

[Table of Contents](#)

**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, 2022

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_

Commission File Number 001-39293

**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.)

6001 Oak Canyon, 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.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

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, 2022, the last business day of the Registrant's most recently completed second fiscal quarter was approximately \$3.28 billion.

The number of shares of Registrant's Common Stock outstanding as of February 24, 2023 was 54,313,676.

**DOCUMENTS INCORPORATED BY REFERENCE**

The Registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2022. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

## Table of Contents

### Table of Contents

	<u>Page</u>
<b>PART I</b>	
Item 1. <a href="#">Business</a>	4
Item 1A. <a href="#">Risk Factors</a>	24
Item 1B. <a href="#">Unresolved Staff Comments</a>	64
Item 2. <a href="#">Properties</a>	64
Item 3. <a href="#">Legal Proceedings</a>	65
Item 4. <a href="#">Mine Safety Disclosures</a>	65
<b>PART II</b>	
Item 5. <a href="#">Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</a>	66
Item 6. <a href="#">[Reserved]</a>	67
Item 7. <a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	68
Item 7A. <a href="#">Quantitative and Qualitative Disclosures About Market Risk</a>	80
Item 8. <a href="#">Financial Statements and Supplementary Data</a>	80
Item 9. <a href="#">Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</a>	80
Item 9A. <a href="#">Controls and Procedures</a>	80
Item 9B. <a href="#">Other Information</a>	83
Item 9C. <a href="#">Disclosure Regarding Foreign Jurisdictions that Prevent Inspections</a>	83
<b>PART III</b>	
Item 10. <a href="#">Directors, Executive Officers and Corporate Governance</a>	84
Item 11. <a href="#">Executive Compensation</a>	84
Item 12. <a href="#">Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</a>	84
Item 13. <a href="#">Certain Relationships and Related Transactions, and Director Independence</a>	84
Item 14. <a href="#">Principal Accountant Fees and Services</a>	84
<b>PART IV</b>	
Item 15. <a href="#">Exhibits and Financial Statement Schedules</a>	85
Item 16. <a href="#">Form 10-K Summary</a>	89

## [Table of Contents](#)

### **Forward-Looking Statements**

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to substantial risks and uncertainties. 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, 2022. 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.

## [Table of Contents](#)

### **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 may incur operating losses in the future and we may not be able to sustain profitability;
- Our business is dependent upon the broad adoption of our solutions and catheter-based thrombectomy procedures by hospitals, physicians and patients;
- The market for our solutions is highly competitive, and our competitors may have longer operating histories, more established products and greater resources than we do;
- We face a number of manufacturing risks that may adversely affect our manufacturing abilities;
- We depend on a limited number of single source suppliers, which makes us vulnerable to supply shortages and price fluctuations;
- The use, misuse or off-label use of our solutions may result in enforcement action by the FDA or injuries that lead to product liability suits or regulatory action, either of which could be expensive, divert management's attention and harm our reputation and business;
- We may not be able to maintain adequate levels of third-party coverage and reimbursement or third parties may rescind or modify their coverage or delay payments related to our solutions;
- If the quality of our solutions does not meet the expectations of physicians or patients, then our brand and reputation or our business could be adversely affected;
- Our long-term growth depends on our ability to enhance our solutions, expand our indications and develop and commercialize additional new solutions in a timely manner and if we fail to do so we may be unable to grow our business;
- We may be unable to manage the anticipated growth of our business;
- We operate our business, including manufacturing our solutions, out of a single site in Irvine, California, and we may experience delays in production or an increase in costs if this facility is damaged or becomes inoperable;
- Our solutions and operations are subject to extensive government regulation and oversight in the United States and in foreign countries;
- We may not receive, or may be delayed in receiving, the necessary clearances, certifications or approvals for our future solutions or modifications to our current solutions, and failure to timely obtain necessary clearances, certifications or approvals for our future solutions or modifications to our current solutions would adversely affect our ability to grow our business; and
- Our success will depend on our, and any of our current and future licensors', ability to obtain, maintain and protect our intellectual property rights.

## [Table of Contents](#)

## PART I

### **Item 1. Business.**

#### **Overview**

Patients first. No small plans. Take care of each other. These are the guiding principles that form the ethos of Inari Medical. We are committed to improving lives in extraordinary ways by creating innovative solutions for both unmet and underserved health needs. In addition to our purpose-built solutions, we leverage our capabilities in education, clinical research, and program development to improve patient outcomes. We are passionate about our mission to establish our treatments as the standard of care for venous thromboembolism and beyond. We are just getting started.

We purpose build minimally invasive, novel, catheter-based mechanical thrombectomy systems for the unique characteristics of specific disease states. The key elements of our growth strategy are:

- Continuing to expand our sales force;
- Driving deeper penetration of our solutions with our hospital customers;
- Building clinical evidence to support changes to current standard of care;
- Innovating new solutions to address unmet needs; and
- Expanding into new markets.

We have experienced significant growth since we began commercializing our products in the United States. We generated revenue of \$383.5 million, with a gross margin of 88.4% and net loss of \$29.3 million for the year ended December 31, 2022, compared to revenue of \$277.0 million, with a gross margin of 91.1% and net income of \$9.8 million for the year ended December 31, 2021.

#### **Our Opportunities**

##### ***Venous Thromboembolism – Pulmonary Embolism and Deep Vein Thrombosis***

Venous thromboembolism, or 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 includes both deep vein thrombosis, or DVT, and pulmonary embolism, or PE. Our first two solutions, ClotTriever and FlowTriever, were developed to treat the debilitating effects of VTE and this remains a core focus of our business.

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. In addition to anticoagulants, some patients also receive thrombolytic drug therapy. Thrombolytic drugs accelerate the body's natural mechanisms for breaking down clot but have limited effectiveness due to the chronic nature of most venous clots. 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.

Patients with DVT can experience swelling, cramping and unexplained pain in the foot, ankle or leg, warm skin and discoloration of the skin. Symptoms can persist and worsen over time if left untreated and can ultimately progress into chronic venous disease. If DVT is treated with conservative therapies only, patients can develop painful, debilitating ulcers, and up to 50% of patients will develop post-thrombotic syndrome, or PTS, a severe, lifestyle-limiting disease that is characterized by chronic pain, swelling and skin ulcers.

## [Table of Contents](#)

PE represents the third leading cause of cardiovascular death in the United States after myocardial infarction and stroke. Patients with PE can experience trouble breathing, chest pain, coughing blood, rapid heartbeat, passing out and, ultimately, death. Up to 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, and have a statistically higher rate of recurrent PE, pulmonary hypertension, heart failure and death. PE is a leading cause of preventable deaths in hospitals. For example, high-risk PE has a mortality rate of up to 50%, with approximately 5% of all PE patients considered high risk. Intermediate risk PE has a 12% to 15% mortality rate and represents approximately 45% of all PE patients.

We believe the best way to treat VTE and improve the quality of life for patients suffering from this disease is to safely and effectively remove the blood clot. Through our clinical evidence, we have proven that removing all or almost all of the clot matters. We purpose built our clot-removing ClotTriever and FlowTriever systems to effectively treat DVT and PE.

We estimate that approximately 1.6 million people present with VTE in the United States each year, with approximately 1.0 million patients diagnosed with DVT and approximately 560,000 patients diagnosed with PE each year. Based on our recent reassessment of the total addressable market for VTE in the United States, of these estimated annual DVT and PE diagnoses, we believe approximately 410,000 DVT patients and approximately 280,000 PE patients could benefit from safe and effective treatment with our ClotTriever and FlowTriever systems each year, respectively. In addition, we believe there are approximately 20,000 patients with clot in transit in the right atrium who could benefit from treatment with our FlowTriever system. Taken together, these patients represent a potential annual addressable U.S. market opportunity for these solutions of approximately \$5.8 billion. We also believe there is a substantial market opportunity internationally.

### **Chronic Venous Disease**

Chronic venous disease, or CVD, often progresses from DVT and includes scarred vein walls and wall-adherent obstructions. If these obstructions are left unaddressed, patients can develop painful, debilitating ulcers and ultimately progress to PTS. Up to 50% of patients suffering from DVT that are treated with conservative therapies will develop CVD, which is often caused by chronic scarring and occlusion of vessels. Because of the severity and lifestyle-limiting nature of CVD symptoms, approximately 90% of patients with PTS are unable to work 10 years after diagnosis.

The current standard of care for treating CVD is conservative medical management with anticoagulants, compression therapy and superficial treatment of wounds and leg ulcers. Nearly all patients receive this treatment, many of whom remain on anticoagulants for the remainder of their lives. The poor outcomes for many patients with DVT described above occur despite being treated with conservative medical management.

We believe the best way to treat CVD and improve the quality of life for patients suffering from this disease is to safely and effectively restore the flow through opening the obstructed vein, including the removal of any chronic clot that may remain. In addition to treating CVD with our existing ClotTriever and FlowTriever systems, we purpose built our ClotTriever BOLD catheter to address a range of clot chronicity, including chronic clot. We plan to continue our efforts in treating the debilitating effects of CVD and related diseases through additional solutions to our ClotTriever toolkit in the near and medium term.

We estimate that approximately 100,000 people in the United States each year present with a new case of obstructive CVD, with an estimated prevalence of approximately 1.0 million patients. These patients represent a potential annual addressable U.S. market opportunity of approximately \$1.0 billion, with a prevalence of approximately \$10.0 billion. We also believe there is a substantial market opportunity internationally.

### **Small Vessel Thrombosis**

## Table of Contents

Small vessel thrombosis refers to clots that occur in the smaller vessels, including the upper extremities, below the knee, and arteriovenous (AV) thrombosis primarily in dialysis fistulas or grafts. Thrombosis that occurs at the AV access point in an AV fistula or graft can result in loss of access to life-saving dialysis.

Current treatments for small vessel thrombosis generally are limited due to conservative medical management similar to VTE. In addition, with respect to dialysis patients, current treatments are limited due to a number of factors, including that most methods for removing clot from the AV send clot to the lungs, exacerbating pulmonary hypertension in an already sick patient. In addition, thrombosis in the AV has a high recurrence rate and current treatments are not as effective for chronic or larger clot burdens.

We believe the best way to treat small vessel thrombosis and improve the quality of life for patients suffering from the underlying diseases is to safely and effectively remove as much clot as possible. We purpose built our InThrill system to effectively treat small vessel thrombosis generally, and AV thrombosis specifically. We plan to continue our efforts in treating the debilitating effects of clot in the small vessels through additional solutions or enhancements.

We estimate that approximately 200,000 patients in the United States each year present with AV thrombosis and another approximately 80,000 patients present with thrombosis below the knee or in the upper extremities. These patients represent a potential annual addressable U.S. market opportunity of approximately \$1.0 billion. We also believe there is a substantial market opportunity internationally.

### ***Arterial Thromboembolism***

Acute limb ischemia (ALI), acute visceral ischemia, and certain cases of chronic limb ischemia are all acute embolization events that can cause extensive damage if not treated quickly. Due to the emergent nature of these diseases and because there are no purpose-built solutions, over 50% of patients often require open surgical procedures which can result in distal embolization and vessel trauma. If a patient is not a candidate for open embolectomy, they are often treated with thrombolytic drugs or other conservative forms of medical treatment.

We believe the best way to treat ALI and related diseases is to quickly, safely and effectively remove the clot. We are purposefully designing our Artix system to effectively remove thrombosis to alleviate the symptoms of these underlying and emergent diseases, and we plan to continue developing solutions for these disease states.

We estimate that approximately 80,000 patients in the United States each year present with ALI or other arterial thromboembolism in the peripheral vasculature. These patients represent a potential annual addressable U.S. market opportunity of approximately \$600.0 million. We also believe there is a substantial market opportunity internationally.

