHRA (but manufacturers will be given a grace period of four to 12 months to comply with the new registration process). Manufacturers based outside the UK will need to appoint a UK Responsible Person to register devices with the MHRA in line with the grace periods. By July 1, 2023, in the UK (England, Scotland, and Wales), all medical devices will require a UKCA (UK Conformity Assessed) mark but CE marks issued by EU Notified Bodies will remain valid until this time. However, UKCA marking alone will not be recognized in the EU. The rules for placing medical devices on the Northern Ireland market will differ from those in the UK.

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

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

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

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

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

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

Legislative or regulatory reforms in the United States or the EU may make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products after clearance or approval is obtained."

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

The methods used in, and the facilities used for, the manufacture of our products must comply with the FDA's QSR, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices. Furthermore, we are required to maintain, and to verify that our suppliers maintain, facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. No FDA inspection has been conducted at our current facility in Irvine, California. As described below, we initiated a voluntary recall of three lots of our Triever aspiration catheters in March 2020, and it is possible that the FDA will conduct an announced or unannounced inspection of our facility to review our procedures and operations. Our products will also be subject to similar state regulations, various laws and regulations of foreign countries governing manufacturing and a requirement for adherence to industry standards of the International Standards Organization, or ISO, in connection with our medical device operations to maintain future CE marks.

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

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

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

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

We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an

adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance or approval, seizure of our products or delay in clearance or approval of future products.

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

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

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

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

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

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

Any future sales of our products outside of the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the United States. While the regulations of some countries may not impose barriers to marketing and selling our products or

only require notification, others require that we obtain the clearance or approval of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations, clearances or approvals, can be expensive and time-consuming, and we may not receive regulatory clearances or approvals in each country in which we plan to market our products or we may be unable to do so on a timely basis. The time required to obtain registrations, clearances or approvals, if required by other countries, may be longer than that required for FDA clearance or approval, and requirements for such registrations, clearances or approvals may significantly differ from FDA requirements. If we modify our products, we may need to apply for regulatory clearances or approvals before we are permitted to sell the modified product.

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

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

Legislative or regulatory reforms in the United States or the EU may make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. These proposals have not yet been finalized or adopted, although 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 issued revised final 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 maintains a list of device types appropriate for the "safety and performance based" pathway and continues to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as recommended testing methods, where feasible. The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain new 510(k) clearances or otherwise create competition that may negatively affect our business.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of

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

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay regulatory clearance or approval of our product candidates. For example, the results of the 2020 U.S. Presidential Election may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the 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 whether or how these orders will be implemented, or whether they will be rescinded and replaced under the Biden administration. The policies and priorities of the new administration are unknown and could materially impact the regulations governing our products.

On May 25, 2017, the EU Medical Devices Regulation (Regulation 2017/745)entered into force, which repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EU member states, regulations are directly applicable (i.e., without the need for adoption of EEA member state laws implementing them) in all EU member states and are intended to eliminate current differences in the regulation of medical devices among EU member states. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensure a high level of safety and health while supporting innovation.

The Medical Devices Regulation was originally intended to become effective three years after publication, but in April 2020 the transition period was extended by the European Parliament and the Council of the EU by an additional year – until May 26, 2021. Devices lawfully placed on the market pursuant to the EU Medical Devices Directive prior to May 26, 2021 may generally continue to be made available on the market or put into service until May 26, 2025.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 design and manufacture products and how we conduct our business in the EU.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Following the end of the "Brexit" Transition Period, from 1 January 2021 onwards, the Medicines and Healthcare Products Regulatory Agency ("MHRA") will be responsible for the UK medical device market. The new regulations will require medical devices to be registered with the MHRA (but manufacturers will be given a grace period of four to 12 months to comply with the new registration process). Manufacturers based outside the UK will need to appoint a UK Responsible Person to register devices with the MHRA in line with the grace periods. By July 1, 2023, in the UK (England, Scotland, and Wales), all medical devices will require a UKCA (UK Conformity Assessed) mark but CE marks issued by EU Notified Bodies will remain valid until this time. However, UKCA

marking alone will not be recognized in the EU. The rules for placing medical devices on the Northern Ireland market will differ from those in the UK.

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

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

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

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

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new devices to be reviewed and/or approved or cleared by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone inspections of foreign manufacturing facilities and products, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Other regulatory authorities may adopt similar restrictions or other policy measures in response to the

COVID-19 pandemic. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting business as usual or conducting inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

Clinical testing is difficult to design and implement, can take many years, can be expensive and carries uncertain outcomes. We are currently enrolling patients in our CLOUT and FLASH registries and may in the future conduct additional clinical trials for our future products. The results of preclinical studies and clinical trials of our products conducted to date and ongoing or future studies and trials of our current, planned or future products may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical trials have nonetheless failed to produce strong results in later clinical trials. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials. We incur substantial expense for, and devote significant time to, clinical trials but cannot be certain that the trials will continue to result in commercial revenue. Failure can occur at any stage of clinical testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned.

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

- We may be required to submit an Investigational Device Exemption, or IDE, application to FDA, which must become effective prior to commencing certain human clinical trials of medical devices, and FDA may reject our IDE application and notify us that we may not begin clinical trials;
- Regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- Regulators and/or institutional review boards, or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- We may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- Clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- The number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;

- Our third-party contractors, including those manufacturing products or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- We might have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- We may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and/or regulatory authorities for re-examination;
- Regulators, IRBs, or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- The cost of clinical trials may be greater than we anticipate;
- Clinical sites may not adhere to our clinical protocol or may drop out of a clinical trial;
- We may be unable to recruit a sufficient number of clinical trial sites;
- Regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- Approval policies or regulations of FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval; and
- Our current or future products may have undesirable side effects or other unexpected characteristics.

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

- delays in receiving authorizations from local regulatory authorities to initiate planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruptions in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue such clinical trials altogether;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- risk that participants enrolled in our clinical trials will contract COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;

- delays in necessary interactions with local regulators, ethics committees and other third parties and contractors due to limitations in employee resources or forced furlough of government employees;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and
- refusal of the FDA to accept data from clinical trials in affected geographies.

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

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

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

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

We are subject to certain federal, state and foreign fraud and abuse laws and physician payment 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 payment laws. Our business practices and relationships with providers are subject to scrutiny under these laws. 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. The U.S. government has interpreted this law broadly to apply to the marketing and sales activities of manufacturers. In addition, 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 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. 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;

- The federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- The Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- The federal Physician Payments Sunshine Act which requires certain applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, or CHIP, to report annually to the DHHS Centers for Medicare and Medicaid Services, or CMS, information related to payments and other transfers of value to physicians, which is defined broadly to include other healthcare providers and teaching hospitals, and applicable manufacturers and group purchasing organizations, to report annually ownership and investment interests held by physicians and their immediate family members. Additionally, beginning in 2022, such obligations will include payments and other transfers of value provided in the previous year to certain other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives;

- 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 and state laws related to insurance fraud in the case of claims involving private insurers.

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

Any action brought against us for violations of these laws or regulations, even if successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We may be subject to private qui tam actions brought by individual whistleblowers on behalf of the federal or state governments, with potential liability under the federal False Claims Act including mandatory treble damages and significant per-claim penalties.

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

Our activities, including those relating to providing billing, coding, coverage and reimbursement information about procedures using our products to our customers and the sale and marketing of our products, may be subject to scrutiny under these laws. The growth of our business and sales organization and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to significant penalties, including significant criminal, civil, and administrative penalties, damages, fines, exclusion from participation in government programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputation harm and disgorgement and we could be required to curtail, restructure or cease our operations. Any of the foregoing consequences will negatively affect our business, financial condition and results of operations.

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

In the conduct of our business, we may at times process personal data, including health-related personal data. The U.S. federal government and various states have adopted or proposed laws, regulations, guidelines and rules for the collection, distribution, use and storage of personal information of individuals. We may also be subject to U.S. federal rules, regulations and guidance concerning data security for medical devices, including guidance from the FDA. Further, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH Act, and their respective implementing regulations, impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and

transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements. Failure to comply with the HIPAA privacy and security standards can result in significant civil monetary penalties, and, in certain circumstances, criminal penalties with fines and/or imprisonment. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages on behalf of residents of his or her state.

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. 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 GDPR, govern the privacy and security of health-related and other personal 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 CCPA on June 28, 2018, which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. Further, the CPRA recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In Europe, the GDPR went into effect in May 2018 and introduces strict requirements for processing the personal data of individuals within the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenue of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the European Union and the United States remains uncertain. For example, in 2016, the European Union and United States agreed to a transfer framework for data transferred from the European Union to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union. Further, from January 1, 2021, companies have to comply with the GDPR and also the United Kingdom GDPR, or the UK GDPR, which, together with the amended United Kingdom Data Protection Act 2018, retains the GDPR in United Kingdom national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. Currently there is a four to six-month grace period agreed in the European Union and United Kingdom Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. However, it is not clear whether (and when) an adequacy decision may be granted by the European Commission enabling data transfers from European Union member states to the United Kingdom long term without additional measures. These changes may lead to additional costs and increase our overall risk exposure.

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

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

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

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

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

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

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

Our research, development and manufacturing operations involve the use of hazardous substances, such as isopropyl alcohol and various adhesives. We are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, handling, generation, manufacture, treatment,

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

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

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

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

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

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

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. The Budget Control Act of 2011, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further 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. In addition, the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. It is unclear what effect new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations or cash flows.

We expect additional state and federal healthcare policies and reform measures to be adopted in the future, any of which could limit reimbursement for healthcare products and services or otherwise result in reduced demand for our FlowTriever and/or ClotTriever or additional pricing pressure and have a material adverse effect on our industry generally and on our customers. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may negatively affect our business, financial condition and results of operations. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

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

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

Risks Related to Ownership of Our Common Stock

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

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

- Changes in analysts' estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' estimates;
- Quarterly variations in our or our competitors' results of operations;
- Periodic fluctuations in our revenue, which could be due in part to the way in which we recognize revenue;
- The financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;
- Future sales of our common stock or other securities, by us or our stockholders, as well as the anticipation of lock-up releases or lock-up waivers;
- The trading volume of our common stock;
- General market conditions and other factors unrelated to our operating performance or the operating performance of our competitors;

- Changes in reimbursement by current or potential payors;
- Changes in operating performance and stock market valuations of other technology companies generally, or those in the medical device industry in particular;
- Actual or anticipated changes in regulatory oversight of our products;
- The results of our clinical trials;
- The loss of key personnel, including changes in our board of directors and management;
- Product recalls or other problems associated with our products;
- Legislation or regulation of our market;
- Lawsuits threatened or filed against us, including litigation by current or former employees alleging wrongful termination, sexual harassment, whistleblower or other claims;
- The announcement of new products or product enhancements by us or our competitors;
- Announced or completed acquisitions of businesses or technologies by us or our competitors;
- Announcements related to patents issued to us or our competitors and related litigation; and
- Developments in our industry.

In addition, the trading prices for common stock of other medical device companies have been highly volatile as a result of the COVID-19 pandemic. The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

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

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

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

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

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

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

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

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

As of December 31, 2020, our officers, directors and principal stockholders each holding more than 5% of our common stock collectively control approximately 48% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to control the management and affairs of the Company and most matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change of control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of our other stockholders.

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

Under Section 404 of the Sarbanes-Oxley Act, we will be required to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting beginning with our Annual Report on Form 10-K for the year ended December 31, 2021. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual and interim financial statements will not be detected or prevented on a timely basis. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting in our first annual report required to be filed with the SEC following the date we are no longer an "emerging growth company".

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

In connection with the preparation of our financial statements for the year ended December 31, 2019, we concluded there were material weaknesses in our internal controls over financial reporting. The material weaknesses that were identified related to the segregation of duties throughout various financial processes and our documentation of internal controls. While we believe we have remediated the previously identified material weaknesses, we may have future material weaknesses.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. The effectiveness of our controls and procedures may be limited by a variety of factors, including:

- Faulty human judgment and simple errors, omissions or mistakes;

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

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

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

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the U.S. Securities and Exchange Commission. We believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

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

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

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

- Our board of directors has the exclusive right to expand the size of our board of directors and to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- Our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three-year terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- Our stockholders may not act by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- A special meeting of stockholders may be called only by the chair of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- Our amended and restated certificate of incorporation prohibits cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- Our board of directors may alter our bylaws without obtaining stockholder approval;
- The required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- Stockholders must provide advance notice and additional disclosures in order to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of our company; and
- Our board of directors is authorized to issue shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer.