### **Our Solutions**

We believe our products are transformational because they provide the following key benefits:

- Simple, intuitive and easy to use solutions to physicians;
- Enable short, single-session treatment with improved hospital and physician efficiency;
- Offer positive clinical outcomes for patients and economic value to hospitals;
- Capture and remove clot burden from vessels with tools designed to fit the vessel size, including large bore catheters for the venous system;
- Liberate clot mechanically where aspiration technology may not be as effective;
- Eliminate the need for thrombolytic drugs; and

## [Table of Contents](#)

- Remove clot safely with minimal blood loss and return blood to patients when treating PE using our proprietary FlowSaver blood return system.

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 purpose-built solutions. 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 solutions could be the catalyst to drive the same evolution of treatment for our target opportunities, establishing our solutions as the standard of care.

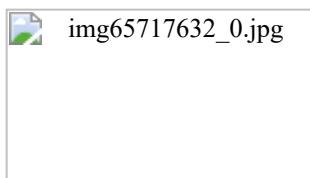
All of our systems are designed as single-use, sterile systems, to be deployed over a wire. They do not require capital equipment. Procedures are typically performed in a catheterization laboratory, or cath lab, interventional suite or operating room. Each component of a system is packaged separately, and we generally price our systems on a per procedure basis instead of charging for each component used in a procedure. Our sales representatives generally target interventional radiologists, interventional cardiologists, and vascular surgeons in selling each of our systems.

### ***ClotTriever and Other Systems***

#### ***ClotTriever System***

The ClotTriever system is a comprehensive solution for DVT and peripheral thrombus. The ClotTriever system was designed to core, capture, and remove large clots from large vessels. The ClotTriever is 510(k) cleared for the non-surgical removal of thrombi and emboli from blood vessels, and for the injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel, is intended for use in the peripheral vasculature including in patients with DVT, and is CE marked for the treatment of DVT. We began commercializing our ClotTriever system in 2017 and continue to expand the system through indication expansions, component enhancements and new solutions.

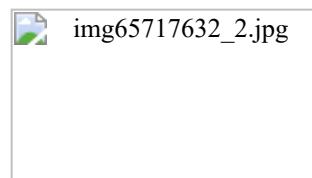
Each component is packaged separately and may be sold individually or as part of a system. The ClotTriever system consists of the following primary components:



**ClotTriever Sheath**



**ClotTriever Bold Catheter**



**ClotTriever Catheter**



**ProTrieve Sheath**

#### ***Chronic Venous Disease Toolkit***

We are currently designing a toolkit for treating CVD. The first device in the toolkit is the ClotTriever BOLD which also forms part of our DVT toolkit. The ClotTriever BOLD is similar to the original ClotTriever catheter and is designed to core, capture and remove large clots from large vessels and address a range of clot chronicity, including chronic clot. The ClotTriever BOLD is 510(k) cleared for the non-surgical removal of thrombi and emboli from blood vessels, and for the injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel, is intended for use in the peripheral vasculature, including in patients with DVT, and is CE marked for the treatment of DVT. We began commercializing the ClotTriever BOLD in early 2022, and we are continuing to expand our CVD toolkit to include a recanalization device, crossing device and stent cleaner device among other enhancements

## [Table of Contents](#)

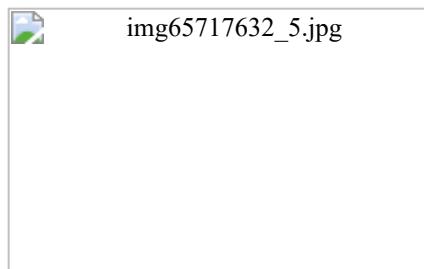
and expansions. We expect the CVD toolkit devices to be packaged separately and sold individually or as a part of the ClotTriever system.



**ClotTriever Bold Catheter**

### *InThrill System*

The InThrill system was purpose-built to treat small vessel thrombosis. The InThrill system is 510(k) cleared for the non-surgical removal of emboli and thrombi from blood vessels, and the injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel, and is intended for use in the peripheral vasculature but not intended for use in DVT treatment. We began commercializing the InThrill system in the fourth quarter of 2022. Each component is packaged separately and sold individually.



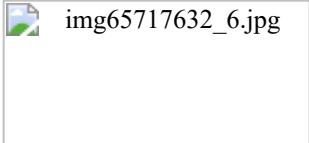
**InThrill Catheter and Sheath**

### *FlowTriever System*

The FlowTriever is a large bore catheter-based aspiration and mechanical thrombectomy system designed to remove large clots from large vessels in the peripheral vasculature and specifically to treat PE, although it is also used by physicians to treat other complex venous thromboembolism cases. The FlowTriever is 510(k)-cleared by the FDA for the non-surgical removal of emboli and thrombi from blood vessels, and injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel, is intended for use in the peripheral vasculature and for the treatment of PE, and is CE marked for the treatment of PE. Triever catheters, a component of the FlowTriever system, are also intended for use in the treatment of clot in transit from the right atrium. We began commercializing our FlowTriever system in 2017 and continue to expand the system through indication expansions, component enhancements and new solutions.

The FlowTriever system consists of the following components, which are included in the price of the system:

## Table of Contents



**Triever** Catheters



**FlowTriever** Catheters



**Triever20 Curve** Catheter



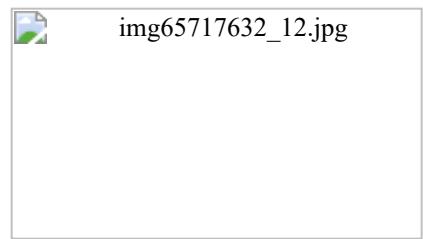
**FlowSaver** Blood Return System



**Intri24** Sheath



**Large Bore** Syringe and Whoosh  
Mechanism



**FlowStasis** Suture Retention Device

## **Four Pillar Foundation**

Our ethos is to put patients first, make no small plans, and take care of each other. We have established a four pillar foundation for our business:

- Education and Training – we develop specialized content for both internal and external users, including providing robust sales team training and external training through our Clot Warrior Academy;
- Clinical Research – we believe we are the market leader for building clinical evidence with a mission of changing the standard of care;
- Solutions Development – we have an industry-leading pipeline of enhanced and new solutions, with the ability to rapidly iterate; and
- Program Development – we have a team dedicated to program building, including our VTE Excellence platform.

### ***Education and Training***

We have an established and experienced team of medical education professionals, who lead the training program and content development for our internal and external users. Because our sales representatives attend many of the procedures where our devices are used, we have a robust sales training program to ensure they are able to support our customers and to keep them up to speed on clinical and device-related updates real-time.

In addition, this team develops and leads regular national, regional, and local training and educational programs for both interventional and non-interventional physicians, nursing staff and other personnel involved in our procedures at a hospital. Our medical affairs team, led by Thomas Tu, M.D., our Chief Medical Officer and an interventional cardiologist by training, consists of four full-time physicians (two interventional cardiologists, including Dr. Tu, one interventional radiologist and one pulmonologist with expertise in PE). With our team of experts, we have greatly expanded our Clot Warrior Academy since its launch in 2020 to provide regular and interactive training dozens of times per year. We host other events

## Table of Contents

designed to help physicians who are familiar with our solutions and procedures to learn additional and enhanced techniques.

### **Clinical Research**

Since our inception, we have focused on generating clinical data to build evidence to change the standard of care for the treatment of VTE and other diseases.

Following completion of U.S. enrollment in our FLASH study for the FlowTriever system in PE patients (the largest prospective PE device study with up to 1,000 patients), we reported the results during a late-breaking clinical trial session at the TCT (Transcatheter Cardiovascular Therapeutics) conference in September 2022. We also completed enrollment in our FLAME study which is the largest prospective high-risk PE device study with over 100 patients. We commenced enrollment in our first randomized control trial (RCT) – PEERLESS, a prospective, multicenter trial enrolling up to 700 patients at up to 60 centers that will compare the clinical outcomes of patients with intermediate risk PE treated with FlowTriever to those treated with catheter-directed thrombolysis.

With respect to DVT, we completed enrollment in our CLOUD study for the ClotTriever system in DVT patients, which is the largest prospective DVT thrombectomy study of 500 patients. We also announced the first industry-sponsored RCT for DVT - DEFIANCE, studying ClotTriever's performance in patients with moderate to severe iliofemoral DVT as compared to conservative medical management alone. We enrolled our first patient in this study in January 2023.

In addition to our RCTs and studies, we have a number of investigator-initiated research underway as well as multiple publications annually on the safety, efficacy and cost effectiveness of our devices.

### **Solutions Development**

We are committed to improving lives in extraordinary ways by creating innovative solutions for both unmet and underrecognized health needs and we are dedicated to the treatment of venous and other diseases. We believe our ability to develop innovative solutions is attributable to our focus on the specific anatomical system, the design philosophy and development 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 solutions 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. Our development efforts are focused on developing the best treatment for patients and we center our efforts on feedback from our customers, who are at the front lines of treating patients with VTE and other complex diseases. This process has allowed us to rapidly innovate and enhance our solutions, and we continue to develop new and enhanced solutions for our portfolio.

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

For the years ended December 31, 2022, 2021 and 2020, our research and development expenses, which includes clinical research expenses, were \$74.2 million, \$51.0 million and \$18.4 million, respectively.

### **Program Development**

## Table of Contents

We believe that the standard of care for the treatment of VTE and other diseases will evolve similar to that of other thrombotic diseases, such as myocardial infarction and stroke, to anticoagulants together with catheter-based interventions. We believe our purpose-built solutions are further driving this evolution of treatment and we are committed to changing the standard of care for VTE and other diseases. In this regard, we have a team who develops innovative ideas for educating facilities and administrators on the benefits of having a dedicated VTE response team, institutional guidelines for treatment of VTE, and a comprehensive quality review of their respective VTE programs. The efforts we make to improve VTE treatment awareness and procedural excellence overlap with our continued push for more robust clinical evidence and collaboration with, and input from key stakeholders, including physicians that treat VTE and non-interventional stakeholders who are instrumental in making referrals or establishing treatment protocols within medical facilities.

### **Sales and Marketing**

We believe our mission-focused and highly-trained 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 recruit sales representatives who have substantial and applicable medical device or other relevant sales experience. Our front-line sales representatives typically attend procedures, which puts us at the intersection of the patient and physician. We have developed systems and processes to harness the information gained from these relationships and we leverage this information to rapidly iterate solutions, introduce and execute physician education and training programs and scale our sales organization. We market and sell our solutions 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 over 280 territories as of December 31, 2022. We continue to actively expand our sales organization through additional sales representatives and territories.

We currently sell our solutions to over 1,600 of the approximately 2,000 hospitals in the United States with a cath lab or interventional suite where catheter-based procedures can be performed. 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 customer account level in order to drive greater adoption of our solutions as the preferred first-line choice treatment for patients. This strategy enables our sales representatives to have regular and targeted communications to convey the benefits of our solutions to non-interventional physicians, such as emergency department physicians and pulmonologists.

### **Manufacturing and Supply**

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

We are registered with the FDA as a medical device manufacturer and are licensed by the State of California to manufacture and distribute our medical devices. We are required to manufacture our devices 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. In October 2021, we moved to our current Irvine, California facility. The FDA conducted its most recent inspection in August 2016. This inspection was conducted at our prior facility, 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,

## Table of Contents

scheduled annual surveillance audits and periodic unannounced audits. The most recent recertification audit was conducted at our prior facility, also located in Irvine, California, in October 2021 and an unannounced audit in November 2021, both of which resulted in no major non-conformities noted. We also had one special assessment audit in December 2021 of our new facility, with no major non-conformities identified.

We use a combination of internally manufactured and externally-sourced components to produce our medical device systems. Externally-sourced components include off-the-shelf materials, sub-assemblies and custom parts that are provided by approved suppliers. Some of these components 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 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 continually looking for opportunities to approve 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 could 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 solutions are then ethylene oxide sterilized by qualified third-party suppliers.

## **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. For our VTE solutions, 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 divisions of Boston Scientific Corporation, Penumbra, Abbott, Philips, AngioDynamics, and Teleflex, and multiple smaller companies that have single products or a limited range of products. There is growing interest in the treatment of VTE disease with catheter-based solutions, and there are a significant number of approved thrombectomy devices available or entering the market in the near term. 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 ClotTriever and FlowTriever systems 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.

## Table of Contents

With respect to our other systems, we are just entering the market and believe there are currently limited competitors offering purpose-built solutions for our target opportunities. Therefore, we currently compete with manufacturers of thrombolytic drugs or anticoagulants, or with physicians' treatment decisions, such as surgery instead of intervention.

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 solutions will be overcoming established treatment patterns, which we seek to accomplish through our four-pillar foundation and driving the education of referral sources and physicians, generating supportive clinical data and developing treatment programs with hospitals and other customers.

### **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, 2022, we held 33 U.S. patents, which are expected to expire between March 2025 and May 2039, 32 pending U.S. patent applications, six issued foreign patents, and 43 pending foreign patent applications including five 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 devices and methods for treating vascular occlusions and embolisms.

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, 2022, we had 32 registered trademarks and 45 pending trademark applications worldwide, including trademark registrations for "Inari Medical", "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 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.

### **Coverage and Reimbursement**

In the United States, we sell our solutions 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. We do not participate in the billing or reimbursement process and as such, do not engage directly with patients or payors with respect to billing. Government agencies, private insurers and other payors determine whether to provide coverage for a particular procedure and to reimburse hospitals

## [Table of Contents](#)

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.

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. 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 device or procedure.

As we continue to expand into new geographies, we work with the local government agencies to establish relevant reimbursement for our solutions.

## **Cybersecurity**

In the normal course of business, we may collect and store personal information and other sensitive information, including proprietary and confidential business information, trade secrets, intellectual property, information regarding trial participants in connection with clinical trials, sensitive third-party information and employee information. To protect this information, our existing cybersecurity policies require continuous monitoring and detection programs and network security precautions. We maintain various protections designed to safeguard against cyberattacks, such as network intrusion detection and prevention systems and endpoint detection response software. We periodically scan our environment for any vulnerabilities.

Our cybersecurity program is led by a cross functional team which consists of cybersecurity, data protection and risk-skilled professionals. The program incorporates industry-standard frameworks, policies and practices designed to protect the privacy and security of our sensitive information. Our cybersecurity team reports to the Audit Committee on information security and cybersecurity matters on a regular basis. The Audit Committee of our Board of Directors has oversight responsibility for our data security practices.

Despite our cybersecurity program, our security measures cannot guarantee that a significant cyberattack will not occur. A successful attack on our information technology systems could have significant consequences for our business. While we devote resources to our security measures to protect our systems and information, these measures cannot provide absolute security. See "Risk Factors – General Risk Factors" for additional information about the risks to our business associated with a breach or compromise to our information technology systems.

## **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.

## [Table of Contents](#)

### ***United States Regulation***

The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, sale, 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 application, or PMA. 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, also referred to as a 510(k) clearance. Class III devices are those deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices deemed not substantially equivalent to a previously cleared 510(k) device, requiring approval of a PMA. 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, 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.

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

## [Table of Contents](#)

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.

### *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 approval of 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. 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.

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.

### *De novo classification process*

Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a route to market for low-to-moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the de novo classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act, or FDASIA, in July 2012, a medical device could only be eligible for de novo classification if the manufacturer first submitted a 510(k) pre-market notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the de novo classification pathway by permitting manufacturers to request de novo classification directly without first submitting a 510(k) pre-market notification to the FDA and receiving a not-substantially-equivalent determination. Under FDASIA, FDA is required to classify the device within 120 days following receipt of the de novo request, although the process may take significantly longer. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of safety and effectiveness of the medical device.

If FDA grants the de novo request, the device may be legally marketed in the United States. However, the FDA may reject the request if the FDA identifies a legally marketed predicate device that would be appropriate for a 510(k) notification, determines that the device is not low-to-moderate risk, or determines that general controls would be inadequate to control the risks and/or special controls cannot be developed. After a device receives de novo classification, any modification that could significantly affect its safety or efficacy, or that would constitute a major change or modification in its intended use, will

## [Table of Contents](#)

require a new 510(k) clearance or, depending on the modification, another de novo request or even PMA approval.

### *Clinical Trials*

Clinical trials are almost always required to support a PMA or a *de novo* request 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, the sponsor, 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 (Ongoing) Regulation*

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

## [Table of Contents](#)

- 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 or devices authorized through the *de novo* process 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.

Manufacturers 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. The discovery of previously unknown problems with 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

## [Table of Contents](#)

- criminal prosecution.

### *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

## [Table of Contents](#)

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 non-physician practitioners 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.

## ***Foreign Regulation***

### ***General***

International sales of medical devices are subject to a variety of foreign government regulations, which may vary substantially from country to country. We expect this global regulatory environment will continue to be complex and evolving, which could impact the cost, the time needed to approve, and our ability to maintain existing approvals or certifications or obtain future approvals or certifications for our products and require extensive compliance and monitoring obligations in the countries where we sell or distribute our products. In addition, our international operations, distribution and sales require us to comply with: the U.S. Foreign Corrupt Practices Act and similar anti-bribery laws in other jurisdictions; U.S. and foreign export control, trade embargo and customs laws; U.S. and foreign tax laws; employment, immigration and labor laws; local intellectual property laws, which may not protect intellectual property rights to the same extent as U.S. law; and privacy laws such as the European General Data Protection Regulation (GDPR).

### ***Regulation of Medical Devices in the European Union***

The European Union, or EU, has adopted specific directives and regulations regulating the design, manufacture, clinical investigation, conformity assessment, labeling and adverse event reporting for medical devices.

Until May 25, 2021, medical devices were regulated by Council Directive 93/42/EEC, or the EU Medical Devices Directive, which has been repealed and replaced by Regulation (EU) No 2017/745, or the EU Medical Devices Regulation. Our current certificates have been granted under the EU Medical Devices

## [Table of Contents](#)

Directive whose regime is described below. However, as of May 26, 2021, some of the EU Medical Devices Regulation requirements apply in place of the corresponding requirements of the EU Medical Devices Directive with regard to registration of economic operators and of devices, post-market surveillance and vigilance requirements. Pursuing the importation and subsequent marketing of our solutions in the EU requires that our devices be certified under the new regime set forth in the EU Medical Devices Regulation. We have obtained these new certifications for our ClotTriever system and our FlowSaver ancillary system, and we are currently in the process of obtaining them for the other products in our portfolio.

### *Medical Devices Directive*

Under the EU Medical Devices Directive, all medical devices placed on the market in the EU must meet the relevant essential requirements laid down in Annex I to the EU Medical Devices Directive, including the requirement 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 performance 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 as it 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. 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. 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 independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. A notified body would typically audit and examine a product's technical dossiers and the manufacturers' quality system (the notified body must presume that quality systems which implement the relevant harmonized standards – which is ISO 13485:2016 for Medical Devices Quality Management Systems – conform to these requirements). 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.

Throughout the term of the certificate of conformity, the manufacturer will be subject to periodic surveillance audits to verify continued compliance with the applicable requirements. In particular, there will be a new audit by the notified body before it will renew the relevant certificate(s).

### *Medical Devices Regulation*

On April 5, 2017, the EU Medical Devices Regulation was adopted with the aim of ensuring better protection of public health and patient safety. The EU Medical Devices Regulation establishes a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensures a high level of safety and health while supporting innovation. Unlike the EU Medical Devices

## [Table of Contents](#)

Directive, the EU Medical Devices Regulation is directly applicable in EU member states without the need for member states to implement into national law. This aims at increasing harmonization across the EU. The EU Medical Devices Regulation became effective on May 26, 2021.

The EU Medical Devices Regulation requires that before placing a device, other than a custom-made device, on the market, manufacturers (as well as other economic operators such as authorized representatives and importers) must register by submitting identification information to the electronic system (Eudamed), unless they have already registered. The information to be submitted by manufacturers (and authorized representatives) also includes the name, address and contact details of the person or persons responsible for regulatory compliance. The new Regulation also requires that before placing a device, other than a custom-made device, on the market, manufacturers must assign a unique identifier to the device and provide it along with other core data to the unique device identifier, or UDI, database. These new requirements aim at ensuring better identification and traceability of the devices. Each device – and as applicable, each package – will have a UDI composed of two parts: a device identifier, or UDI-DI, specific to a device, and a production identifier, or UDI-PI, to identify the unit producing the device. Manufacturers are also notably responsible for entering the necessary data on Eudamed, which includes the UDI database, and for keeping it up to date. The obligations for registration in Eudamed will become applicable at a later date (as Eudamed is not yet fully functional). Until Eudamed is fully functional, the corresponding provisions of the EU Medical Devices Directive continue to apply for the purpose of meeting the obligations laid down in the provisions regarding exchange of information, including, and in particular, information regarding registration of devices and economic operators.

All manufacturers placing medical devices on the market in the EU must comply with the EU medical device vigilance system which has been reinforced by the EU Medical Devices Regulation. Under this system, serious incidents and Field Safety Corrective Actions, or FSCAs, must be reported to the relevant authorities of the EU member states. These reports will have to be submitted through Eudamed – once functional – and aim to ensure that, in addition to reporting to the relevant authorities of the EU member states, other actors such as the economic operators in the supply chain will also be informed. Until Eudamed is fully functional, the corresponding provisions of the EU Medical Devices Directive continue to apply. A serious incident is defined as any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect, which, directly or indirectly, might have led or might lead to the death of a patient or user or of other persons or to a temporary or permanent serious deterioration of a patient's, user's or other person's state of health or a serious public health threat. Manufacturers are required to take FSCAs defined as any corrective action for technical or medical reasons to prevent or reduce a risk of a serious incident associated with the use of a medical device that is made available on the market. 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. For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a FSCA implemented or where the incidents are common and well documented, manufacturers may provide periodic summary reports instead of individual serious incident reports.

The advertising and promotion of medical devices is subject to some general principles set forth in EU legislation. According to the EU Medical Devices Regulation, only devices that are CE-marked may be marketed and advertised in the EU in accordance with their intended purpose. Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, while not specific to the advertising of medical devices, also apply to the advertising thereof and contain general rules, for example, requiring that advertisements are evidenced, balanced and not misleading. Specific requirements are defined at a national level. EU member states' laws related to the advertising and promotion of medical devices, which vary between jurisdictions, may limit or restrict the advertising and promotion of products to the general public and may impose limitations on promotional activities with healthcare professionals.

## [Table of Contents](#)

Many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medical devices, in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU member states have adopted national "Sunshine Acts" which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on medical device manufacturers. Certain countries also mandate implementation of commercial compliance programs.

In the EU, regulatory authorities have the power to carry out announced and, if necessary, unannounced inspections of companies, as well as suppliers and/or sub-contractors and, where necessary, the facilities of professional users. Failure to comply with regulatory requirements (as applicable) could require time and resources to respond to the regulatory authorities' observations and to implement corrective and preventive actions, as appropriate. Regulatory authorities have broad compliance and enforcement powers and if such issues cannot be resolved to their satisfaction can take a variety of actions, including untitled or warning letters, fines, consent decrees, injunctions, or civil or criminal penalties.

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.