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

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

Our amended and restated certificate of incorporation specifies that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the Court of Chancery of the State of

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

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

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

General Risk Factors

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

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

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

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

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

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

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

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

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

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

We do not carry specific hazardous waste insurance coverage, and our insurance policies generally exclude coverage for damages and fines arising from hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

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

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

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

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

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

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate headquarters, which includes our manufacturing facility, is located in Irvine, California, where we occupy a facility totaling approximately 40,000 square feet under a lease agreement that expires in September 2024. This facility contains dedicated research and development, training, education and manufacturing spaces.

In October 2020, we entered into a ten-year lease for a larger facility in Irvine, California, totaling approximately 120,000 square feet. The new lease is expected to commence in the second quarter of 2021, at which time we will move all of our operations to this new facility. The lease contains two optional extension periods of five years each.

We believe these facilities are 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.

Item 3. Legal Proceedings.

We are not currently a party to any material legal proceedings. From time to time we may become involved in legal proceedings or investigations which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is traded on the Nasdaq Global Select Market under the symbol NARI. Public trading of our common stock began on May 22, 2020. Prior to that, there was no public market for our common stock. The following table sets forth for the periods indicated the high and low sales prices per share of our common stock on the Nasdaq Global Select Market:

	Low	High
Fiscal year ending December 31, 2020		
First quarter [1]	$ —	$ —
Second quarter (beginning May 22, 2020)	39.55	54.86
Third quarter	46.16	84.91
Fourth quarter	58.66	88.75

(1) We completed our public offering during the second quarter of 2020, so no data is available for first quarter.

Stockholders

As of March 1, 2021, there were approximately 30 holders of record of our common stock. This number does not include stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid, and do not anticipate declaring or paying in the foreseeable future, any cash dividends on our capital stock. Any future determination as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors, subject to applicable laws and will depend on then existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects, and other factors our board of directors may deem relevant.

Unregistered sales of equity securities

None.

Purchases of equity securities by the issuer and affiliated purchasers

None.

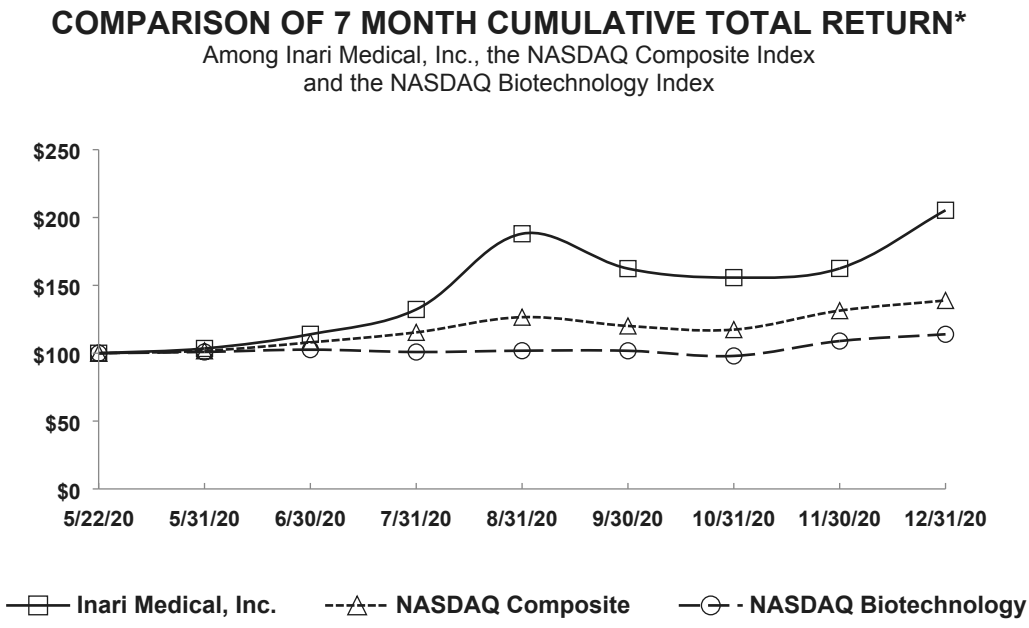
Securities authorized for issuance under equity compensation plans

The information required by this item with respect to our equity compensation plans is incorporated by reference to our definitive proxy statement relating to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates.

Stock Performance Graph

The graph below shows a comparison, from May 22, 2020 (the date our common stock commenced trading on the Nasdaq) through December 31, 2020, of the cumulative total return to stockholders of our common stock relative to the Nasdaq Composite Index ("NBI") and the Nasdaq Biotechnology Index ("IXIC"). The graph assumes that

$100 was invested in each of our common stock, the Nasdaq Composite and the Nasdaq Biotechnology at their respective closing prices on May 22, 2020 and assumes reinvestment of gross dividends. The stock price performance shown in the graph represents past performance and should not be considered an indication of future stock price performance. This graph is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference into any of our filings under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.



*$100 invested on 5/22/20 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

Item 6. Selected Financial Data.

The consolidated statements of operations data for the fiscal years ended December 31, 2020, 2019, and 2018, and the selected consolidated balance sheets data as of December 31, 2020 and 2019, are derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

The selected consolidated balance sheet data as of December 31, 2018 is derived from our audited consolidated financial statements which are not included in this Annual Report on Form 10-K.

The information set forth below is not necessarily indicative of results of future operations, and should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Consolidated Financial Statements and related notes included in Part II, Item 8, "Consolidated Financial Statements and Supplementary Data" in this Annual Report on Form 10-K.

	Years Ended December 31,		
Consolidated Statement of Operations Data:	**2020**	**2019**	**2018**
Revenue	$ 139,670	$ 51,129	$ 6,829
Cost of goods sold	13,106	5,911	1,281
Gross profit	126,564	45,218	5,548
Operating expenses			
Research and development	18,399	7,220	3,990
Selling, general and administrative	89,746	37,197	10,698
Total operating expenses	108,145	44,417	14,688
Income (loss) from operations	18,419	801	(9,140)
Other income (expense)			
Interest income	484	89	92
Interest expense	(1,135)	(920)	(887)
Change in fair value of warrant liabilities	(3,317)	(957)	(85)
Other expenses	(662)	(205)	(133)
Total other expenses	(4,630)	(1,993)	(1,013)
Net income (loss)	$ 13,789	$ (1,192)	$ (10,153)
Net income (loss) per share			
Basic	$ 0.43	$ (0.20)	$ (2.01)
Diluted	$ 0.27	$ (0.20)	$ (2.01)
Weighted average common shares used to compute net income (loss) per share,			
Basic	32,033,827	5,887,542	5,056,743
Diluted	51,554,996	5,887,542	5,056,743

	As of December 31,		
Consolidated Balance sheet Data:	**2020**	**2019**	**2018**
Cash, cash equivalents and short-term investments	$ 164,210	$ 23,639	$ 21,834
Working capital	191,835	30,538	23,837
Total assets	214,092	44,546	26,901
Total liabilities	13,838	29,520	12,177
Total warrant liabilities	—	1,169	213
Redeemable convertible preferred stock	—	54,170	54,170
Total stockholders' equity (deficit)	200,254	(39,144)	(39,446)

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes included in Part II, Item 8 of this Annual Report on Form 10-K.

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Exchange Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended ("the Exchange Act"). Forward-looking statements are identified by words such as "believe," "will," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "could," "potentially" or the negative of these terms or similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in Part I, Item 1A — "Risk Factors," and elsewhere in this report. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

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 treatment of DVT. Our FlowTriever product is the first thrombectomy system FDA-cleared for the treatment of pulmonary embolism, or PE, and is also FDA-cleared for clot in transit in the right atrium.

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

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

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

Prior to our IPO, our primary sources of capital were private placements of preferred stock, debt financing arrangements and revenue from sales of our products. Since inception, we had raised a total of approximately $54.2 million in net proceeds from private placements of preferred stock. As of December 31, 2020, we had cash and cash

equivalents and short-term investments of $164.2 million, no long-term debt outstanding and an accumulated deficit of $27.4 million.

For the year ended December 31, 2020, we generated revenue of $139.7 million, with a gross margin of 90.6% and net income of $13.8 million, compared to revenue of $51.1 million, with a gross margin of 88.4% and net loss of $1.2 million for the year ended December 31, 2019.

COVID-19

In December 2019, a novel strain of coronavirus, SARS-CoV-2, was identified in Wuhan, China. Since then, SARS-CoV-2, and the resulting disease, COVID-19, has spread to most countries, including all 50 states in the United States. In response to the pandemic, numerous state and local jurisdictions imposed and may continue to impose from time to time "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. For example, in the United States, governmental authorities recommended, and in certain cases required, that elective, specialty and other procedures and appointments be suspended or canceled to avoid non-essential patient exposure to medical environments and potential infection with COVID-19 and to focus limited resources and personnel capacity toward the treatment of COVID-19 patients. Similarly, in March 2020, the governor of California, where our headquarters are located, issued a "stay at home" order limiting non-essential activities, travel and business operations. In December 2020, the governor of California issued an additional regional "stay at home" order with tiered restrictions based on each region's ICU availability. Such orders or restrictions resulted in reduced operations at our headquarters (including our manufacturing facility), work stoppages, slowdowns and delays, travel restrictions and cancellation of events. Taken as a whole, these orders and restrictions significantly decreased the number of procedures performed using our products, particularly during the second quarter of 2020, and otherwise negatively impacted our operations, including new customer procurement and onboarding.

In response to the impact of COVID-19, beginning in the second quarter of 2020, we implemented a variety of measures to help us manage through its impact and position us to resume operations quickly and efficiently once these restrictions were lifted. These measures existed across several operational areas and included:

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

Despite the negative impacts from COVID-19, for the year ended December 31, 2020, we completed our IPO and approximately 13,200 procedures were performed using our products, compared to approximately 4,600

procedures in the year ended December 31, 2019. During the second quarter of 2020, we experienced disruptions to our procedure volume beginning in mid-March as a result of COVID-19, and weekly procedure volumes declined by approximately 40% by mid-April when compared to weekly procedure volumes in early March. The decrease in procedure volume impacted DVT procedures and PE procedures relatively equally, with both types of procedures declining during this period. However, we saw a recovery in procedure volume in June that was higher than our pre-COVID-19 peak. During the third and fourth quarters, we saw continued sequential growth beyond previous quarters.

While we are encouraged by our third and fourth quarters results, we are aware that the actual and perceived impact of COVID-19 is changing and cannot be predicted. As a result, we cannot assure you that our recent procedure volumes are indicative of future results or that we will not experience additional negative impacts associated with COVID-19, which could be significant. The COVID-19 pandemic has negatively impacted our business, financial condition and results of operations by significantly decreasing and delaying the number of procedures performed using our products, and we expect the pandemic could continue to negatively impact our business, financial condition and results of operations.

Procedure Volume

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

	Three Months Ended							
Procedures[1]	**Dec 31, 2020**	**Sept 30, 2020**	**June 30, 2020**	**March 31, 2020**	**Dec 31, 2019**	**Sept 30, 2019**	**June 30, 2019**	**March 31, 2019**
DVT	2,400	2,000	1,400	1,300	1,000	700	500	300
PE	2,200	1,700	1,100	1,100	800	600	400	300
	4,600	3,700	2,500	2,400	1,800	1,300	900	600

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

Components of our Results of Operations

Revenue

We currently derive all our revenue from the sale of our ClotTriever and FlowTriever products to hospitals in the United States. Our customers typically purchase an initial stocking order of our products and then reorder replenishment product as procedures are performed. No single customer accounted for 10% or more of our revenue during the years ended December 31, 2020, 2019 and 2018. For the year ended December 31, 2020, approximately 55% of our customers used both of our products, 33% used ClotTriever only and 12% used FlowTriever only. We expect revenue to increase in absolute dollars as we expand our sales organization and sales territories, add customers, expand the base of physicians that are trained to use our products, expand awareness of our products with new and existing customers and as physicians perform more procedures using our products. Revenue for ClotTriever and FlowTriever products as a percentage of total revenue is as follows:

	Years Ended December 31,		
	2020	**2019**	**2018**
ClotTriever	37%	38%	41%
FlowTriever	63%	62%	59%

For the year ended December 31, 2020, our blended revenue per procedure was over $9,100. Blended revenue per procedure represents the average of the average selling price per ClotTriever and the average price per FlowTriever procedure.