### *Brexit*

Since January 1, 2021, the Medicines and Healthcare Products Regulatory Agency, or MHRA, has become the sovereign regulatory authority responsible for Great Britain (i.e. England, Wales and Scotland) medical device market according to the requirements provided in the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) that sought to give effect to the three pre-existing EU directives governing active implantable medical devices, general medical devices and in vitro diagnostic medical devices whereas Northern Ireland continues to be governed by EU rules according to the Northern Ireland Protocol. Following the end of the Brexit transitional period on January 1, 2021, new regulations require all medical devices to be registered with the MHRA before being placed on the Great Britain market. The MHRA only registers devices where the manufacturer or their United Kingdom, or UK, Responsible Person has a registered place of business in the UK. From January 1, 2022, manufacturers based outside the UK need to appoint a UK Responsible Person that has a registered place of business in the UK to register devices with the MHRA.

On June 26, 2022, the MHRA published its response to a 10-week consultation on the post-Brexit regulatory framework for medical devices and diagnostics. MHRA seeks to amend the UK Medical Devices Regulations 2002 (which are based on EU legislation, primarily the EU Medical Devices Directive and the EU In Vitro Diagnostic Medical Devices Directive 98/79/EC), in particular to create new access pathways to support innovation, create an innovative framework for regulating software and artificial intelligence (AI) as medical devices, reform IVD regulation, and foster sustainability through the reuse and remanufacture of medical devices. Regulations implementing the new regime were originally scheduled to come into force in July 2023, but have recently been postponed to July 2024. Devices bearing CE marks issued by EU notified bodies under the EU Medical Devices Regulation or EU Medical Devices Directive are now subject to transitional arrangements. In its consultation response, the MHRA indicated that the future UK regulations will allow devices certified under the EU Medical Devices Regulation to be placed on the market in Great Britain under the CE mark until either the certificate expires or for five years after the new regulations take effect, whichever is sooner. Devices certified under the EU Medical Devices Directive could continue to be placed on the market until either the certificate expires or for three years after the new regulations take effect, whichever is sooner. Following these transitional periods, it is expected that all medical devices will require a UK Conformity Assessed ("UKCA") mark. Manufacturers may choose to use the UKCA mark on a voluntary basis until June 30, 2023. However, UKCA marking will not be recognized in the EU. The rules for placing medical devices on the market in Northern Ireland, which is part of the UK, differ from those in the rest of the UK. Compliance with this legislation is a prerequisite to be able to affix the UKCA mark to our products, without which they cannot be sold or marketed in Great Britain.

## Table of Contents

In addition, the Trade Deal between the UK and the EU generally provides for cooperation and exchange of information between the parties in the areas of product safety and compliance, including market surveillance, enforcement activities and measures, standardization-related activities, exchanges of officials, and coordinated product recalls. As such, processes for compliance and reporting should reflect requirements from regulatory authorities.

### ***United States and Foreign Data Privacy and Security Laws***

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

### **Human Capital Resources and Employees**

We employ a growing and highly-skilled employee base across all employee functions and promote a culture focused on serving and improving the quality of life of our patients. We believe that our solutions 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 taking care of 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 and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

As of December 31, 2022, we had approximately 1,100 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](http://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](http://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*

## [Table of Contents](#)

*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. 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.*

### **Specific Risks Related to Our Business and Solutions**

#### ***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 formation in 2011. For the years ended December 31, 2022, 2021 and 2020, we had net losses of \$29.3 million and net income of \$9.8 million and \$13.8 million, respectively. We plan to continue to invest to support the planned growth of the business and, as a result of these investments, we may incur net losses in the future. Accordingly, we cannot assure that we will be able to sustain profitability in the future. Our failure to sustain profitability in the future may 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.

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

We began commercializing our FlowTriever and ClotTriever systems in the United States in 2017 and outside of the United States in 2021. We expect to continue to devote a substantial amount of resources to expand our commercialization efforts, drive increased adoption of our solutions and continue to develop new and improved solutions. To date, substantially all of our revenue has been derived, and we expect for the near term to continue to be significantly derived, from sales of our ClotTriever and FlowTriever systems. We believe these systems have the potential to become the standard of care for the DVT and PE, the two diseases making up venous thromboembolism or VTE.

Our growth and profitability largely depend on our ability to increase physician and patient awareness of our solutions and on the willingness of physicians and hospitals to adopt our solutions. 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 solutions. Physicians and hospitals may not adopt our solutions unless they are able to determine, based on experience, clinical data, medical society recommendations and other analyses, that our solutions provide a safe and effective treatment alternative for VTE. In addition, our current and new solutions must often be approved for use by hospital value analysis committees, group purchasing organizations and integrated delivery networks, or the staff of hospitals or health systems. Such approvals or requirements could deter or delay the use of our solutions by physicians. We cannot provide assurance that our efforts to obtain such approvals and satisfy any other requirements or generate adoption will be successful or increase the use of our solutions, and if we are not successful, it could have a material adverse effect on our business, financial condition and results of operations.

The rate of adoption and sales of our solutions is heavily influenced by clinical data. The primary sources of currently available clinical data regarding our solutions are the FlowTriever Pulmonary Embolectomy Clinical Study, or FLARE study, the ClotTriever Outcomes, or CLOUT, registry study, and the FlowTriever All-Comer Registry for Patient Safety and Hemodynamics, or FLASH, registry study. We have also announced the initiation of enrollment in two randomized controlled trials – PEERLESS, evaluating FlowTriever's performance in patients with intermediate risk PE, and DEFIANCE, evaluating ClotTriever's performance in patients with moderate to severe iliofemoral DVT as compared to conservative medical management alone. We plan to conduct additional clinical studies and trials to help drive increased awareness and adoption of our solutions with existing and new customers. The outcomes and updates resulting from these studies and trials, including interim results, may not be favorable which could limit the adoption of our solutions. In addition, our competitors and other third parties may also conduct clinical

## [Table of Contents](#)

trials of our solutions without our participation. Unfavorable or inconsistent clinical data from existing or future clinical studies 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 clearance, approval or certification, 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.

***The market for our solutions is highly competitive and our competitors may have longer operating histories, more established products and greater resources than we do.***

The medical device industry is highly competitive, subject to rapid change and significantly affected by the introduction of new technologies and other activities of industry participants. For our VTE solutions, 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 divisions of Boston Scientific Corporation, Penumbra, Abbott, Philips, AngioDynamics, and Teleflex, and multiple smaller companies that have single products or a limited range of products. There is growing interest in the treatment of VTE disease with catheter-based solutions, and there are a significant number of approved thrombectomy devices available or entering the market in the near term. As this interest continues to grow, we anticipate that this competition will intensify. Competing technologies or therapies could demonstrate better safety, effectiveness, clinical results, lower costs or greater physician and market acceptance than our solutions.

In addition, 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, 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 offerings to offer greater discounts or incentives to gain a competitive advantage; and established sales, marketing and worldwide distribution networks.

As one of the major hurdles to adoption of our solutions is overcoming established treatment patterns, 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 solutions due to the prevalence of VTE and other complex diseases and the research and technological progress that exist within the market.

With respect to our other systems, we are just entering the market and believe there are currently limited competitors offering purpose-built solutions. Therefore, we currently compete with manufacturers of thrombolytic drugs or anticoagulants or with physicians' treatment decisions such as surgery instead of intervention.

***We face a number of manufacturing risks that may adversely affect our manufacturing abilities.***

We depend on our ability to manufacture our current and future solutions in sufficient quantities and on a timely basis to meet customer demand, while adhering to device 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 solutions. We currently produce all of our solutions at this facility, and we do not have additional facilities. If this facility

## [Table of Contents](#)

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

As demand for our solutions and our development pipeline increases, we will have to invest additional resources to purchase components, sub-assemblies and materials, services, 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 solutions may share features, components, sub-assemblies and materials with our existing solutions, the manufacture of these components 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 solutions at a cost or in quantities sufficient to make them 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, which makes us vulnerable to supply shortages and price fluctuations.***

We rely on single source suppliers for many components, sub-assemblies, materials, and sterilization of our solutions. These components, sub-assemblies, materials, and sterilization services 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 solutions reliably and at the levels we anticipate or that are required by the market. We have experienced and may continue to experience delays resulting from longer production and delivery times since the onset of the COVID-19 pandemic. We cannot guarantee that our suppliers will in the future be able to meet our demand, either because of acts of nature, the regulatory climate in which our suppliers operate, 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.

Qualifying or obtaining necessary regulatory approvals takes considerable time and is costly, and we do not carry significant inventory. We cannot be certain that we will be available to qualify new suppliers 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 solutions if our existing suppliers and providers were unable to satisfy our requirements. To utilize other

## [Table of Contents](#)

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, increase our expenses and impact our ability to meet demand for our solutions.

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

- Interruption of supply or sterilization resulting from modifications to, or discontinuation of, a third party's operations;
- Delays in 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 solutions 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, state or foreign regulatory authorities or notified bodies;
- Inability to ensure the availability or quality of components manufactured or sterilization conducted by third parties;
- Production delays related to the evaluation and testing of components and services from alternative third parties and corresponding regulatory qualifications; and
- Delays in delivery by our suppliers and service providers.

***The use, misuse or off-label use of our solutions may result in enforcement action by the FDA or injuries that lead to product liability suits or regulatory action, either of which could be expensive, divert management's attention and harm our reputation and business.***

Our solutions have been cleared by the FDA and certified by a notified body for specific indications and meet certain treatment parameters. If physicians expand the patient population in which they elect to use our solutions such that it is outside of the intended use that has been cleared by the FDA or certified by our notified body, then such use, misuse or off-label use of our solutions may result in outcomes and adverse events including death, potentially leading to product liability claims. Our solutions are not indicated for use in all patients with VTE or for the treatment of all diseases that they could be used for, and therefore cannot be marketed or advertised in the United States and internationally for certain uses without additional clearances from the FDA or certifications by the applicable authority. However, we cannot prevent a physician from using our solutions for off-label applications or using components or services that are not our solutions when performing procedures with our solutions. 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 solutions. Complications resulting from the use of our solutions 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

## [Table of Contents](#)

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

We derive our revenue from sales of our solutions to hospitals and other medical centers, which typically bill various third-party payors, including Medicare, Medicaid, private commercial insurance companies, health maintenance organizations and other healthcare-related organizations for the procedures in which our solutions are used. Because we sell our solutions to hospitals that purchase them for use in catheter-based thrombectomy procedures and do not sell our solutions to commercial payors, access to adequate coverage and reimbursement for our solutions by third-party payors is essential to the acceptance and adoption of our solutions.

Because there is often no separate reimbursement for supplies used in procedures, the additional cost associated with the use of our solutions 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 solutions 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 solutions and could create additional pricing pressure for us. If we are forced to lower the price we charge for our solutions, 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 solutions exists among third-party payors. Therefore, coverage and reimbursement for procedures using our solutions 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 solutions. We may not be able to provide data sufficient to satisfy governmental and third-party payors that procedures using our solutions should be covered and reimbursed.

## Table of Contents

Payors continually review new and existing technologies for possible coverage and can, without notice, deny or reverse coverage for new or existing solutions and procedures. There can be no assurance that third-party payor policies will provide coverage for procedures in which our solutions are used.

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 solutions, 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 solutions or in another manner unfavorable to our business. Third-party coverage and reimbursement for procedures using our solutions or any of our solutions in development for which we may receive regulatory clearance, approval or certification may not be available or adequate in either the United States or international markets. Further, other 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 solutions. If hospital, physician and/or patient demand for our solutions 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.

In addition, we expect state and federal healthcare policies and reform measures may be adopted in the future, any of which could limit reimbursement for healthcare products and services or otherwise result in reduced demand for our solutions 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, among other things, our ability to set a price that we believe is fair for our solutions, our ability to generate revenue and achieve or maintain profitability or the availability of capital. Any changes of, or uncertainty with respect to, future coverage or reimbursement rates could affect demand for our solutions, 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.