Cost of Goods Sold and Gross Margin

We manufacture and/or assemble all 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, however, we also expect to realize opportunities to increase operating leverage in our manufacturing operations.

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, adopt new manufacturing processes and technologies, and as we expand internationally.

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

Research and Development Expenses

Research and development, or R&D, expenses consist primarily of engineering, product development, clinical studies to develop and support our products, regulatory expenses, and other costs associated with products that are in development. These expenses include employee compensation, including stock-based compensation, supplies, consulting, prototyping, testing, materials, travel expenses, depreciation and an allocation of facility overhead expenses. Additionally, R&D expenses include costs associated with our clinical trials and registries, including clinical study design, clinical study site initiation and study costs, data management, and internal and external costs associated with our regulatory compliance, including the costs of outside consultants and contractors that assist in the process of submitting and maintaining regulatory filings. We expense R&D costs as incurred. We expect R&D expenses as a percentage of revenue to vary over time depending on the level and timing of our new product development efforts, as well as our clinical development, clinical trials and registries and other related activities.

Selling, General and Administrative Expenses

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

Interest Income

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

Interest Expense

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

Change in Fair Value of Warrant Liabilities

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

Results of Operations

Comparison of the years ended December 30, 2020 and 2019

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

	Years Ended December 31,				
	2020	%	2019	%	Change $
Revenue	$ 139,670	100.0%	$ 51,129	100.0%	$ 88,541
Cost of goods sold	13,106	9.4%	5,911	11.6%	7,195
Gross profit	126,564	90.6%	45,218	88.4%	81,346
Operating expenses:					
Research and development	18,399	13.2%	7,220	14.1%	11,179
Selling, general and administrative	89,746	64.3%	37,197	72.8%	52,549
Total operating expenses	108,145	77.5%	44,417	86.9%	63,728
Income from operations	18,419	13.1%	801	1.5%	17,618
Other income (expense)					
Interest income	484	0.3%	89	0.2%	395
Interest expense	(1,135)	(0.8%)	(920)	(1.8%)	(215)
Other expenses	(662)	(0.5%)	(205)	(0.4%)	(457)
Change in fair value of warrant liabilities	(3,317)	(2.4%)	(957)	(1.9%)	(2,360)
Total other expenses, net	(4,630)	(3.4%)	(1,993)	(3.9%)	(2,637)
Net income (loss)	$ 13,789	9.7%	$ (1,192)	(2.4%)	$ 14,981

Revenue. Revenue increased $88.6 million, or 173%, to $139.7 million during the year ended December 31, 2020, compared to $51.1 million during the year ended December 31, 2019. The increase in revenue was due primarily to an increase in the number of products sold. The increase in revenue was offset in part by the negative impact of the COVID-19 pandemic on procedure volume and new orders during the year ended December 31, 2020.

Cost of Goods Sold and Gross Margin. Cost of goods sold increased $7.2 million, or 122%, to $13.1 million during the year ended December 31, 2020, compared to $5.9 million during the year ended December 31, 2019. This increase was due to the increase in the number of products sold and additional manufacturing overhead costs incurred as we invested significantly in our operational infrastructure to support anticipated future growth. Cost of goods sold for the year ended December 31, 2020 was also impacted by $1.1 million in idle production capacity costs associated with the COVID-19 pandemic. Gross margin for the year ended December 31, 2020 increased to 90.6%, compared to 88.4% for the year ended December 31, 2019 due to an increase in the average selling prices of our products and improved operating leverage.

Research and Development Expenses. R&D expenses increased $11.2 million, or 155%, to $18.4 million during the year ended December 31, 2020, compared to $7.2 million during the year ended December 31, 2019. The

increase in R&D expenses was primarily due to increases of $5.5 million of personnel-related expenses, $2.5 million of clinical study and registry expenses, $2.4 million in materials and supplies, and $0.7 million in professional fees, in support of our growth drivers to increase our new product pipeline and build the clinical evidence base.

Selling, General and Administrative Expenses. SG&A expenses increased $52.5 million, or 141%, to $89.7 million during the year ended December 31, 2020, compared to $37.2 million during the year ended December 31, 2019. The increase in SG&A costs was primarily due to an increase of $41.9 million in personnel-related expenses as a result of increased headcount across our organization and increased commissions due to higher revenue, an increase of $3.8 million in professional fees, an increase of $2.4 million in insurance costs, an increase of $0.8 million in facility costs, and an increase in $0.8 million in travel costs.

Interest Income. Interest income increased by $395,000 to $484,000 during the year ended December 31, 2020, compared to $89,000 during the year ended December 31, 2019. The increase in interest income was primarily due to an increase in average cash, cash equivalents and short-term investments during the year ended December 31, 2020, compared to the year ended December 31, 2019, resulting from the receipt of IPO proceeds in May 2020.

Interest Expense. Interest expense increased by $0.2 million or 23% during the year ended December 31, 2020, compared to the year ended December 31, 2019. This increase was primarily due to higher average borrowings under our credit facilities during the year ended December 31, 2020.

Change in Fair Value of Warrant Liabilities. Change in fair value of warrant liabilities increased $2.4 million to $3.3 million for the year ended December 31, 2020, compared to $0.9 million for year ended December 31, 2019. This increase was due to the fair value remeasurement of our convertible preferred stock warrant liabilities.

Other expenses. Other expenses for the year ended December 31, 2020 consisted primarily of a $0.7 million loss on extinguishment of debt related to the payoff of our debt facility with Signature Bank.

Comparison of the years ended December 30, 2019 and 2018

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

	Years Ended December 31,				
	2019	%	2018	%	Change $
Revenue	$ 51,129	100.0%	$ 6,829	100.0%	$ 44,300
Cost of goods sold	5,911	11.6%	1,281	18.8%	4,630
Gross profit	45,218	88.4%	5,548	81.2%	39,670
Operating expenses:					
Research and development	7,220	14.1%	3,990	58.4%	3,230
Selling, general and administrative	37,197	72.8%	10,698	156.7%	26,499
Total operating expenses	44,417	86.9%	14,688	215.1%	29,729
Income (loss) from operations	801	1.5%	(9,140)	(133.9%)	9,941
Other income (expense)					
Interest income	89	0.2%	92	1.3%	(3)
Interest expense	(920)	(1.8%)	(887)	(13.0%)	(33)
Other expenses	(205)	(0.4%)	(133)	(1.9%)	(72)
Change in fair value of warrant liabilities	(957)	(1.9%)	(85)	(1.2%)	(872)
Total other expenses, net	(1,993)	(3.9%)	(1,013)	(14.8%)	(980)
Net loss	$ (1,192)	(2.4%)	$ (10,153)	(148.7%)	$ 8,961

Revenue. Revenue increased $44.3 million, or 648.7%, to $51.1 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 $4.6 million, or 361.4%, to $5.9 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 88.4%, compared to 81.2% in the year ended December 31, 2018 due to an increase in the average selling prices of our products and improved operating leverage.

Research and Development Expenses. R&D expenses increased $3.2 million, or 80.9%, to $7.2 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 $1.3 million of personnel-related expenses, $1.1 million of clinical study and registry expenses and $0.5 million in materials and supplies.

Selling, General and Administrative Expenses. SG&A expenses increased $26.5 million, or 247.7%, to $37.2 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 $20.1 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 $2.1 million in professional fees, an increase of $1.6 million in travel costs and an increase of $1.2 million in marketing and event costs.

Interest Income. Interest income decreased by 3.3% during the year ended December 31, 2019, compared to the year ended December 31, 2018. The decrease in interest income was primarily due to a decrease in average cash and cash equivalents during the year ended December 31, 2019, compared to the year ended December 31, 2018.

Interest Expense. Interest expense increased by 3.7% during the year ended December 31, 2019, compared to the year ended December 31, 2018. This increase was primarily due to $10.0 million of additional borrowings drawn under the credit facility with Signature Bank in December 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 $20.0 million.

Change in Fair Value of Warrant Liabilities. Change in fair value of warrant liabilities increased $0.9 million to $1.0 million for the year ended December 31, 2019, compared to $0.1 million for the year ended December 31, 2018. This increase was due to the fair value remeasurement of our convertible preferred stock warrant liabilities.

Other Expenses. Other expenses increased to $0.2 million for the year ended December 31, 2019, compared to $0.1 million for the year ended December 31, 2018. This increase was primarily due to a loss on extinguishment of debt related to the refinancing of our debt facility.

Selected Unaudited Quarterly Financial Information

The following table represents certain unaudited quarterly information for the periods presented. The unaudited quarterly information set forth below has been prepared on a basis consistent with our audited annual financial statements included elsewhere in this Annual Report and includes, in our opinion, all normal recurring adjustments necessary for the fair presentation of the results of operations for the periods presented. Our historical unaudited quarterly results are not necessarily indicative of the results that may be expected in the future.

The following unaudited quarterly financial information for 2020 and 2019 should be read in conjunction with our audited financial statements and related notes thereto included elsewhere in this Annual Report (in thousands, except share and per share amounts):

	2020 Quarters ended			
	March 31	June 30	September 30	December 31
Revenue	$ 26,953	$ 25,392	$ 38,715	$ 48,610
Cost of goods sold	2,706	3,487	3,228	3,686
Gross profit	24,247	21,905	35,487	44,924
Operating expenses				
Research and development	3,018	3,628	5,217	6,535
Selling, general and administrative	16,393	18,880	23,080	31,393
Total operating expenses	19,411	22,508	28,297	37,928
Income (loss) from operations	4,836	(603)	7,190	6,996
Other income (expense)				
Interest income	55	146	208	75
Interest expense	(346)	(463)	(251)	(75)
Change in fair value of warrant liabilities	(433)	(2,884)	—	-
Other expenses	—	—	(651)	(11)
Total other expenses	(724)	(3,201)	(694)	(11)
Net income (loss)	$ 4,112	$ (3,804)	$ 6,496	$ 6,985
Net income (loss) per share				
Basic	$ 0.64	$ (0.16)	$ 0.13	$ 0.14
Diluted	$ 0.09	$ (0.16)	$ 0.12	$ 0.13
Weighted average common shares used to compute net income (loss) per share,				
Basic	6,398,897	24,295,900	48,335,443	48,742,302
Diluted	44,952,704	24,295,900	55,355,846	55,221,012

	2019 Quarters ended			
	March 31	June 30	September 30	December 31
Revenue	$ 6,945	$ 10,072	$ 14,225	$ 19,887
Cost of goods sold	931	1,331	1,510	2,139
Gross profit	6,014	8,741	12,715	17,748
Operating expenses				
Research and development	1,209	1,580	1,722	2,709
Selling, general and administrative	5,426	7,803	10,100	13,868
Total operating expenses	6,635	9,383	11,822	16,577
Income (loss) from operations	(621)	(642)	893	1,171
Other income (expense)				
Interest income	23	24	19	23
Interest expense	(227)	(229)	(226)	(238)
Change in fair value of warrant liabilities	(123)	(118)	(320)	(395)
Other expenses	—	—	—	(205)
Total other expenses	(327)	(323)	(527)	(815)
Net income (loss)	$ (948)	$ (965)	$ 366	$ 356
Net income (loss) per share				
Basic	$ (0.17)	$ (0.17)	$ 0.06	$ 0.06
Diluted	$ (0.17)	$ (0.17)	$ 0.01	$ 0.01
Weighted average common shares used to compute net income (loss) per share,				
Basic	5,599,815	5,753,332	5,962,665	6,226,610
Diluted	5,599,815	5,753,332	43,911,252	44,660,631

Liquidity and Capital Resources

To date, our primary sources of capital have been the net proceeds we received through private placements of preferred stock, debt financing agreements, the sale of common stock in our IPO, and revenue from the sale of our products. On May 27, 2020, we completed our IPO, including the underwriters full exercise of their over-allotment option, selling 9,432,949 shares of our common stock at $19.00 per share. Upon completion of our IPO, we received net proceeds of approximately $163.0 million, after deducting underwriting discounts and commissions and offering expenses. In August 2020, we repaid in full the $30.0 million of principal owed under the credit facility with Signature Bank. As of December 31, 2020, we had cash and cash equivalents of $114 million, short-term investments of $50.0 million, and an accumulated deficit of $27.4 million. In September 2020, we entered into a new revolving Credit Agreement with Bank of America which provides for loans up to a maximum of $30 million. As of December 31, 2020, we had no principal outstanding under the Credit Agreement and the amount available to borrow was approximately $28.5 million.

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

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

Cash Flows

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

	Years Ended December 31,		
	2020	2019	2018
Net Cash (used in) provided by:			
Operating activities	$ 1,912	$ (4,936)	$ (10,892)
Investing activities	(55,437)	(3,144)	(753)
Financing activities	144,115	10,223	26,758
Net increase in cash and cash equivalent	$ 90,590	$ 2,143	$ 15,113

Net Cash Used in Operating Activities

Net cash provided by operating activities for the year ended December 31, 2020 was $1.9 million, consisting primarily of net income of $13.8 million and non-cash charges of $9.3 million, offset by an increase in net operating assets of $21.2 million. The increase in net operating assets was primarily due to increases in accounts receivable of $16.7 million and inventories of $6.6 million to support the growth of our operations, an increase in prepaid and other assets of $2.5 million primarily from prepaid insurance, which were partially offset by increases in accounts payable of $0.5 million and accrued liabilities of $4.1 million due to timing of payments and growth of our operations. The non-cash charges primarily consisted of $3.3 million in change in fair value of the preferred stock warrant liabilities, stock-based compensation of $3.5 million, $1.4 million in depreciation, and $0.6 million in loss on extinguishment of debt.

Net cash used in operating activities for the year ended December 31, 2019 was $4.9 million, consisting primarily of a net loss of $1.2 million and an increase in net operating assets of $6.3 million, partially offset by non-cash charges of $2.5 million. The increase in net operating assets was primarily due to increases in accounts receivable of $9.0 million and inventories of $2.9 million to support the growth of our operations, an increase in

prepaid and other assets of $1.2 million from deferred offering costs, partially offset by increases in accounts payable of $1.8 million and accrued liabilities of $4.9 million due to timing of payments and growth of our operations. The non-cash charges primarily consisted of $0.6 million in depreciation, stock-based compensation of $0.5 million, 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 of $0.3 million, and the change in fair value of the preferred stock warrant liability of $1.0 million.

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 for the year ended December 31, 2020 was $55.4 million consisting of purchases of short-term securities of $50.0 million and purchases of property and equipment of $5.4 million.

Net cash used in investing activities for the years ended December 31, 2019 and 2018 was $3.1 million and $0.8 million, respectively, consisting of purchases of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2020 was $144.1 million primarily consisting of net IPO proceeds of $164.4 million and net proceeds of $10.0 million received from additional borrowings under the credit facility with Signature Bank, partially offset by the $30.3 million repayment of the amount outstanding under the credit facility.

Net cash provided by financing activities for the year ended December 31, 2019 was $10.2 million primarily consisting of net proceeds of $10.0 million received from additional borrowings under the credit facility with Signature Bank, $0.8 million in proceeds received from subscription receivable, $0.5 million in deferred financing costs paid, and $0.1 million in proceeds received from the exercise of stock options.

Net cash provided by financing activities for 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.

Off-Balance Sheet Arrangements

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

Contractual Obligations and Commitments

The following table shows our contractual obligations due by period as of December 31, 2020:

	Less than 1 year	1-3 years	4-5 years	More than 5 years	Total
Operating lease obligations	$ 1,506	$ 4,636	$ 4,536	$ 13,672	$ 24,350
Total	$ 1,506	$ 4,636	$ 4,536	$ 13,672	$ 24,350

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated 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 the Note 2 to our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, 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.

Revenue Recognition

On January 1, 2019, we adopted Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers,* using the modified retrospective method applied to contracts which were not completed as of that date. Revenue for reporting periods beginning after January 1, 2019 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting under ASC 605, *Revenue Recognition*.

Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine whether revenue recognition for arrangements is within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

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

Performance Obligation—We have revenue arrangements that consist of a single performance obligation, delivery of our products. The satisfaction of this performance obligation occurs with the transfer of control of our product to our customers, either upon shipment or delivery of the product.

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

Assuming all other revenue recognition criteria have been met, we recognize revenue for arrangements where the Company has satisfied its performance obligation of delivering the product. For sales where our sales representatives hand deliver products directly to the hospital, control of the products transfers to the customer upon such hand delivery. For sales where products are shipped, control of the products transfers either upon shipment or delivery of the products to the customer, depending on the shipping terms and conditions. As of December 31, 2020 and 2019, we recorded $498,000 and $330,000, respectively, of unbilled receivables, which are included in accounts receivable, net, in the accompanying consolidated balance sheets.

Revenue for ClotTriever and FlowTriever products as a percentage of total revenue was derived as follow:

	Years Ended December 31,		
	2020	2019	2018
ClotTriever	37%	38%	41%
FlowTriever	63%	62%	59%

We offer payment terms to our customers of less than three months and these terms do not include a significant financing component. We exclude taxes assessed by governmental authorities on revenue-producing transactions from the measurement of the transaction price.

We offer a standard warranty to all customers. We do not sell any warranties on a standalone basis. Our warranty provides that its products are free of material defects and conform to specifications, and we offer to repair, replace or refund the purchase price of defective products. This assurance does not constitute a service and is not considered a separate performance obligation. We estimate warranty liabilities at the time of revenue recognition and record it as a charge to cost of goods sold.

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

Cash, Cash Equivalents and Short-Term Investments

We consider 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. We maintain our 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 we are exposed to any significant related credit risk.

Short-term investments have been classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. We determine the appropriate classification of our investments in debt securities at the time of purchase. Available-for-sale securities with original maturities less than 12 months at the date of purchase are considered short-term investments.

Accounts Receivable, net

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.

The allowance for doubtful accounts was $62,000 as of December 31, 2020 and 2019, and no accounts receivable write offs were recognized during the years ended December 31, 2020, 2019 and 2018. Despite the Company's efforts to minimize credit risk exposure, customers could be adversely affected if future economic and industry trends, including those related to COVID-19, change in such a manner as to negatively impact their cash flows. The full effects of COVID-19 on the Company's customers are highly uncertain and cannot be predicted. As a result, the Company's future collection experience can differ significantly from historical collection trends. If the Company's clients experience a negative impact on their cash flows, it could have a material adverse effect on the Company's results of operations and financial condition.

Inventories, net

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 consolidated statements of operations and comprehensive income (loss).

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. We also offer an employee stock purchase plan which allows participating employees to purchase shares of our common stock at a discount through payroll deductions.

We recognize equity-based compensation expense for awards of equity instruments to employees and directors based on the grant date fair value of those awards. We estimate the fair value of our stock option awards made to employees and non-employees based on the estimated fair values as of the grant date using the Black-Scholes option-pricing model, net of estimated forfeitures. The fair value of restricted stock unit ("RSU") awards is determined based on the number of units granted and the closing price of the Company's common stock as of the grant date. The fair value of each purchase under the employee stock purchase plan ("ESPP") is estimated at the beginning of the offering period using the Black-Scholes option pricing model.

The model requires us to make a number of assumptions including expected volatility, expected term, risk-free interest rate and expected dividend yield. We expense the fair value of our equity-based compensation awards on a straight-line basis over the requisite service period, which is the period in which the related services are received.

Recent Accounting Pronouncements

Please refer to Note 2 to our consolidated financial statements appearing under Part 2, Item 8 for a discussion of new accounting standards updates that may impact us.

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.

Item 7A. 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, 2020, we had repaid in full the SB Credit Facility and had no long-term debt outstanding. A hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material impact on our financial statements. We do not currently engage in hedging transactions to manage our exposure to interest rate risk.

Credit Risk

As of December 31, 2020, our cash and cash equivalents and short-term investments were maintained with five 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, 2020.

Foreign Currency Risk

Our business is primarily conducted in U.S. dollars. Any transactions that may be conducted in foreign currencies are not expected to have a material effect on our results of operations, financial position or cash flows. As we expand internationally, our results of operations and cash flows may become increasingly subject to fluctuations due to changes in foreign currency exchange rates.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found in Item 15 of Part IV of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

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

Evaluation of disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated, as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2020.

Management's annual report on internal control over financial reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) or an attestation report of our independent registered accounting firm due to a transition period established by rules of the

SEC for newly public companies. Additionally, our independent registered accounting firm will not be required to opine on the effectiveness of our internal control over financial reporting pursuant to Section 404 until we are no longer an "emerging growth company" as defined in the JOBS Act.

Attestation report of the registered public accounting firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

Changes in internal control over financial reporting

Other than the remediation efforts identified below to remediate the material weaknesses disclosed in the September 30, 2020 Form 10-Q, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Remediation of Material Weaknesses in Internal Control Over Financial Reporting

Management has implemented remediation measures related to segregation of duties throughout various financial processes and our documentation of internal controls. We have supplemented the accounting and finance function with additional personnel with technical accounting and financial reporting experience, and have enhanced the accounting and financial reporting procedures and systems to improve the completeness, timeliness and accuracy of our financial reporting and disclosures including the assessment of more judgmental areas of accounting.

We believe these measures have remediated the material weaknesses as of December 31, 2020.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Except as provided below, the information required by this item is incorporated by reference from the applicable information set forth in "Executive Officers," "Election of Directors," "Corporate Governance," and Section 16(a) Beneficial Ownership Reporting Compliance" which will be included in our Proxy Statement for our 2021 Annual Meeting of Stockholders, or the Proxy Statement, to be filed with the SEC.

Code of Ethics and Conduct

Our Board of Directors has adopted a code of ethics and conduct that applies to the principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions. A copy of this code of ethics and conduct is posted on the Investors section of our website under Governance at www.inarimedical.com. This code of ethics and conduct also applies to all employees, officers and directors. If the Company waives or amends any provisions of these codes of conduct that apply to the directors and executive officers, including our principal executive officer, principal financial officer, principal accounting officer or controller and persons performing similar functions, it will disclose such waivers or amendments on our website, at the address and location specified above, to the extent required by applicable rules of the Securities and Exchange Commission or the NASDAQ.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference from the applicable information set forth in "Executive Compensation," and "Director Compensation" and "Corporate Governance" which will be included in our Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item is incorporated by reference from the applicable information set forth in "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" which will be included in our Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is incorporated by reference from the applicable information set forth in "Certain Relationships and Related Party Transactions" and "Corporate Governance" which will be included in our definitive Proxy Statement.

Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated by reference from the applicable information set forth in "Ratification of Selection of Independent Registered Public Accounting Firm" which will be included in our Proxy Statement.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) List the following documents filed as a part of this Annual Report on Form 10-K:

(1) Financial Statements: The financial statements included in Part II, Item 8 of this document are filed as part of this Annual Report on Form 10-K.