***If the quality of our solutions does not meet the expectations of physicians or patients, then our brand and reputation or our business could be adversely affected.***

In the course of conducting our business, we must adequately address quality issues that may arise with our solutions, including defects in third-party components included in our solutions. Although we have established internal procedures designed to minimize risks that may arise from quality issues, we may not be able to eliminate or mitigate occurrences of these issues and associated liabilities. In addition, even in the absence of quality issues, we may be subject to claims and liability if the performance of our solutions does not meet the expectations of physicians or patients. If the quality of our solutions does not meet the expectations of physicians or patients, then our brand and reputation with those physicians or patients, and our business, financial condition and results of operations, could be adversely affected.

***Our long-term growth depends on our ability to enhance our solutions, expand our indications and develop and commercialize additional new solutions in a timely manner and if we fail to do so we may be unable to grow our business.***

The market for our solutions is highly competitive, dynamic, and marked by rapid and substantial technological development and innovation. New entrants or existing competitors have attempted and will continue to attempt to develop products that compete directly with ours. Demand for our solutions and future related solutions could be diminished by equivalent or superior technologies offered by competitors. If we are unable to innovate successfully, our existing solutions could become obsolete and our revenue would decline as our customers purchase our competitors' products. Developing our new solutions and enhancing our current solutions is expensive and time-consuming and could divert

## [Table of Contents](#)

management's attention away from our core business. The success of any new offering or enhancements will depend on several factors, including our ability to:

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

If we are unable to develop or improve solutions, applications or features in a timely manner or at all, we may not be able to maintain our competitive position compared to other companies. In addition, we may choose to focus our efforts and resources on potential solutions or indications that ultimately prove to be unsuccessful, or to license or purchase a technology that does not meet our financial expectations. As a result, we may fail to capitalize on viable commercial solutions or profitable market opportunities, be required to forego or delay pursuit of opportunities with other potential solutions or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such potential solutions 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.

### ***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 solutions, 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, operational and manufacturing 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 solutions or any of our future solutions increases, we will need to continue to scale our capacity, expand our customer service and sales force, billing and systems processes and enhance our internal quality assurance program. We cannot assure that any increases in scale or expanded manufacturing capacity, related improvements and quality assurance, or the expansion of our sales force 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. Moreover, members of our sales force are

## [Table of Contents](#)

trained and possess technical expertise. If we are unable to maintain and grow our sales force with individuals that possess the necessary qualifications and expertise, or business could suffer. If we encounter difficulty meeting market demand, quality standards or physician expectations, our reputation could be harmed and our business could suffer.

***We operate our business, including manufacturing our solutions, out of a single site in Irvine, California, and we may experience delays in production or an increase in costs if this facility is damaged or becomes inoperable.***

We currently conduct our research and development, manufacturing, distribution and administrative operations in a single facility in Irvine, California, which is situated on or near earthquake fault lines. Our goal is to expand our manufacturing operations to additional facilities outside of Irvine. Should our facilities 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 research, development and manufacturing capabilities would cease or be delayed, our employees may seek other positions, and our solutions 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 operations 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 solutions 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 solutions 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.

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

As of December 31, 2022, we had U.S. federal, state, and foreign net operating loss carryforwards, or NOLs, of \$10.5 million, \$21.0 million, and \$27.3 million, respectively, and U.S. federal and state research and development credit carryforwards of \$9.0 million and \$8.0 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

## [Table of Contents](#)

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 \$30.3 million and \$17.9 million as of December 31, 2022 and 2021, respectively.

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

We operate in an industry with significant price competition, and we can give no assurance that we will be able to achieve satisfactory prices for our current or any new solutions or maintain prices at the levels we have historically achieved. Any decline in the amount that payors reimburse our customers for our solutions could make it difficult for customers to continue using, or to adopt, our solutions and could create additional pricing pressure for us. If we are forced to lower the price we charge for our solutions, if we add more components to our systems or bundle solutions, or if we are required to reduce the price of our solutions in certain foreign markets, 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 manufacture and sell solutions that are used in a limited number of procedures and even with expanding into new disease states with new solutions, there is a limited total addressable market for our solutions.***

Our estimates of the annual total addressable markets for our current solutions are based on a number of internal and third-party estimates, the number of patients treatable by our solutions, and the assumed prices at which we can sell our solutions. 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, any estimates of the annual total addressable market for our current and future solutions may prove to be incorrect. If the actual number of patients who would benefit from our solutions, the price at which we can sell our solutions, or the annual total addressable market for our solutions is smaller than we have estimated, it may impair our sales growth and negatively affect our business, financial condition and results of operations.

### **General Business Risks**

#### ***We may require additional capital to finance our planned operations, which may not be available to us on acceptable terms or at all. In addition, the terms of our current or future financing arrangements may limit our ability to operate our business as planned.***

Our operations have consumed substantial amounts of cash since inception, primarily due to our research and development activities, conducting clinical studies for our solutions, and building our dedicated direct sales organization. Our expenses have also increased substantially in connection with the commercialization of our solutions, including hiring qualified personnel, retaining our sales team and expanding internationally. We expect that certain of these activities and the associated expenses will continue. Additional expenditures also include costs associated with manufacturing and supply, sales and marketing costs, costs and expenses incidental to being a public company, and general operations. Other unanticipated costs may arise.

As of December 31, 2022, we had cash, cash equivalents and short-term investments of \$326.4 million. In December 2022, we amended our senior secured revolving credit agreement with Bank of America (the "Amended Credit Agreement") to (i) increase from (A) the lesser of \$30.0 million and the amount of the borrowing base to (B) the lesser of \$40.0 million and the amount of the borrowing base, (ii) increases the optional accordion from \$20.0 million to \$120.0 million, (iii) join Inari Medical Latin America as a guarantor of the obligations under the Amended Credit Agreement, (iv) modify the borrowing base to include eligible inventory, (v) remove the negative pledge on intellectual property, (vi) remove and replaces the LIBOR benchmark provisions with Bloomberg Short-Term Bank Yield Index ("BSBY")

## [Table of Contents](#)

benchmark provisions and (vii) provide that advances under the credit agreement will bear interest at rate per annum equal to the BSBY rate (as defined in the Amended Credit Agreement) or Base Rate (as defined in the Amended Credit Agreement), at the option of the Borrowers, plus a margin that ranges from 0.50% to 1.00% in the case of Base Rate loans and 1.50% and 2.00% in the case of BSBY Rate loans depending on average daily availability, in each case with a floor of 0%. In February 2023, we amended the Letter of Credit subline facility to increase the limit to up to \$10.0 million. As of December 31, 2022, there were no amounts outstanding under the Amended Credit Agreement. We are required to pay an unused line fee at an annual rate of 0.25% of the average daily unused portion of the amounts available under the Amended Credit Agreement. We are also required to make monthly interest payments on any borrowed amounts outstanding under the Amended Credit Agreement, which may divert resources from other activities.

Our obligations under the Amended 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. These covenants, 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 are not currently in breach of these or any other covenants contained in our Amended Credit Agreement, there can be no guarantee that we will not breach these covenants in the future. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in a default under the Amended Credit Agreement. If not waived, future defaults could cause all of the outstanding indebtedness under the Amended 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 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 need to raise additional capital, and if we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or liens, making capital expenditures or declaring dividends. If we are unable to obtain adequate financing when needed and on terms that are acceptable to us, we may have to delay, reduce the scope of or suspend the implementation of our sales and marketing plan and our ongoing research and development efforts, which would have a material adverse effect on our business, financial condition, and results of operations.

***If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our common stock.***

## [Table of Contents](#)

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, our management is required to report upon the effectiveness of our internal control over financial reporting and, as we are a large accelerated company, our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting beginning with this Annual Report on Form 10-K. The rules governing the standards that must be met for our management and our independent registered public accounting firm to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. In connection with our and our independent registered public accounting firm's evaluations of our internal control over financial reporting, we may need to upgrade our systems, including information technology; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff.

Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us or our independent registered public accounting firm conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002 may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. Internal control deficiencies could also result in a restatement of our financial results in the future. We could become subject to stockholder or other third-party litigation, as well as investigations by the SEC, the stock exchange on which our securities are listed, or other regulatory authorities, which could require additional financial and management resources and could result in fines, trading suspensions, payment of damages or other remedies.

In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Global Select Market or other adverse consequences that would materially harm our business.

***Changes in public health insurance coverage and government reimbursement rates for our solutions could affect the adoption of our solutions 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 solutions 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 solutions in commercially acceptable quantities at acceptable prices.

***Cost-containment efforts or consolidation in the industry of our customers, purchasing groups and governmental organizations could have a material adverse effect on our sales and profitability.***

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,

## [Table of Contents](#)

or maintain existing, contract positions with major GPOs and IDNs. Furthermore, the increasing leverage of organized buying groups may reduce market prices for our solutions, 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 solutions.

***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 Andrew Hykes, our Chief Executive Officer, Mitchell Hill, our Chief Financial Officer, and Dr. Thomas Tu, our Chief Medical Officer, are essential to driving adoption of our solutions, 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 solutions. 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. 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.

Further, 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. 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.

## [Table of Contents](#)

***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 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.

***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 technologies or 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. 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

## [Table of Contents](#)

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, milestone payment, 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.

***Failure to protect our information technology infrastructure against cyberattacks, security breaches, service interruptions, or data corruption could materially disrupt our operations and adversely affect our business and operating results.***

The operation of our business depends on our information technology systems. We rely on our information technology systems to, among other things, effectively manage sales and marketing data, accounting and financial functions, inventory management, product development tasks, clinical data, customer service and technical support functions. Our information technology systems are vulnerable to attack, damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, power losses, computer system or data network failures, security breaches, data corruption, and cyberattacks. Cyberattacks can include, but are not limited to, computer viruses, computer denial-of-service attacks, phishing attacks, ransomware attacks, worms, and other malicious software programs or other attacks, covert introduction of malware to computers and networks, impersonation of authorized users, and efforts to discover and exploit any design flaws, bugs, security vulnerabilities, or security weaknesses, as well as intentional or unintentional acts by employees or other insiders with access privileges, intentional acts of vandalism by third parties and sabotage. A variety of our software systems are cloud-based data management applications, hosted by third-party service providers whose security and information technology systems are subject to similar risks.

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. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. 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. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in decreased sales, result in liability claims or regulatory penalties, or lead to increased overhead costs, product shortages, loss or misuse of proprietary or confidential information, intellectual property, or sensitive or personal information, all of which could have a material adverse effect on our reputation, business, financial condition, and operating results. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

***Changes in and actual or perceived failures to comply with applicable data privacy, security and protection laws, regulations, standards and contractual obligations may adversely affect our business, operations and financial performance.***

## [Table of Contents](#)

We and our partners may be subject to federal, state, and foreign laws and regulations that govern data privacy and security. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues, which may affect our business and may increase our compliance costs and exposure to liability. In the United States, numerous federal and state laws and regulations govern the collection, use, disclosure, and protection of personal information, including state data breach notification laws, federal and state health information privacy laws, and federal and state consumer protection laws. For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations implemented thereunder, or collectively HIPAA, imposes privacy, security and breach notification obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities, and their covered subcontractors. HIPAA requires covered entities and business associates to develop and maintain policies with respect to the protection of, use and disclosure of PHI, including the adoption of administrative, physical and technical safeguards to protect such information, and certain notification requirements in the event of a breach of unsecured PHI. Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA. While we do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly regulated under HIPAA, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws will be subject to varying interpretations by courts and government agencies, creating complex compliance issues. For example, the California Consumer Privacy Act of 2018, or the CCPA, went into effect on January 1, 2020, and creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. 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. Further, the California Privacy Rights Act, or the CPRA, recently passed in California. The CPRA significantly amends the CCPA and 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. Similar laws have passed in Virginia, Connecticut, Utah and Colorado, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

We are also or may become subject to rapidly evolving data protection laws, rules and regulations in foreign jurisdictions. For example, the European Union General Data Protection Regulation, or the GDPR, governs certain collection and other processing activities involving personal data about individuals in the European Economic Area, or the EEA. Among other things, the GDPR imposes requirements regarding the security of personal data, the rights of data subjects to access and delete personal data, requires having lawful bases on which personal data can be processed, includes requirements relating to the consent of individuals to whom the personal data relates, and requires detailed notices for clinical trial participants and investigators. The GDPR imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of our annual global revenue), and also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR. In addition, the

## [Table of Contents](#)

GDPR also 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; in July 2020, the Court of Justice of the EU, or the CJEU, limited how organizations could lawfully transfer personal data from the EU/EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses, or SCCs. In March 2022, the US and EU announced a new regulatory regime intended to replace the invalidated regulations; however, this new EU-US Data Privacy Framework has not been implemented beyond an executive order signed by President Biden on October 7, 2022 on Enhancing Safeguards for United States Signals Intelligence Activities. The European Commission also issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021; existing SCC arrangements must be migrated to the revised clauses by December 27, 2022. The new SCCs apply only to the transfer of personal data outside of the EEA and not the UK. The UK's Information Commissioner's Office has published new data transfer standard contracts for transfers from the UK under the UK GDPR. This new documentation will be mandatory for relevant data transfers from September 21, 2022; existing SCC arrangements must be migrated to the new documentation by March 21, 2024. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Further, from January 1, 2021, companies have been subject to the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, e.g. fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EU member states to the UK without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/extends that decision. In September 2021, the UK government launched a consultation on its proposals for wide-ranging reform of UK data protection laws following Brexit and the response to this consultation was published in June 2022. There is a risk that any material changes which are made to the UK data protection regime could result in the European Commission reviewing the UK adequacy decision, and the UK losing its adequacy decision if the European Commission deems the UK to no longer provide adequate protection for personal data. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. These changes may lead to additional costs and increase our overall risk exposure.

Compliance with applicable data privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' ability to operate in certain jurisdictions. Each of these constantly evolving laws can be subject to varying interpretations. If we fail to comply with any such laws, rules or regulations, we may face government investigations and/or enforcement actions, fines, civil or criminal penalties, private litigation or adverse publicity that could adversely affect our business, financial condition and results of operations.

## [Table of Contents](#)

***As we expand internationally, it will increasingly 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 or certifications in targeted countries internationally. 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 or certification where required for our solutions 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 solutions 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 solutions 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 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.

***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

## [Table of Contents](#)

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 that our internal control policies and procedures will protect us from improper acts committed by our employees or agents, nor can we assure 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.

***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 solutions 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 solutions 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 solutions on a timely basis.

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

***A new pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide, such as 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. For example, the December 2019 outbreak of COVID-19 has adversely impacted nearly all aspects of our business and markets, including our workforce and operations and the operations of our customers, suppliers, and business partners. Although we believe

## [Table of Contents](#)

that our operations have generally recovered, our financial condition will depend on future developments, which are highly uncertain and are difficult to predict. These developments include, but are not limited to, the duration and spread of staffing shortages, continued impact to the global healthcare system, and the ability of our suppliers to continue to recover.

To the extent a global 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 business may be adversely affected by unfavorable macroeconomic conditions.***

Various macroeconomic factors could adversely affect our business, financial condition and results of operations, including changes in inflation, interest rates and overall economic conditions and uncertainties, including those resulting from political instability (including workforce uncertainty), trade disputes between nations and the current and future conditions in the global financial markets. For example, if inflation or other factors were to significantly increase our business costs, we may be unable to pass through price increases to our customers.

Interest rates and the ability to access credit markets could also adversely affect the ability of our customers to purchase our products. Similarly, these macroeconomic factors could affect the ability of our current or potential future manufacturers, sole source or single source suppliers, licensors or licensees to remain in business, or otherwise manufacture or supply components, materials or services relevant to our products. Failure by any of them to remain in business could affect our ability to manufacture products or meet demand for our products.

Also, as a result of the current geopolitical tensions and conflict between Russia and Ukraine, and the recent invasion by Russia of Ukraine, the governments of the United States, European Union, Japan and other jurisdictions have recently announced the imposition of sanctions on certain industry sectors and parties in Russia and certain impacted regions, as well as enhanced export controls on certain products and industries. These and any additional sanctions and export controls, as well as any counter responses by the governments of Russia or other jurisdictions, could adversely affect, directly or indirectly, the global supply chain, with negative implications on the availability and prices of raw materials and components, as well as the on global financial markets and financial services industry.

## **Risks Related to Government Regulation**

### ***Our solutions and operations are subject to extensive government regulation and oversight in the United States and in foreign countries.***

Our solutions are regulated as medical devices. We and our solutions are subject to extensive regulation in the United States, including by the FDA, and in the EU by the regulatory authorities of the EU member states, 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, approval, certification; 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 and foreign regulatory authorities enforce 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 or foreign

## [Table of Contents](#)

regulatory authorities' inspections. Failure to comply with applicable regulations could jeopardize our ability to sell our solutions 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, approvals or certifications; withdrawals or suspensions of current approvals or certifications, resulting in prohibitions on sales of our solutions; 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 solutions or modifications to our current solutions, and failure to timely obtain necessary clearances, certifications or approvals for our future solutions or modifications to our current solutions 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 solution, 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 solutions 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 solutions 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

## [Table of Contents](#)

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, foreign regulatory authorities or notified bodies can delay, limit or deny clearance, approval or certification 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 solutions are safe or effective for their intended uses;
- The disagreement of the FDA or the applicable foreign regulatory authorities or notified bodies with the design or implementation of our clinical studies or the interpretation of data from preclinical studies or clinical studies;
- Serious and unexpected adverse device effects experienced by participants in our clinical studies;
- The data from our preclinical and clinical studies may be insufficient to support clearance, approval or certification, 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.

Subject to transitional provisions, in order to sell our solutions in EU member states, our solutions must comply with the general safety and performance requirements of the EU Medical Devices Regulation (Regulation (EU) No 2017/745 which repeals and replaces the former 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 solutions, without which they cannot be sold or marketed in the EU. All medical devices placed on the market in the EU must meet the general safety and performance requirements laid down in Annex I to the EU Medical Devices Regulation including the requirement that a medical device must be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose. Medical devices must be safe and effective and must not compromise the clinical condition or safety of patients, or the safety and health of users and – where applicable – other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.

To demonstrate compliance with the general safety and performance 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-assess the conformity of its products with the general safety and performance requirements of the EU Medical Devices Regulation (except for any parts which relate to sterility, metrology or reuse aspects), a conformity assessment procedure requires the intervention of a notified body. 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. If satisfied that the relevant product conforms to the relevant general safety and performance 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. If we fail to comply with applicable laws and regulations, we would be unable to affix or to continue to affix the CE mark to our solutions, which would prevent us from selling them within the EU.

## [Table of Contents](#)

Further, we must inform the notified body that carried out the conformity assessment of the medical devices that we market or sell in the EU and the EEA of any planned substantial changes to our quality system or substantial changes to our medical devices that could affect compliance with the general safety and performance requirements laid down in Annex I to the EU Medical Devices Regulation or cause a substantial change to the intended use for which the device has been CE marked. The notified body will then assess the planned changes and verify whether they affect the products' ongoing conformity with the EU Medical Devices Regulation. If the assessment is favorable, the notified body will issue a new certificate of conformity or an addendum to the existing certificate attesting compliance with the general safety and performance requirements and quality system requirements laid down in the Annexes to the EU Medical Devices Regulation. The notified body may disagree with our proposed changes and product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.

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. Non-compliance with the above requirements would also prevent us from selling our solutions in these three countries.

From January 1, 2021 onwards, the Medicines and Healthcare Products Regulatory Agency ("MHRA") became the sovereign regulatory authority responsible for Great Britain (i.e. England, Wales and Scotland) medical device market according to the requirements provided in the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) that sought to give effect to the three pre-existing EU directives governing active implantable medical devices, general medical devices and in vitro diagnostic medical devices whereas Northern Ireland continues to be governed by EU rules according to the Northern Ireland Protocol. Following the end of the Brexit transitional period on January 1, 2021, new regulations require all medical devices to be registered with the MHRA before being placed on Great Britain market. Manufacturers based outside the UK needs to appoint a UK Responsible Person that has a registered place of business in the UK to register devices with the MHRA in line with the grace periods. Under the terms of the Northern Ireland Protocol, Northern Ireland will follow EU rules on medical devices and devices marketed in Northern Ireland will require assessment according to the EU regulatory regime. Such assessment may be conducted by an EU notified body, in which case a CE mark will be required before placing the device on the market in the EU or Northern Ireland. Alternatively, if a UK approved body conducts such assessment, a 'UKNI' mark will be applied and the device may only be placed on the market in Northern Ireland and not the EU. On June 26, 2022, the MHRA published its long-awaited response to its consultation on the UK's post-Brexit regulatory regime for medical devices and in vitro diagnostic medical devices. The MHRA confirmed that the new regulatory landscape will mirror many of the provisions of the EU regulatory regime. However, the response also highlighted that in certain areas, medical devices regulation in Great Britain is likely to deviate from the EU framework. Regulations implementing the new regime were originally scheduled to come into force in July 2023, but have recently been postponed to July 2024. Devices bearing CE marks issued by EU notified bodies under the EU Medical Devices Regulation or EU Medical Devices Directive are now subject to transitional arrangements. In its consultation response, the MHRA indicated that the future UK regulations will allow devices certified under the EU Medical Devices Regulation to be placed on the market in Great Britain under the CE mark until either the certificate expires or for five years after the new regulations take effect, whichever is sooner. Devices certified under the EU Medical Devices Directive could continue to be placed on the market until either the certificate expires or for three years after the new regulations take effect, whichever is sooner. Following these transitional periods, it is expected that all medical devices will require a UKCA ("UK Conformity Assessed") mark. Manufacturers may choose to use the UKCA mark on a voluntary basis until June 30, 2023. However, UKCA marking will not be recognized in the EU. Following the transitional period, compliance with the UK regulations will be a prerequisite to be able to affix the UKCA mark to our solutions, without which they cannot be sold or marketed in Great Britain.

***Our solutions 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 foreign regulatory authorities, 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***

## [Table of Contents](#)

***with our solutions, or a recall of our solutions 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 or foreign regulatory authorities when we receive or become aware of information that reasonably suggests that one or more of our solutions 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 or foreign regulatory authorities 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 solutions or delay in clearance, approval or certification of future solutions.

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 solutions 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 solutions. Furthermore, the submission of these reports, to the extent made publicly available in accordance with FDA or foreign regulations, could be used by competitors against us and cause physicians to delay or cancel 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 or foreign regulatory authorities or notified bodies may require, or we may decide, that we will need to obtain new clearances, approvals or certifications for the device before we may market or distribute the corrected device. Seeking such clearances, approvals or certifications 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 or foreign regulatory authorities warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

## [Table of Contents](#)

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA or foreign regulatory authorities. We may initiate voluntary withdrawals or corrections for our solutions in the future that we determine do not require notification of the FDA or foreign regulatory authorities. If the FDA or foreign regulatory authorities disagree 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.

***Our solutions must be manufactured in accordance with federal, state and foreign 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 solutions 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. In March 2020, we initiated a voluntary recall of three lots of our Triever aspiration catheters, and it is possible that the FDA will conduct an announced or unannounced inspection of our facility to review our procedures and operations. Our solutions are also 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 our certifications.

Our third-party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our solutions. In addition, failure to comply with applicable FDA or foreign requirements or later discovery of previously unknown problems with our solutions 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 solutions; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's or notified bodies' refusal to grant pending or future clearances, approvals or certifications for our solutions; clinical holds; refusal to permit the import or export of our solutions; and criminal prosecution of us, our suppliers, or our employees.