(2) Financial Statement Schedules: All schedules are omitted because they are not applicable

(3) Exhibits

Exhibit Index

Exhibit Number	Description	Form	Incorporated by reference		
			File Number	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation	8-K	001-39293	3.1	5/28/2020
3.2	Amended and Restated Bylaws	8-K	001-39293	3.2	5/28/2020
4.1	Form of Certificate of Common Stock	S-1	333-236568	4.1	2/21/2020
4.2	Second Amended and Restated Investors' Rights Agreement by and between Inari Medical, Inc. and certain investors, dated March 29, 2018	S-1	333-236568	4.2	2/21/2020
4.3	Warrant to purchase common stock, issued by Inari Medical, Inc. to Croton Partners, LLC, dated February 19, 2015	S-1	333-236568	4.3	2/21/2020
4.4	Warrant to purchase Series A preferred stock, issued by Inari Medical, Inc. to Silicon Valley Bank, dated December 10, 2014	S-1	333-236568	4.4	2/21/2020
4.5	Warrant to purchase Series B preferred stock, issued by Inari Medical, Inc. to East West Bank dated April 29, 2016	S-1	333-236568	4.5	2/21/2020
10.1	Form of Indemnification Agreement between Inari Medical, Inc. and its directors and officers	S-1/A	333-236568	10.1	5/5/2020
10.2#	2011 Equity Incentive Plan	S-1	333-236568	10.3	2/21/2020
10.3#	Form of Stock Option Agreement pursuant to 2011 Equity Incentive Plan	S-1	333-236568	10.4	2/21/2020
10.4#	Form of Restricted Stock Unit Agreement pursuant to 2011 Equity Incentive Plan	S-1	333-236568	10.5	2/21/2020
10.5#	2020 Incentive Award Plan	S-1/A	333-236568	10.6	5/18/2020
10.6#	Form of Option Agreement pursuant to 2020 Incentive Award Plan	S-1/A	333-236568	10.6.1	5/18/2020
10.7#	Form of Restricted Stock Unit Agreement pursuant to 2020 Incentive Award Plan	S-1/A	333-236568	10.6.2	5/18/2020
10.8#	Form of Restricted Stock Unit Award Agreement pursuant to 2020 Incentive Award Plan – International				
10.9#	Amended and Restated 2020 Employee Stock Purchase Plan	10-Q	001-39293	10.3	11/12/2020
10.10#	Employment Agreement, dated as of March 5, 2020, by and between Inari Medical, Inc. and William Hoffman	S-1/A	333-236568	10.12	5/5/2020
10.11#	Employment Agreement, dated as of March 5, 2020, by and between Inari Medical, Inc. and Mitchell Hill	S-1/A	333-236568	10.13	5/5/2020
10.12#	Employment Agreement, dated as of March 5, 2020, by and between Inari Medical, Inc. and Andrew Hykes	S-1/A	333-236568	10.14	5/5/2020
10.13#	Employment Agreement, dated as of March 5, 2020, by and between Inari Medical, Inc. and Dr. Thomas Tu				
10.14#	Amended and Restated Non-Employee Director Compensation Program				
10.15	Lease Agreement, dated as of March 6, 2019, by and between Inari Medical, Inc. and Bake Technology Park LLC	S-1	333-236568	10.2	2/21/2020
10.16	Lease Agreement, dated as of October 7, 2020, by and between Inari Medical, Inc. and Oak Canyon Creek LLC	10-Q	001-39293	10.1	11/12/2020

Exhibit Number	Description	Incorporated by reference			
		Form	File Number	Exhibit	Filing Date
10.17	Lease Termination Agreement, dated as of October 7, 2020, as modified by that First Amendment to the Lease Termination Agreement dated February 3, 2021, by and between Inari Medical, Inc. and Bake Technology Park LLC				
10.18	First Amendment to Lease dated March 3, 2021, by and between Inari Medical, Inc. and Oak Canyon Creek LLC				
10.19	Sublicense Agreement, dated as of August 1, 2019, by and between Inari Medical, Inc. and Inceptus Medical, LLC	S-1	333-236568	10.9	2/21/2020
10.20	Amended and Restated Services Agreement, dated as of February 1, 2018, by and between Inari Medical, Inc. and Inceptus Medical, LLC	S-1	333-236568	10.10	2/21/2020
10.21	Amended and Restated Technology Agreement, dated as of March 2, 2018, by and between Inari Medical, Inc. and Inceptus Medical, LLC	S-1	333-236568	10.11	2/21/2020
10.22	Loan, Guaranty and Security Agreement, dated as of September 4, 2020, by and among Inari Medical, Inc., Inari Medical International, Inc. and Bank of America, N.A.	8-K	001-39293	10.1	9/11/2020
21.1	Subsidiaries of the registrant				
23.1	Consent of Independent Registered Public Accounting Firm				
31.1	Certification of Principal Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2	Certification of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1†	Certifications of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2†	Certifications of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

# Indicates management contract or compensatory plan.

† The certifications attached as Exhibit 32.1 and 32.2 that accompany this Annual Report on Form 10-K are deemed furnished and not filed with the U.S. Securities and Exchange Commission and are not to be incorporated by reference into any filing of Inari Medical, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

Item **16. Form 10-K Summary**

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

INARI MEDICAL, INC

Date: March 9, 2021

By: /s/ William Hoffman
William Hoffman
Chief Executive Officer (Principal Executive Officer), President

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENT, that each person whose signature appears below constitutes and appoints William Hoffman and Mitchell Hill, and each of them, his or her true and lawful attorneys-in-fact and agents with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the SEC, 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 fully to all intents and purposes as he or she 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 or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ William Hoffman **William Hoffman**	Chief Executive Officer (Principal Executive Officer), President and Director	March 9, 2021
/s/ Mitchell Hill **Mitchell Hill**	Chief Financial Officer (Principal Financial and Principal Accounting Officer)	March 9, 2021
/s/ Donald Milder **Donald Milder**	Chair of the Board of Directors	March 9, 2021
/s/ Cynthia Lucchese **Cynthia Lucchese**	Director	March 9, 2021
/s/ Kirk Nielsen **Kirk Nielsen**	Director	March 9, 2021
/s/ Geoff Pardo **Geoff Pardo**	Director	March 9, 2021
/s/ Jonathan Root **Jonathan Root, M.D.**	Director	March 9, 2021
/s/ Catherine Szyman **Catherine Szyman**	Director	March 9, 2021

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Inari Medical, Inc. (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive income (loss), mezzanine equity and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020**,** in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. 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 audits 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 consolidated 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 audits 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 audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

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

Costa Mesa, California
March 9, 2021

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

	December 31, 2020	December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 114,229	$ 23,639
Restricted cash	50	50
Short-term investments	49,981	—
Accounts receivable, net	28,008	11,302
Inventories, net	10,597	3,953
Prepaid expenses and other current assets	2,808	464
Total current assets	205,673	39,408
Property and equipment, net	7,498	3,331
Restricted cash	338	338
Deposits and other assets	583	1,469
Total assets	$ 214,092	$ 44,546
Liabilities, Mezzanine Equity and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 3,047	$ 2,549
Payroll-related accruals	8,198	5,225
Accrued expenses and other current liabilities	2,593	1,096
Total current liabilities	13,838	8,870
Notes payable, net	—	19,481
Warrant liabilities	—	1,169
Total liabilities	13,838	29,520
Commitments and contingencies (Note 6)		
Mezzanine equity		
Redeemable convertible preferred stock, par value $0.001, no shares authorized, issued, and outstanding as of December 31, 2020; 32,225,227 shares authorized, 31,968,570 shares issued and outstanding as of December 31, 2019; aggregate liquidation preference of zero as of December 31, 2020 and $54,415 as of December 31, 2019	—	54,170
Stockholders' equity (deficit)		
Preferred stock, $0.001 par value, 10,000,000 shares authorized, no shares issued and outstanding as of December 31, 2020; no shares authorized, issued, and outstanding as of December 31, 2019	—	—
Common stock, $0.001 par value, 300,000,000 and 49,019,607 shares authorized as of December 31, 2020 and 2019, respectively; 49,251,614 and 6,720,767 shares issued and outstanding as of December 31, 2020 and 2019, respectively	49	7
Additional paid in capital	227,624	2,061
Accumulated other comprehensive income	4	—
Accumulated deficit	(27,423)	(41,212)
Total stockholders' equity (deficit)	200,254	(39,144)
Total liabilities, mezzanine equity and stockholders' equity (deficit)	$ 214,092	$ 44,546

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

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

	Years Ended December 31,		
	2020	2019	2018
Revenue	$ 139,670	$ 51,129	$ 6,829
Cost of goods sold	13,106	5,911	1,281
Gross profit	126,564	45,218	5,548
Operating expenses			
Research and development	18,399	7,220	3,990
Selling, general and administrative	89,746	37,197	10,698
Total operating expenses	108,145	44,417	14,688
Income (loss) from operations	18,419	801	(9,140)
Other income (expense)			
Interest income	484	89	92
Interest expense	(1,135)	(920)	(887)
Change in fair value of warrant liabilities	(3,317)	(957)	(85)
Other expenses	(662)	(205)	(133)
Total other expenses	(4,630)	(1,993)	(1,013)
Net income (loss)	$ 13,789	$ (1,192)	$ (10,153)
Other comprehensive income			
Unrealized gain on available-for-sale securities	4	—	—
Comprehensive income (loss)	$ 13,793	$ (1,192)	$ (10,153)
Net income (loss) per share			
Basic	$ 0.43	$ (0.20)	$ (2.01)
Diluted	$ 0.27	$ (0.20)	$ (2.01)
Weighted average common shares used to compute net income (loss) per share,			
Basic	32,033,827	5,887,542	5,056,743
Diluted	51,554,996	5,887,542	5,056,743

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

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

	Redeemable Convertible Preferred Stock		Common Stock		Subscription	Additional Paid In	Accumulated Other Comprehensive	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Receivable	Capital	Income	Deficit	(Deficit)
Balance, December 31, 2017	17,312,703	$ 27,251	5,475,506	$ 5	$ (501)	$ 924	$ —	$ (29,971)	$ (29,543)
Issuance of Series C redeemable preferred stock at $1.84 per share for cash, net of offering costs of $82	14,655,867	26,919	—	—	—	—	—	—	-
Options exercised for common stock	—	—	835,359	1	(245)	258	—	—	14
Interest earned on subscription receivable	—	—	—	—	(12)	—	—	—	(12)
Share based compensation	—	—	—	—	—	248	—	—	248
Net loss	—	—	—	—	—	—	—	(10,153)	(10,153)
Balance, December 31, 2018	31,968,570	54,170	6,310,865	6	(758)	1,430	—	(40,124)	(39,446)
Adjustment to recognize new revenue recognition standard	—	—	—	—	—	—	—	104	104
Options exercised for common stock	—	—	409,902	1	—	126	—	—	127
Interest earned on subscription receivable	—	—	—	—	(15)	—	—	—	(15)
Proceeds from subscription receivable	—	—	—	—	773	—	—	—	773
Share based compensation	—	—	—	—	—	505	—	—	505
Net loss	—	—	—	—	—	—	—	(1,192)	(1,192)
Balance, December 31, 2019	31,968,570	54,170	6,720,767	7	—	2,061	—	(41,212)	(39,144)
Conversion of preferred stock to common stock upon initial public offering	(31,968,570)	(54,170)	31,968,570	32	—	54,138	—	—	54,170
Issuance of common stock in connection with initial public offering, net of issuance costs of $16.3 million	—	—	9,432,949	9	—	162,970	—	—	162,979
Conversion and reclassification of preferred stock warrants to common stock warrants upon initial public offering	—	—	—	—	—	4,486	—	—	4,486
Exercise of common stock warrants	—	—	277,309	1	—	4	—	—	5
Options exercised for common stock	—	—	851,189	—	—	466	—	—	466
Issuance of common stock upon vesting of restricted stock units, net of shares withheld for taxes			830	—	—	(25)	—	—	(25)
Share based compensation	—	—	—	—	—	3,524	—	—	3,524
Unrealized gain on available -for-sale securities	—	—	—	—	—	—	4	—	4
Net income	—	—	—	—	—	—	—	13,789	13,789
Balance, December 31, 2020	—	$ —	49,251,614	$ 49	$ —	$ 227,624	$ 4	$ (27,423)	$ 200,254

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

INARI MEDICAL, INC
Consolidated Statements of Cash Flows
(in thousands)

	Years Ended December 31,		
	2020	2019	2018
Cash flows from operating activities			
Net income (loss)	$ 13,789	$ (1,192)	$ (10,153)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation	1,385	614	283
Amortization of deferred financing costs	181	101	106
Loss on extinguishment of debt	648	205	—
Share based compensation expense	3,524	505	248
Amortization of fair value of warrants issued with debt	—	14	30
Loss on disposal of fixed assets	237	119	29
Provision for doubtful accounts	—	62	—
Loss on change in fair value of warrant liabilities	3,317	957	85
Changes in:			
Accounts receivable	(16,706)	(9,017)	(2,165)
Inventories	(6,644)	(2,874)	(558)
Prepaid expenses, deposits and other assets	(2,458)	(1,158)	41
Accounts payable	498	1,835	372
Payroll-related accruals, accrued expenses and other liabilities	4,141	4,893	790
Net cash provided by (used in) operating activities	1,912	(4,936)	(10,892)
Cash flows from investing activities			
Purchase of property and equipment	(5,460)	(3,144)	(753)
Purchase of short-term investments	(49,977)	—	—
Net cash used in investing activities	(55,437)	(3,144)	(753)
Cash flows from financing activities			
Proceeds from issuance of common stock upon initial public offering, net of issuance costs paid	164,361	—	—
Proceeds from issuance of redeemable convertible preferred stock, net of offering costs paid	—	—	26,919
Proceeds from notes payable	10,000	20,000	—
Repayments of notes payable	(30,250)	(10,140)	—
Debt financing costs	(442)	(536)	(175)
Proceeds from subscriptions receivable	—	772	—
Proceeds from exercise of stock option and warrants	471	127	14
Payment of taxes related to vested restricted stock units	(25)	—	—
Net cash provided by financing activities	144,115	10,223	26,758
Net increase in cash	90,590	2,143	15,113
Cash, cash equivalents and restricted cash beginning of period	24,027	21,884	6,771
Cash, cash equivalents and restricted cash end of period	$ 114,617	$ 24,027	$ 21,884
Supplemental disclosures of cash flow information:			
Cash paid for income taxes	$ 154	$ 14	$ 16
Cash paid for interest	$ 999	$ 810	$ 747
Noncash investing and financing:			
Accrual of deferred interest obligation associated with debt	$ —	$ 150	$ 140
Common stock issued on conversion of convertible preferred stock	$ 54,170	$ —	$ —
Common stock warrants issued on conversion of preferred stock warrants and the reclassification of the warrant liability	$ 4,486	$ —	$ —
Deferred initial public offering cost recorded to additional paid in capital	$ 1,382	$ —	$ —

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

1. Organization

Description of Business

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

Initial Public Offering

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

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

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

Reverse Stock Splits

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

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

2. Summary of Significant Accounting Policies

COVID-19 and CARES Act

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

In response to the impact of COVID-19, the Company implemented a variety of measures to help manage through the impact and position it to resume operations quickly and efficiently once these restrictions were lifted. Some of these measures included: adapting, expanding and improving various sales, physician outreach and training programs to address the current environment; producing approximately four months' worth of inventory before temporarily suspending production, which fully resumed in June 2020, and executing a work from home strategy for administrative functions. The impact of COVID-19 continues to change and cannot be predicted. As a result, the Company expects the pandemic could continue to negatively impact its business, financial condition and results of operations.

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

Principles of Consolidation

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

Management Estimates

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

JOBS Act Accounting Election

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

Cash, Cash Equivalents and Restricted Cash

The Company considers cash on hand, cash in demand deposit accounts including money market funds, and instruments with a maturity date of 90 days or less at date of purchase to be cash and cash equivalents. The Company maintains its cash, cash equivalent and restricted cash balances with banks. Under the Dodd-Frank Wall Street Reform and Consumer Protection Act, deposits of up to $250,000 at FDIC-insured institutions are covered by FDIC insurance. At times, deposits may be in excess of the FDIC insurance limit; however, management does not believe the Company is exposed to any significant related credit risk.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same amounts shown in the consolidated statements of cash flows:

	December 31,	
	2020	2019
Cash and cash equivalents	$ 114,229	$ 23,639
Restricted cash	388	388
Total cash, cash equivalent and restricted cash	$ 114,617	$ 24,027

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

Short-Term Investments

Short-term investments have been classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. The Company determines the appropriate classification of its investments in debt securities at the time of purchase. Available-for-sale securities with original maturities less than 12 months at the date of purchase are considered short-term investments.

Unrealized gains and losses are excluded from earnings and are reported as a component of comprehensive loss. The Company periodically evaluates whether declines in fair values of its marketable securities below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss as well as the Company's ability and intent to hold the marketable security until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the security or it is more likely than not it will be required to sell any marketable securities before recovery of its amortized cost basis. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on marketable securities are included in other income, net. The cost of investments sold is based on the specific-identification method. Interest on marketable securities is included in interest income.

Accounts Receivable, net

Trade accounts receivable are recorded at the invoiced amount, net of any allowance for doubtful accounts. Any allowance for doubtful accounts, which is included in selling, general and administrative ("SG&A") expenses, is developed based upon several factors including the customers' credit quality, historical write-off experience and any known specific issues or disputes which exist as of the balance sheet date. Account receivable balances are written off against the allowance after appropriate collection efforts are exhausted. The allowance for doubtful accounts was $62,000 as of December 31, 2020 and 2019, and no accounts receivable write offs were recognized during the years ended December 31, 2020, 2019 and 2018.

Despite the Company's efforts to minimize credit risk exposure, customers could be adversely affected if future economic and industry trends, including those related to COVID-19, change in such a manner as to negatively impact their cash flows. The full effects of COVID-19 on the Company's customers are highly uncertain and cannot be predicted. As a result, the Company's future collection experience can differ significantly from historical collection trends. If the Company's clients experience a negative impact on their cash flows, it could have a material adverse effect on the Company's results of operations and financial condition.

Inventories, net

The Company values inventory at the lower of the actual cost to purchase or manufacture the inventory or net realizable value for such inventory. Cost, which includes material, labor and overhead costs, is determined on the first-in, first out method, or FIFO. The Company regularly reviews inventory quantities in process and on hand, and when appropriate, records a provision for obsolete and excess inventory. The Company writes down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements based on future demand and as compared to remaining shelf life. The estimate of excess quantities is subjective and primarily dependent on the Company's estimates of future demand for

a particular product. If the estimate of future demand is inaccurate based on actual sales, the Company may increase the write down for excess inventory for that component and record a charge to inventory impairment in the accompanying consolidated statement of operations and comprehensive income (loss).

Property and Equipment

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

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

Deferred Initial Public Offering Costs

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

Impairment of Long-lived Assets

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

Fair Value of Financial Instruments

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

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

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

See Note 3 for further information.

Convertible Preferred Stock Warrant Liability

The Company 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 contained contingent redemption features outside the control of the Company. The warrants were subject to remeasurement at each balance sheet date and any change in fair value was recognized as the change in fair value of warrant liability and recorded to other expense in the consolidated statements of operations and other comprehensive income (loss). The carrying value of the warrants continued to be adjusted until the completion of the IPO, which occurred in May 2020. At that time, the preferred stock warrant liability was adjusted to fair value and reclassified to additional paid-in capital, a component of stockholders' equity (deficit) (see Note 3).

Revenue Recognition

On January 1, 2019, the Company adopted Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers,* using the modified retrospective method applied to contracts which were not completed as of that date. Revenue for reporting periods beginning after January 1, 2019 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with the Company's historic accounting under ASC 605, *Revenue Recognition*.

Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

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

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

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

Assuming all other revenue recognition criteria have been met, the Company recognizes revenue for arrangements where the Company has satisfied its performance obligation of shipping or delivering the product. For sales where the Company's sales representatives hand deliver products directly to the hospital, control of the products transfers to the customer upon such hand delivery. For sales where products are shipped, control of the products transfers either upon shipment or delivery of the products to the customer, depending on the shipping terms and conditions. As of December 31, 2020 and 2019, the Company recorded $498,000 and $330,000, respectively, of unbilled receivables, which are included in accounts receivable, net, in the accompanying consolidated balance sheets.

Revenue for ClotTriever and FlowTriever products as a percentage of total revenue was derived as follow:

	Years Ended December 31,		
	2020	2019	2018
ClotTriever	37%	38%	41%
FlowTriever	63%	62%	59%

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

The Company offers its standard warranty to all customers. The Company does not sell any warranties on a standalone basis. The Company's warranty provides that its products are free of material defects and conform to specifications, and includes an offer to repair, replace or refund the purchase price of defective products. This assurance does not constitute a service and is not considered a separate performance obligation. The Company estimates warranty liabilities at the time of revenue recognition and records it as a charge to cost of goods sold.

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

Cost of Goods Sold

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

Shipping Costs

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

Advertising Costs

Advertising costs are charged to operations as incurred. Advertising costs were $333,000, $90,000 and $99,000 for the years ended December 31, 2020, 2019 and 2018, respectively. Advertising costs are included in SG&A expenses in the accompanying consolidated statements of operations.

Research and Development

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

Patent-related Expenditures

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

Stock-based Compensation

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

Income Taxes

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

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

Foreign Currency Transactions

The functional currencies of the Company's subsidiaries are currencies other than the U.S. dollar. The Company translates assets and liabilities of the foreign subsidiaries into U.S. dollars at the exchange rate in effect on the balance sheet date. Costs and expenses of the subsidiaries are translated into U.S. dollars at the average exchange rate during the period. Gains or losses from these translation adjustments are reported as a separate component of stockholders' equity in accumulated other comprehensive income (loss) until there is a sale or complete or substantially complete liquidation of the Company's investment in the foreign subsidiary at which time the gains or losses will be realized and included in net income (loss). As of December 31, 2020, unrealized foreign currency translation gains (losses) were not significant. Certain vendors are paid in currencies other than the US dollar. Transaction gains and losses are included in other expenses and have not been significant for the periods presented.

Comprehensive Income (Loss)

The Company's comprehensive income (loss) is comprised of net income (loss) and changes in unrealized gain and losses on available-for-sale investments and gains or losses from foreign currency translation adjustments.

Net Income (Loss) per Share of Common Stock

Basic net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, without consideration for potential dilutive common shares. Diluted net income (loss) per share is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of shares of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net income (loss) per share calculation, redeemable convertible preferred stock and warrants, and common stock options are potentially dilutive securities. For the years the Company is in a net loss position, basic net loss per share is the same as diluted net loss per share as the inclusion of all potential dilutive common shares would have been anti-dilutive.

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

Segment Reporting

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

Recently Adopted Accounting Pronouncements

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

Recent Accounting Pronouncements

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

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

In December 2019, the FASB issued ASU 2019-12, *Income Taxes – Simplifying the Accounting for Income Taxes*, which simplifies the accounting for income taxes by clarifying and amending existing guidance related to the recognition of franchise tax, the evaluation of a step-up in the tax basis of goodwill and the effects of enacted changes in tax laws or rates in the effective tax rate computation, among other clarifications. ASU 2019-12 is effective for annual periods beginning after December 15, 2020, including interim periods within those fiscal years, and early adoption is permitted. The Company does not expect adoption will have a material impact on its consolidated financial statements.

3. Fair Value Measurements

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

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Assets				
Money market mutual funds	$ 1,034	$ —	$ —	$ 1,034
U.S. Treasury securities	58,988	—	—	58,988
U.S. Government agencies	—	24,989	—	24,989
Total assets	$ 60,022	$ 24,989	$ —	$ 85,011

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

There were no transfers between Levels 1, 2 or 3 for the periods presented.

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

	Years Ended December 31,		
	2020	2019	2018
Beginning balance	$ 1,169	$ 212	$ 127
Change in fair value of warrant liability	3,317	957	85
Conversion of preferred stock warrants to common stock warrants upon the closing of the IPO	(4,486)	—	—
Ending balance	$ —	$ 1,169	$ 212

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

4. Cash Equivalents and Short-Term Investments

The following is a summary of the Company's cash equivalents and short-term investments as of December 31, 2020 (in thousands):

	December 31, 2020			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Money market mutual funds	$ 1,034	$ —	$ —	$ 1,034
U.S. Treasury and government agencies securities	83,973	4	—	83,977
Total	$ 85,007	$ 4	$ —	$ 85,011
Reported as:				
Cash equivalents				$ 35,030
Short-term investments				49,981
Total				$ 85,011

As of December 31, 2020, the remaining contractual maturities for available-for-sale securities were less than one year. The Company did not have any short-term investments as of December 31, 2019.