In the EU, we are also required to demonstrate compliance with similar quality system requirements which are laid down in the relevant Annexes to the EU Medical Devices Regulation. Such compliance can be supported by, among other things, a certificate of compliance with ISO 13485:2016. Demonstration of compliance with the ISO 13485:2016 standard permits manufacturers to benefit from a presumption of conformity with the corresponding quality system requirements laid down in such Annexes to EU Medical Devices Regulation. 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. Failure to comply with such standards could adversely impact our business.

We can provide no assurance that we will be found to remain in compliance with the QSR or ISO standards upon a regulator's or notified body's review. If the FDA or the California Department of Public Health, or other regulator or notified body, inspects or audits 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 solutions. Taking corrective action may be expensive, time-consuming

## [Table of Contents](#)

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.

### ***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 device from the market.***

Even though we have obtained FDA clearance for our solutions in the United States and these devices have been certified in the EU, 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 or certification 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 solutions;
- 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 or certifications of new solutions, new intended uses, or modifications to existing solutions;
- Withdrawals or suspensions of our current 510(k) clearances or certifications, resulting in prohibitions on sales of our solutions;
- FDA refusal to issue certificates to foreign governments needed to export solutions 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, as is the case in the EU, or take other actions, which may prevent or delay clearance or approval of our future solutions under development or impact our ability to modify our currently cleared solutions 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 solutions.

## [Table of Contents](#)

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

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

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

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

***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, studies 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 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 top-line or preliminary data we previously published. As a result, 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 and clinical studies. Interim data from clinical studies 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 or notified bodies, 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,

## [Table of Contents](#)

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 or notified bodies, disagree with the conclusions reached, our ability to obtain approval or certification for, and commercialize, our solutions and product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

***Disruptions at the FDA, other government agencies or notified bodies caused by funding shortages or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified solutions from being developed, cleared, approved or certified, or commercialized in a timely manner, or at all, which could negatively impact our business.***

The ability of the FDA, other government agencies and notified bodies to review and approve or certify new solutions can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, a government agency's or notified body's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the government agency's or notified body's ability to perform routine functions. Average review times at the FDA, other government agencies and notified bodies 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, other agencies and notified bodies may also slow the time necessary for new medical devices or modifications to cleared, approved or certified medical devices to be reviewed and/or cleared, approved or certified by necessary government agencies or notified bodies, which would adversely affect our business. For example, over the last several years, the United States 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, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Regulatory authorities internationally have adopted similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to hinder or prevent the FDA, other regulatory authorities or notified bodies from conducting their regular inspections, audits, reviews, or other regulatory activities, it could significantly impact the ability of the FDA, other regulatory authorities or notified bodies to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

For instance, in the EU, notified bodies must be officially designated to certify products and services in accordance with the EU Medical Devices Regulation. While several notified bodies have been designated under the EU Medical Devices Regulation, the COVID-19 pandemic has significantly slowed down their designation process, and the current designated notified bodies are facing a large amount of requests to (re) certify products under the new Regulation, as a consequence of which review times have lengthened. This situation could impact the timely review and processing of regulatory submissions and audits by our notified bodies and therefore our ability to grow our business in the EU and EEA.

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

## [Table of Contents](#)

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 solutions under development or impact our ability to modify our currently cleared solutions on a timely basis. For example, on February 23, 2022, the FDA issued a proposed rule to amend the QSR, which establishes current good manufacturing practice requirements for medical device manufacturers, to align more closely with ISO standards. This proposal has not yet been finalized or adopted. Accordingly, it is unclear the extent to which this or any other proposals, if adopted, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise create competition that may negatively affect our business.

Additionally, 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.

Moreover, the EU landscape concerning medical devices in the EU recently evolved. On May 25, 2017, the EU Medical Devices Regulation 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 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 EU 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 EU Medical Devices Regulation became effective on May 26, 2021. We are currently in the process of obtaining our certificates under the EU Medical Devices Regulation.

Similarly, in December 2021, Regulation (EU) No 2021/2282 on Health Technology Assessment (“HTA”) amending Directive 2011/24/EU, was adopted in the EU. This regulation, which entered into force in January 2022 and will become applicable from January 12, 2025 onwards, intends to boost cooperation among EU member states in assessing health technologies, including certain high-risk medical devices, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The regulation foresees a three-year transitional period and will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

These modifications may have an effect on the way we intend to develop our business in the EU and EEA. For example, as a result of the transition towards the new regime, notified body review times have lengthened, and product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.

## [Table of Contents](#)

***The clinical study process is lengthy and expensive with uncertain outcomes. Results of earlier studies may not be predictive of future clinical trial results, or the safety or efficacy profile for such solutions.***

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 first two randomized controlled trials, and we may in the future conduct additional clinical studies for future solutions. The results of preclinical and clinical studies of our solutions conducted to date and ongoing or future studies of our current, planned or future solutions may not be predictive of the results of later clinical studies, and interim results of a clinical study do not necessarily predict final results. Our interpretation of data and results from our clinical studies do not ensure that we will achieve similar results in future clinical studies. 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 and earlier clinical studies have nonetheless failed to produce strong results in later clinical studies. Products in later stages of clinical studies may fail to show the desired safety and efficacy despite having progressed through nonclinical and earlier clinical studies. We incur substantial expense for, and devote significant time to, clinical studies 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 studies 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 studies 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 studies, including related to the following:

- we may be required to submit an investigational device exemption, or IDE, application to FDA, or similar application to foreign regulatory authorities which must become effective prior to commencing certain human clinical studies of medical devices, and FDA may not approve our IDE application and notify us that we may not begin clinical studies;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical studies;
- regulators and/or institutional review boards, or IRBS, or other reviewing bodies may not authorize us or our investigators to commence a clinical study, or to conduct or continue a clinical study at a prospective or specific study site;
- we may not reach agreement on acceptable terms with prospective contract research organizations, or CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;
- clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical studies or abandon product development programs;
- the number of subjects or patients required for clinical studies may be larger than we anticipate, enrollment in these clinical studies may be insufficient or slower than we anticipate, and the number of clinical studies being conducted at any given time may be high and result in fewer available patients for any given clinical study, or patients may drop out of these clinical studies at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing products or conducting clinical studies 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 studies for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;

## Table of Contents

- we may have to amend clinical study 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 studies may be greater than we anticipate;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical study;
- we may be unable to recruit a sufficient number of clinical study 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 studies may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and/or
- our current or future solutions 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 initiating, enrolling, conducting or completing our planned and ongoing clinical studies. Any of these occurrences may significantly harm our business, financial condition and prospects.

Furthermore, patient enrollment in clinical studies and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the study protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical study, patient compliance, competing clinical studies 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 studies if the study 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 studies of a competitor's product candidate. In addition, patients participating in our clinical studies may drop out before completion of the study or experience adverse medical events unrelated to our solutions. Delays in patient enrollment or failure of patients to continue to participate in a clinical study may delay commencement or completion of the clinical study, cause an increase in the costs of the clinical study and delays, or result in the failure of the clinical study.

Clinical studies 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 or ethics committees at the medical institutions where the clinical studies are conducted. In addition, clinical studies 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 study sites to ensure the proper and timely conduct of our clinical studies 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 studies in compliance with good clinical practice, or GCP, requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical studies, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of studies, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical studies that are conducted in countries internationally 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.

## [Table of Contents](#)

Even if our future solutions are cleared or approved in the United States, commercialization of our solutions in foreign countries would require clearance, approval or certification by regulatory authorities or notified bodies in those countries. Clearance, approval or certification 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 or clinical studies. 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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives) and teaching hospitals, and applicable manufacturers and group purchasing

## [Table of Contents](#)

organizations, to report annually ownership and investment interests held by physicians and their immediate family members;

- 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 solutions 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 solutions. 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 solutions 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 solutions to our customers and the sale and marketing of our solutions, 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

## [Table of Contents](#)

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.

### **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.

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 solutions, 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 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. 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.

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.

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.

## [Table of Contents](#)

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. 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 solutions and practicing our own technology. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our solutions. 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 solutions. Competitors could purchase our solutions 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. 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 solutions are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our solutions, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.

Our trademarks could be infringed or diluted by third parties, or be invalidated or found to be infringing on other marks. If any of the foregoing occurs, we could be forced to re-brand our solutions, 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.

***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 solutions, we may not be able to stop a competitor from manufacturing or marketing products that are the same as or similar to our solutions, which would have a material adverse effect on our business.

## [Table of Contents](#)

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

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 solutions, or that we may be accused of misappropriating third parties' trade secrets. Additionally, our solutions 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, 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 solutions 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 solutions 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 solutions. 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 or enforceable for a number of reasons. If a court agrees, our rights could be narrowed or we could lose our rights entirely under 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 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 solutions unless we obtain a license or are able to redesign our solutions 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 solutions 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 solutions. If we fail to obtain any required licenses or make any necessary changes to our solutions or technologies, we may have to withdraw existing solutions from the market or may be unable to commercialize one or more of our solutions.

In addition, we generally indemnify our customers with respect to infringement by our solutions 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

## [Table of Contents](#)

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 solutions.

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 solutions or using product names, which would have a significant adverse impact on our business, financial condition and results of operations.

### ***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, or trademark registrations, 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 solutions 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 internationally. 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 solutions 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 trademark rights in foreign jurisdictions could result in substantial costs and divert our attention from other aspects of our business, could put our patents and trademarks or applications in those jurisdictions, as well as elsewhere, at risk of being invalidated or interpreted narrowly, and could provoke third parties to assert claims against us. We may not prevail in any proceedings 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.

## [Table of Contents](#)

***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 solutions, 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 solutions could have a material adverse effect on our business, financial condition and results of operations, and may prevent us from selling our solutions. 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.

### **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;
- 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;

## [Table of Contents](#)

- 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 solutions;
- 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 solutions;
- 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 solutions or 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.

***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 vacancies;
- Our classified board of directors is divided into three classes, with each class serving a three year term;

## [Table of Contents](#)

- Our stockholders can only take action 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;
- Our amended and restated certificate of incorporation prohibits cumulative voting;
- Our board of directors may alter our bylaws without obtaining stockholder approval;
- Amendments to certain provisions of our amended and restated certificate of incorporation or amendments to our amended and restated bylaws generally require approval of at least two-thirds of the voting power of our outstanding capital stock;
- 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; and
- Our board of directors is authorized to issue shares of preferred stock and to determine the terms of those shares without stockholder approval.

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

## [Table of Contents](#)

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.

***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.

### **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 120,000 square feet under a lease agreement that expires in July 2041. This facility contains dedicated research and development, training, education and manufacturing spaces. We also lease a small office in Basel, Switzerland.

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.

[Table of Contents](#)

**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.

## [Table of Contents](#)

## **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".

#### **Stockholders**

As of February 24, 2023, there were approximately 11 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 2023 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, 2022 of the cumulative total return to stockholders of our common stock relative to the Nasdaq Composite Index ("NBI"), the Nasdaq Biotechnology Index ("IXIC") and the S&P Health Care Equipment Index. The graph assumes that \$100 was invested in each of our common stock, the Nasdaq Composite, the Nasdaq Biotechnology and the S&P Health Care Equipment Index 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.

[Table of Contents](#)



img65717632\_13.jpg

---

**Item 6. [Reserved]**

Not applicable.

## [Table of Contents](#)

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

*The following discussion and analysis of our financial condition and results of operations should be read 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**

Patients first. No small plans. Take care of each other. These are the guiding principles that form the ethos of Inari Medical. We are committed to improving lives in extraordinary ways by creating innovative solutions for both unmet and underserved health needs. In addition to our purpose-built solutions, we leverage our capabilities in education, clinical research, and program development to improve patient outcomes. We are passionate about our mission to establish our treatments as the standard of care for venous thromboembolism and beyond. We are just getting started.