5. Inventories, net

Inventories are net of reserves totaling $264,000 and $537,000 as of December 31, 2020 and 2019, respectively, and consist of the following (in thousands):

	December 31,	
	2020	2019
Raw materials	$ 2,607	$ 1,067
Work in process	787	640
Finished goods	7,203	2,246
	$ 10,597	$ 3,953

6. Property and Equipment. net

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

	December 31,	
	2020	2019
Manufacturing equipment	$ 4,003	$ 2,190
Leasehold improvements	1,737	932
Computer software	128	296
Furniture and fixtures	363	259
Computer hardware	980	527
Assets in progress	2,320	406
	9,531	4,610
Accumulated depreciation	(2,033)	(1,279)
	$ 7,498	$ 3,331

Depreciation expense of $1,039,000, $511,000 and $208,000 was included in SG&A expenses and $346,000, $103,000 and $75,000 was included in cost of goods sold for the years ended December 31, 2020, 2019 and 2018, respectively. The Company recorded aggregate losses on retirement of assets no longer in service of $237,000 and $119,000 for the years ended December 31, 2020 and 2019, respectively. $135,000 and $92,000 of these losses were included in cost of goods sold for the years ended December 31, 2020 and 2019, respectively, with the remaining $102,000 and $27,000 included in SG&A expenses. A loss on retirement of assets no longer in service of $29,000 was included in SG&A expenses for the year ended December 31, 2018.

Capitalized Implementation Costs of a Hosting Arrangement

The Company has several software systems that are cloud based hosting arrangements with service contracts. The Company early and prospectively adopted ASU 2018-15, *Intangibles—Goodwill and Other-Internal Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract* in the classification of costs incurred in connection with the implementation of these various software systems. Based on the guidance, the Company expenses all costs (internal and external) that are incurred in the planning and post-implementation operation stages and has capitalized approximately $344,000 in implementation costs related to the application development stage. The capitalized costs are amortized on a straight-line basis over the non-cancelable contract terms, generally three years. As of December 31, 2020 and 2019, approximately $228,000 and $46,000, respectively, of the capitalized costs were classified in current assets and $0 and $87,000, respectively, were classified in noncurrent assets. The Company starts amortizing capitalized implementation costs when the systems are placed in production and ready for their intended use. Amortization expense for the years ended December 31, 2020, 2019 and 2018 was approximately $100,000, $16,000 and $0, respectively, and is included in SG&A expenses.

7. Commitments and Contingencies

Operating Leases

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

In October 2020, the Company entered into a ten-year lease for a facility in Irvine, California (the "Oak Canyon" lease). The Oak Canyon lease is expected to commence in the second quarter of 2021, at which time the Company will move all of its operations to this new facility. The Oak Canyon lease contains two optional extension periods of five years each. In connection with the Oak Canyon lease, the Company maintains a letter of credit for the benefit of the landlord in the amount of $1.5 million, which is secured by the Company's Credit Agreement. The Company has not taken control of the Oak Canyon lease facility as of December 31, 2020.

Concurrently with the signing of the Oak Canyon lease, the Company entered into a termination agreement, as amended, that will release the Company from its current facility lease obligation within up to 15 months of the Oak Canyon lease commencement date.

Rent expense under the lease agreements was $790,000, $332,000 and $203,000 for the years ended December 31, 2020, 2019 and 2018, respectively. The Company also leases certain equipment under operating leases expiring in 2024. Future minimum commitments under all lease agreements are as follows (in thousands):

Year ending December 31:	Amount
2021	$ 1,506
2022	2,472
2023	2,164
2024	2,235
2025	2,301
Thereafter	13,672
	$ 24,350

Indemnification

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

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

Legal Proceedings

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

8. Concentrations

All the Company's revenue is derived from the sale of catheter-based therapeutic devices in the United States. For the years ended December 31, 2020, 2019 and 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, 2020 and 2019.

No vendor accounted for more than 10% of the Company's purchases for the years ended December 31, 2020, 2019 and 2018. There were no vendors which accounted for more than 10% of the Company's accounts payable as of December 31, 2020 and 2019.

9. Related Party

Licensed Patents

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

Included in prepaid expenses and other current assets was a non-interest-bearing retainer paid by the Company to Inceptus. The retainer was applied to amounts owed by the Company to Inceptus at a time mutually agreed to by both parties. For the years ended December 31, 2019 and 2018, the Company incurred development expenses with Inceptus of $28,000 and $16,000, respectively, which were applied against the balance of the retainer and included in research and development expense. In December 2019, Inceptus repaid in full to the Company the outstanding balance of the retainer. For the year ended December 31, 2020, the Company incurred and paid development expenses with Inceptus of $21,000, which were included in research and development expense.

Sublicense Agreement

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

In connection with the sublicense agreement, during the year ended 2019 the Company paid Inceptus $139,000 for the reimbursement of expenses and milestone and administration fees. The Company was originally required to pay an ongoing quarterly administration fee of $18,000, which increased to $29,000 per quarter upon the

completion of the Company's IPO. During the year ended December 31, 2020, the Company paid Inceptus $95,000 in administration fees.

Additionally, the Company is obligated to pay Inceptus an ongoing royalty ranging from 1% to 1.5% of the net sales of products utilizing the licensed intellectual property, subject to a minimum royalty quarterly fee of $1,000. For the years ended December 31, 2020 and 2019, the Company recorded royalty expense of $488,000 and $103,000, respectively. Royalty expense is included in cost of goods sold.

Other Services

The Company utilizes MRI The Hoffman Group ("MRI"), a recruiting services company owned by the brother of the Chief Executive Officer and President and member of the board of directors of the Company. The Company paid for recruiting services provided by MRI amounting to $427,000, $380,000 and $90,000 for the years ended December 31, 2020, 2019 and 2018, respectively. No amounts were due to MRI as of December 31, 2020 and 2019.

10. Debt

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

	December 31,	
	2020	2019
Revolving line of credit	$ —	$ 5,000
Term loan	—	15,000
Final payment fee	—	150
Total notes payables	—	20,150
Unamortized discount and debt issuance costs	—	(669)
Notes payable, net	$ —	$ 19,481

Signature Bank Credit Facility

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

The maturity date of the term loan was in December 2024. Under the agreement, the Company was required to make monthly interest payments through December 2021. The term loan bore interest at an annual rate equal to the greater of 5.50% or the Prime Rate plus 0.50%.

Under the revolving line of credit, the Company could borrow, repay and re-borrow up to 80% of eligible accounts receivable up to a maximum of $15 million. The revolving line of credit bore interest at an annual rate equal to the greater of 5.00% or the prime rate.

In August 2020, the Company repaid the SB Credit Facility in full, including the final payment fee of $250,000. Upon the repayment, the Company terminated the SB Credit Facility and recorded a loss on extinguishment of debt in the amount of $648,000 resulting from the write off of the unamortized deferred financing cost related to the SB Credit Facility which is reflected as Other Expenses in the consolidated statements of operations and comprehensive income (loss) for the year ended December 31, 2020.

Bank of America Credit Facility

In September 2020, the Company entered into a senior secured revolving credit facility with Bank of America (the "Credit Agreement"), under which the Company may borrow loans up to a maximum principal amount of $30.0 million. The amount available to borrow under the Credit Agreement is comprised of a) 85% of eligible accounts receivable, plus b) pledged cash (up to $10 million). There was no principal amount outstanding and no cash was pledged under the Credit Agreement as of December 31, 2020.

Advances under the Credit Agreement will bear interest at a base rate per annum (the "Base Rate") plus an applicable margin (the "Margin"). The Base Rate equals the greater of (i) the Prime Rate, (ii) the Federal funds rate plus 0.50%, or (iii) the LIBOR rate, or successor rate, based upon an interest period of 30 days plus 1.00%. The Margin will be 1.25% until March 31, 2021 and thereafter, will range from 1.00% to 1.50% based on the Company's applicable fixed charge coverage ratio. Advances under the Credit Agreement designated as "LIBOR Loans" will bear interest at a rate per annum equal to the LIBOR rate plus the applicable Margin of 2.25% until March 31, 2021 and thereafter, ranging from 2.00% to 2.50% based on the Company's applicable fixed charge coverage ratio. Interest on loans outstanding under the Credit Agreement is payable monthly. Loan principal balances outstanding under the Credit Agreement are due at maturity in September 2023. The Company may prepay any loans under the Credit Agreement at any time without any penalty or premium. The Company is also required to pay an unused line fee at an annual rate ranging from 0.25% to 0.375% per annum of the average daily unused portion of the aggregate revolving credit commitments under the Credit Agreement.

The Credit Agreement also includes a Letter of Credit subline facility (the "LC Facility") of up to $5 million. The aggregate stated amount outstanding of letter of credits reduces the total borrowing base available under the Credit Agreement. The Company is required to pay the following fees under the LC Facility are as follows: (a) a fee equal to the applicable margin in effect for LIBOR loans (currently 2.25%) times the average daily stated amount of outstanding letter of credits; (b) a fronting fee equal to 0.125% per annum on the stated amount of each letter of credit outstanding. As of December 31, 2020, the Company had one letter of credit in the amount of $1.5 million outstanding under the LC Facility.

The Company paid Bank of America a closing fee of $150,000 and incurred approximately $280,000 in legal and other fees directly related to the Credit Agreement. The Credit Agreement contains certain customary covenants and events of default, including: payment defaults, breaches of any representation, warranty or covenants, judgment defaults, cross defaults to certain other contracts, certain events with respect to governmental approvals if such events could cause a material adverse change, a material impairment in the perfection or priority of the lender's security interest or in the value of the collateral, a material adverse change in the business, operations, or condition of us or any of our subsidiaries, and a material impairment of the prospect of repayment of the loans. Upon the occurrence of an event of default, a default increase in the interest rate of an additional 2.0% could be applied to the outstanding loan balance and the lender could declare all outstanding obligations immediately due and payable and take such other actions as set forth in the loan and security agreement. The Company was in compliance with its covenant requirements as of December 31, 2020.

Obligations under the Credit Agreement are secured by substantially the Company's assets, excluding intellectual property.

Deferred Financing Costs

As of December 31, 2020, costs incurred directly related to debt are presented in other assets and are being amortized over the three-year life of the Credit Agreement on the straight-line basis. As of December 31, 2019, deferred financing costs were presented as a reduction of the related debt instrument and were amortized over the life of the related loan on an effective interest method as follows (in thousands):

	December 31,	
	2020	2019
Deferred financing costs	$ 430	$ 686
Accumulated amortization	(47)	(17)
Unamortized deferred financing costs	$ 383	$ 669

11. Redeemable Convertible Preferred Stock

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

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

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

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

12. Stockholders' Equity

Authorized Stock

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

Upon the closing of the IPO in May 2020, and as of December 31, 2020, the Company had authorized 310,000,000 shares of stock, of which 300,000,000 shares are designated as common stock and 10,000,000 shares are designated as preferred stock. All stock has a par value of $0.001 per share. There are no shares of preferred stock outstanding as of December 31, 2020.

Warrants

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

There are no warrants outstanding as of December 31, 2020. Warrants issued and outstanding as of December 31, 2019 were as follows:

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

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

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

In November 2020, the remaining 179,558 warrants were net exercised and the Company issued 174,776 shares of common stock.

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

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

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

13. Equity Incentive Plans

2011 Equity Incentive Plan and 2020 Incentive Award Plan

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

In March 2020, the Company adopted the 2020 Incentive Award Plan (the "2020 Plan"), which became effective in connection with the IPO. As a result, the Company may not grant any additional awards under the 2011 Plan. The 2011 Plan will continue to govern outstanding equity awards granted thereunder. The Company has initially reserved 3,468,048 shares of common stock for the issuance of a variety of awards under the 2020 Plan, including stock options, stock appreciation rights, awards of restricted stock and awards of restricted stock units. In addition, the number of shares of common stock reserved for issuance under the 2020 Plan will automatically increase on the first day of January for a period of up to ten years, commencing on January 1, 2021, in an amount equal to 3% of the total number of shares of the Company's capital stock outstanding on the last day of the preceding year, or a lesser number of shares determined by the Company's board of directors. As of December 31, 2020, there were 3,540,899 shares available for issuance under the 2020 Plan, including 269,268 shares which remained available under the 2011 Plan at the time the 2020 Plan became effective.

Stock Options

A summary of stock option activity under the 2011 Plan for the years ended December 31, 2020, 2019 and 2018 is as follows (intrinsic value in thousands):

	Number of Awards	Weighted Average Exercise Price	Weighted Average Fair Value	Weighted Average Remaining Contractual Life (in years)	Intrinsic Value
Outstanding, December 31, 2017	1,682,619	$ 0.30	$ 0.24	8.22	$ 29
Granted	1,928,799	0.43	0.36		
Exercised	(835,359)	0.31	0.26		96
Cancelled	(87,532)	0.31	0.26		
Outstanding, December 31, 2018	2,688,527	0.39	0.31	8.95	190
Granted	1,901,837	1.48	1.19		
Exercised	(409,893)	0.31	0.26		560
Cancelled	(98,169)	0.40	0.34		
Outstanding, December 31, 2019	4,082,302	0.90	0.74	8.76	22,667
Granted	305,494	7.47	3.73		
Exercised	(851,190)	0.55	0.50		49,413
Cancelled	(99,821)	8.39	3.62		
Outstanding, December 31, 2020	3,436,785	$ 1.36	$ 0.98	8.05	$ 295,331
Vested and exercisable at December 31, 2020	1,370,991	$ 0.88	$ 0.68	7.84	$ 118,473
Vested and expected to vest at December 31, 2020	3,409,054	$ 1.29	$ 0.93	7.98	$ 293,185

The aggregate intrinsic values of options outstanding, vested and exercisable, and vested and expected to vest were calculated as the difference between the exercise price of the options and the estimated fair value of the Company's common stock.

The fair value of each option grant under the 2011 Plan was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	Years Ended December 31,		
	2020	2019	2018
Expected volatility	40.60%	53.5% - 93.4%	109.10%
Weighted-average volatility	40.60%	83.24%	109.10%
Common stock fair value (per share)	$7.88 - $9.05	$0.59 - $6.15	$0.31 - $0.43
Dividend yield	0.00%	0.00%	0.00%
Risk free interest rates	1.46% - 1.68%	1.67% - 2.44%	2.63% - 3.00%
Expected remaining term in years	5.90 - 6.07	5.02 - 7.00	6.01 - 6.06

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.

Common Stock fair value—The fair value of the Company's common stock is determined by the board of directors with assistance from management. The board of directors determines the fair value of common stock by considering independent valuation reports and a number of objective and subjective factors, including valuations of comparable companies, sales of convertible preferred stock, operating and financial performance, the lack of liquidity of the Company's common stock and the general and industry-specific economic outlook.

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 as the Company believes this represents the best estimate of the expected terms of a new employee stock option.

The Company uses its historical rate of cancelled or expired unvested shares since inception of the plan as the expected forfeiture rate.

Restricted Stock Units

In March 2019, the Company granted, under the 2011 Plan, 2,867,326 restricted stock unit awards ("RSUs") to certain employees that vest only upon the satisfaction of both a time-based service condition and a performance-based condition. The performance-based condition is a liquidity event requirement that was satisfied on the effective date of the IPO of the Company's common stock. These RSUs are subject to a four-year cliff vesting and will vest in March 2023. If the RSUs vest, the actual number of RSUs that will vest will be dependent on the per share value of the Company's common stock, which is a market-based condition, determined based on the average closing price of the Company's common stock for the three-month period immediately preceding the satisfaction of the service condition.

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

The estimated fair value of these RSUs were determined on the date of grant using the Monte Carlo simulation model, which utilizes multiple input variables to simulate a range of our possible future equity values and estimates the probabilities of the potential payouts. The determination of the estimated grant date fair value of these RSUs is affected by our equity valuation and a number of assumptions including our future estimated enterprise value, our risk-free interest rate, expected volatility and dividend yield. The following assumptions were used to calculate the fair value of these options and restricted stock units in the Monte Carlo simulation model at the grant date:

	Year ended December 31, 2019
Expected term (in years)	4.00
Expected volatility	50.00%
Dividend yield	0.00%
Risk free interest rate	2.41%

As of December 31, 2019 and through May 21, 2020, no stock-based compensation expense had been recognized for these awards because the liquidity event performance condition described above for the RSUs was not considered probable of being satisfied. Upon the completion of the Company's IPO, the Company recognized $159,000 of cumulative stock-based compensation expense related to such awards, which is included in SG&A expenses for the year ended December 31, 2020.

2020 Plan

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

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

	Number of Awards	Weighted Average Fair Value	Intrinsic Value
Outstanding, December 31, 2019	—	$ —	$ —
Granted	227,963	58.68	13,356
Vested	(1,199)	51.41	80
Cancelled	(4,200)	51.41	232
Outstanding, December 31, 2020	222,564	$ 58.86	$ 19,428

Stock Based Compensation

Total compensation cost for all share-based payment arrangements recognized, including $560,000 of stock-based compensation expense related to the ESPP for the year ended December 31, 2020, was as follows (in thousands):

	Years Ended December 31,		
	2020	2019	2018
Cost of goods sold	$ 155	$ 52	$ 2
Research and development	592	99	70
Selling, general and administrative	2,776	354	176
	$ 3,523	$ 505	$ 248

Total compensation costs as of December 31, 2020 related to all non-vested awards to be recognized in future periods was $14,382,000 and is expected to be recognized over the remaining weighted average period of 3.4 years.

Employee Stock Purchase Plan (ESPP)

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

As of December 31, 2020, no shares of common stock have been purchased under the ESPP.

The fair value of the ESPP shares is estimated using the Black-Scholes option pricing model.

	Year ended December 31, 2020
Expected term (in years)	0.5
Expected volatility	49.23%
Dividend yield	0.00%
Risk free interest rate	0.11%

14. Income Taxes

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

	Years Ended December 31,		
	2020	2019	2018
Income (loss) before taxes	$ 13,789	$ (1,192)	$ (10,153)
Income tax provision (benefit)	—	—	—
Net income (loss)	$ 13,789	$ (1,192)	$ (10,153)
Income tax provision (benefit) as a percentage of income taxes	0.00%	0.00%	0.00%

The Company's effective tax was 0% for the years ended December 31, 2020, 2019 and 2018. The Company's effective tax rate for all periods is driven by pre-tax income (loss), business credits, equity compensation, debt warrants, and the change in valuation allowance. No tax provision (benefit) was recorded for the years ended December 31, 2020, 2019 and 2018.

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:

	December 31,	
	2020	2019
Deferred tax assets		
Inventory	$ 97	$ 170
Intangible Asset Basis	1,475	1,810
Accrued Employee Compensation	547	203
NOLs and Capital Loss Carryforwards	8,033	8,180
Credit Carryforwards	2,379	1,409
Equity Compensation	358	—
Other	64	355
Total deferred tax assets	$ 12,953	$ 12,127
Deferred tax liabilities		
Fixed Asset Basis	$ (1,069)	$ (349)
Other liabilities	(18)	(21)
Total deferred tax liabilities	$ (1,087)	$ (370)
Valuation allowance	$ (11,866)	$ (11,756)
Net deferred tax losses and tax credit carryforwards	$ —	$ —

ASC 740 requires that the tax benefit of net operating losses, or NOLs, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable

income within the carryback or carryforward periods. Management believes that recognition of the deferred tax assets arising from the above-mentioned tax benefits from NOLs and credit carryforwards is currently not likely to be realized and, accordingly, has provided a valuation allowance against its deferred tax assets. The valuation allowance increased by $110,000 during 2020.

The effective tax rate of the Company's (provision) benefit for income taxes differs from the federal statutory rate as follows:

	Years Ended December 31,		
	2020	2019	2018
Statutory rate	$ 2,896	$ (265)	$ (2,132)
Meals and entertainment	213	93	26
Stock -based compensation	(3,576)	106	52
162(m) Limitation	197	—	—
Stock warrants	696	—	—
Return to provision	258	(26)	—
Other permanent adjustments	827	29	—
General business credits	(1,621)	(152)	(308)
Change in valuation allowance	110	215	2,362
Total	$ —	$ —	$ —

As a result of losses incurred in the past, the Company has NOL carry-forwards that are available to offset future taxable income and subject to expiration rules and to Internal Revenue Code of 1986, as amended ("IRC") §382. In general, IRC §382 may impact the amount of NOLs that can be utilized each year after certain ownership changes occur. An ownership change occurs, generally, if the percentage of stock of the loss corporation owned by one or more 5% shareholders has increased by more than 50 percentage points relative to the lowest percentage of stock of the loss corporation owned by the same 5% shareholders at any time during the testing period (generally, the three-year period preceding a testing date).

Net operating losses and tax credit carryforwards as of December 31, 2020 are as follows:

	Amount	Expiration Years
Net operating losses, federal - Expiring	$ 20,843	2031 - 2037
Net operating losses, federal - Indefinite	$ 9,305	Indefinite
Net operating losses, state	24,959	2031 - 2038
Net operating losses, foreign	813	2028
Tax credits, federal	2,341	2021 - 2031
Tax credits, state	1,725	Indefinite

Pursuant to an IRC §382 limitation analysis performed by the Company, it was noted that an ownership change, as defined under IRC §382, occurred on March 29, 2018. Usage of NOL's generated prior to March 29, 2018 will be limited to $3.0M for calendar years 2019 through 2022 and $0.6M from 2023 through 2039 for both federal and state purposes. Of the federal net operating loss and the state net operating loss carryforward amounts, $22.6 million and $22.0 million are subject to the IRC §382 limitation, respectively. There is not an IRC §382 limitation on the foreign NOLs.

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 and are, therefore, eligible for the Increasing Research Activities credit under IRC §41. R&D credit carryovers generated prior to March 29, 2018 are limited under IRC §383 to $0.3 million a year for both federal and state purposes. The Company has adjusted the deferred tax assets related to Federal R&D credit carryover to account for any tax credits that will expire unused due to the IRC §383 limitations.

As of December 31, 2020 and 2019, the Company has total uncertain tax positions of $882,000 and $1,091,000, respectively. The Company estimates that these liabilities would be reduced by $882,000 and

$1,091,000, respectively, from offsetting tax benefits associated with the correlative effects of net operating losses and other timing adjustments. The net amounts of all years, if not required, would favorably affect the Company's effective tax rate. No interest or penalties have been recorded related to the uncertain tax positions. A reconciliation of the beginning and ending balances of unrecognized tax benefits is as follows:

	Years Ended December 31,		
	2020	2019	2018
Balance at the beginning of the year	$ 1,091	$ 859	$ 560
Deductions based on tax positions related to prior years	(496)	(226)	—
Additions based on tax positions related to the current year	287	458	299
Balance at the end of the year	$ 882	$ 1,091	$ 859

It is not expected that there will be a significant change in uncertain tax position in the next 12 months. The Company is subject to U.S. federal and state income tax in multiple state jurisdictions, and various foreign jurisdictions. In the normal course of business, the Company is subject to examination by tax authorities. As of the date of the financial statements, there are no tax examinations in progress. The statute of limitations for tax years ended after December 31, 2017, December 31, 2016 and December 31, 2015 are open for federal, state and foreign tax purposes, respectively.

CARES Act

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

15. Retirement Plan

In December 2017, the Company adopted the Inari Medical, Inc. 401(k) Plan which allows eligible employees after one month of service to contribute pre-tax and Roth contributions to the plan, as allowed by law. The plan assets are held by Vanguard and the plan administrator is Ascensus. For the years ended December 31, 2020, 2019 and 2018, the Company did not make any fund-matching contributions. Beginning in January 2021, the Company will contribute a $1.00 match for every $1.00 contributed by a participating employee up to the greater of $3,000 or 4% of eligible compensation under the plan, with such Company contributions becoming fully vested immediately.

16. Net Income (Loss) Per Share

The components of net income (loss) per share are as follows:

	Years Ended December 31,		
	2020	2019	2018
Numerator:			
Net income (loss)	$ 13,789	$ (1,192)	$ (10,153)
Denominator:			
Weighted average number of common shares outstanding - basic	32,033,827	5,887,542	5,056,743
Common stock equivalents from convertible preferred stock	12,490,452	—	—
Common stock equivalents from outstanding common stock options	3,856,222	—	—
Common stock equivalents from unvested RSUs	2,858,224	—	—
Common stock equivalents from outstanding warrants	191,194	—	—
Common stock equivalents from restricted stock	125,077	—	—
Weighted average number of common shares outstanding - diluted	51,554,996	5,887,542	5,056,743

The Company did not have any anti-dilutive common stock equivalents for the year ended December 31, 2020. 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:

	Years Ended December 31,	
	2019	2018
Convertible preferred stock	31,968,570	31,968,570
Common stock options	4,082,302	2,688,527
RSUs	2,867,326	-
Restricted stock subject to future vesting	397,199	805,300
Convertible preferred stock warrants	256,588	256,588
Common stock warrants	27,810	27,810
	39,599,795	35,746,795