Through the third quarter of 2022, our solutions ("products") primarily consisted of our ClotTriever and FlowTriever systems, which are minimally invasive, novel, catheter-based mechanical thrombectomy systems that are purpose-built for the specific characteristic of the venous system and the treatment of the two distinct manifestations of venous thromboembolism, or VTE - deep vein thrombosis, or DVT, and pulmonary embolism, or PE. Our ClotTriever system is FDA-cleared for the treatment of DVT, and our FlowTriever system is the first thrombectomy system FDA-cleared for the treatment of PE and is also FDA-cleared for clot in transit in the right atrium. In the fourth quarter of 2022, we began commercializing our InThrill system, which is FDA-cleared for the removal of thrombus from the peripheral vasculature and designed for smaller vessels, and our ProTriever sheath, which is FDA-cleared for removal of thrombus from the peripheral vasculature through aspiration. We also commenced a limited market release of our Artix system in 2022.

We believe our mission-focused and highly-trained 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 recruit sales representatives who have substantial and applicable medical device and/or sales experience. Our front-line sales representatives typically attend procedures, which puts us at the intersection of the patients and physicians. We have developed systems and processes to harness the information gained from these relationships and we leverage this information to rapidly iterate our solutions, introduce and execute physician education and training programs and scale our sales organization. We market and sell our solutions to hospitals, which are reimbursed by various third-party payors.

## Table of Contents

As of December 31, 2022, we had cash, cash equivalents and short-term investments of \$326.4 million, no long-term debt outstanding and an accumulated deficit of \$46.9 million.

For the year ended December 31, 2022, we generated revenue of \$383.5 million, with a gross margin of 88.4% and net loss of \$29.3 million, compared to revenue of \$277.0 million, with a gross margin of 91.1% and net income of \$9.8 million for the year ended December 31, 2021.

### **COVID-19**

From 2020 through 2022, the global healthcare system faced unprecedented challenges as a result of the COVID-19 situation and its impact. Although the lingering effects of COVID-19, many of which are unpredictable and impossible to quantify or measure, may have an adverse impact on the healthcare system generally and certain aspects of our business specifically, we do not expect it to have a material effect on our business going forward.

## Table of Contents

### **Components of our Results of Operations**

#### **Revenue**

During 2022, we derived substantially all our revenue from the sale of our ClotTriever and FlowTriever systems directly to hospitals primarily located in the United States. Our customers typically purchase our products through an initial stocking order, and then reorder replenishment inventory as procedures are performed. No single customer accounted for 10% or more of our revenue during the years ended December 31, 2022, 2021 and 2020. We expect our revenue to increase in absolute dollars as we expand our offerings, grow 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.

We disaggregate revenue by products. ClotTriever and other systems includes revenue from the sale of our ClotTriever system, including ClotTriever BOLD and ProTrieve, and revenue from the sale of our InThrill system. FlowTriever includes revenue from the sale of our FlowTriever system and revenue from the sale of FlowStasis, when sold separately from our FlowTriever system price. Revenue from ClotTriever and other systems and FlowTriever system as a percentage of total revenue is as follows:

	Years Ended December 31,		
	2022	2021	2020
ClotTriever and other systems	32 %	32 %	37 %
FlowTriever system	68 %	68 %	63 %

#### **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. We expect cost of goods sold to continue to increase in absolute dollars as our revenue grows, we introduce new products, and more of our products are sold; however, we also expect to realize opportunities to increase operating leverage as we continue to expand 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 year to year as we introduce new products, adopt new manufacturing processes and technologies, and as we expand internationally.

Additionally, treatments using our systems can be billed on a per system price or price per component. For our products sold on a per system price, we typically charge customers the same price, regardless of the number of components used during the procedure. As a result, changes in the number of components used, the cost of these components and the introduction of additional components into the systems 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 and depreciation expenses. Additionally, R&D expenses include costs associated with our clinical trials and registries,

## Table of Contents

including clinical study design, clinical study site initiation and study costs, data management, and internal and external costs incurred in the process of regulatory submissions, which include the costs of outside consultants and contractors. We expense R&D costs as incurred. We expect R&D to increase in absolute dollars in the near term and generally 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 evidence 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, human resource and other corporate 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.

### **Interest Income**

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

### **Interest Expense**

Interest expense consists primarily of fees related to our Amended Credit Agreement and non-cash interest related to the amortization of debt discount and issuance costs associated with our Amended Credit Agreement.

## [Table of Contents](#)

### Results of Operations

#### **Comparison of the years ended December 31, 2022 and 2021**

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

	Years Ended December 31,				
	2022	%	2021	%	Change \$
Revenue	\$ 383,471	100.0 %	\$ 276,984	100.0 %	\$ 106,487
Cost of goods sold	44,506	11.6 %	24,757	8.9 %	19,749
Gross profit	338,965	88.4 %	252,227	91.1 %	86,738
Operating expenses:					
Research and development	74,221	19.4 %	51,018	18.4 %	23,203
Selling, general and administrative	292,843	76.4 %	190,365	68.7 %	102,478
Total operating expenses	367,064	95.8 %	241,383	87.1 %	125,681
(Loss) income from operations	(28,099 )	(7.4 %)	10,844	4.0 %	(38,943 )
Other income (expense)					
Interest income	1,852	0.5 %	154	0.1 %	1,698
Interest expense	(294 )	(0.1 %)	(295 )	(0.1 %)	1
Other income (expense)	356	0.1 %	(18 )	0.0 %	374
Total other expenses, net	1,914	0.5 %	(159 )	0.0 %	2,073
(Loss) income before income taxes	(26,185 )	(6.9 %)	10,685	4.0 %	(36,870 )
Provision for income taxes	3,082	0.8 %	845	0.3 %	2,237
Net (loss) income	\$ (29,267 )	(7.6 %)	\$ 9,840	3.6 %	\$ (39,107 )

**Revenue.** Revenue increased \$106.5 million, or 38.4%, to \$383.5 million during the year ended December 31, 2022, compared to \$277.0 million during the year ended December 31, 2021. The increase in revenue was primarily due to an increase in the number of products sold as we expanded our sales territories, opened new accounts and achieved deeper penetration of our products into existing accounts, and introduced new products.

**Cost of Goods Sold and Gross Margin.** Cost of goods sold increased \$19.8 million, or 79.8%, to \$44.5 million during the year ended December 31, 2022, compared to \$24.8 million during the year ended December 31, 2021. This increase was due to the increase in the number of products sold and additional manufacturing overhead costs to support anticipated future growth. Gross margin for the year ended December 31, 2022 decreased to 88.4%, compared to 91.1% for the year ended December 31, 2021, primarily due to the costs associated with the addition of new components offered under our FlowTriever system price.

**Research and Development Expenses.** R&D expenses increased \$23.2 million, or 45.5%, to \$74.2 million during the year ended December 31, 2022, compared to \$51.0 million during the year ended December 31, 2021. The increase in R&D expenses was primarily due to increases of \$19.1 million of personnel-related expenses, \$1.4 million of clinical and regulatory expenses, and \$1.2 million in software costs and depreciation expenses, in support of our growth drivers to develop new products and build the clinical evidence base.

**Selling, General and Administrative Expenses.** SG&A expenses increased \$102.5 million, or 53.8%, to \$292.8 million during the year ended December 31, 2022, compared to \$190.4 million during the year ended December 31, 2021. The increase in SG&A costs was primarily due to increases of \$71.8 million in personnel-related expenses as a result of increased headcount and increased commissions due to higher revenue, \$9.3 million in travel and related expenses, \$6.8 million in marketing expenses, \$6.1 million in professional fees, \$4.0 million in facility related expenses, and \$3.0 million in software costs and depreciation expenses.

## [Table of Contents](#)

***Interest Income.*** Interest income increased by \$1.7 million to \$1.9 million for the year ended December 31, 2022, compared to \$0.2 million for the year ended December 31, 2021. The increase in interest income was primarily due to higher interest rates and higher average balances in cash and cash equivalents, and short-term investments in debt securities during the year ended December 31, 2022, compared to the year ended December 31, 2021.

***Interest Expense.*** Interest expense remained consistent at \$0.3 million for both the year ended December 31, 2022 and December 31, 2021.

***Other income (expenses).*** Other income of \$0.4 million for the year ended December 31, 2022 consisted primarily of foreign currency transaction gains. Other expenses for the year ended December 31, 2021 of \$18,000 consisted primarily of foreign currency transaction losses.

***Income Taxes.*** Income taxes increased by \$2.2 million to \$3.1 million for the year ended December 31, 2022, compared to \$0.8 million for the year ended December 31, 2021. The increase in the income taxes primarily relates to an increase in the current year U.S. federal and state income taxes due to newly enacted tax law changes requiring the capitalization and amortization of certain research and development expenses.

### **Comparison of the years ended December 31, 2021 and 2020**

For a comparison of our results of operations and cash flows for the years ended December 31, 2021 and 2020, see "Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" of our annual report on Form 10-K for the year ended December 31, 2021 filed with the SEC on February 23, 2022, which comparative information is incorporated by reference in this Report.

### **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 completed on May 27, 2020 and follow-on offering completed in March 2022, and revenue from the sale of our products. As of December 31, 2022, we had cash and cash equivalents of \$60.2 million and short-term investments in debt securities of \$266.2 million.

In December 2022, we amended our revolving Credit Agreement with Bank of America which provides for loans up to a maximum of \$40.0 million and increases the optional accordion to \$120.0 million. As of December 31, 2022, we had no principal outstanding under the Amended Credit Agreement and the amount available to borrow was approximately \$38.0 million. The Amended Credit Agreement also includes a Letter of Credit subline facility ("LC Facility") of up to \$5.0 million. In February 2023, we amended the LC Facility to increase the limit to up to \$10.0 million. The aggregate stated amount outstanding of letter of credits reduces the total borrowing base available under the Amended Credit Agreement and is subject to certain fees. As of December 31, 2022, we had three letters of credit in the aggregated amount of \$2.0 million outstanding under the LC Facility. For additional information about the Amended Credit Agreement, see Note 10. Credit Facility.

Our other short-term and long-term material cash requirements, from known contractual obligations as of December 31, 2022, include operating lease liabilities and uncertain tax positions, as discussed in the Consolidated Financial Statements section of this report.

Based on our current planned operations, we anticipate that our cash and cash equivalents, short-term investments and available borrowings under our Amended Credit Agreement will be sufficient to fund our operating expenses for at least the next 12 months. Our primary short-term needs for capital for our current planned operations, which are subject to change, include:

## [Table of Contents](#)

- support of commercialization efforts to expand our sales force along with expanding into new markets, and developing products to enhance performance and address unmet market needs;
- the continued advancement of research and development including clinical study activities; and
- potential expansion needs of our facilities.

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,	
	2022	2021
Net cash provided by (used in):		
Operating activities	\$ (13,972)	\$ 25,486
Investing activities	(195,216)	(51,022)
Financing activities	177,138	4,073
Effect of foreign exchange rate on cash and cash equivalents	(480)	(402)
Net decrease in cash and cash equivalents	\$ (32,530)	\$ (21,865)

### ***Net Cash (Used in) Provided by Operating Activities***

Net cash used by operating activities for the year ended December 31, 2022 was \$14.0 million, consisting primarily of net loss of \$29.3 million and a decrease in net operating assets of \$21.5 million, offset by non-cash charges of \$36.8 million. The change in net operating assets was primarily due to increases in accounts receivable of \$17.0 million, inventories of \$11.7 million, and decrease in prepaid expenses, deposits and other assets of \$0.6 million, which were partially offset by the increases in payroll-related accruals, accrued expenses and other liabilities of \$10.7 million and accounts payable of \$1.1 million primarily due to timing of payments and growth of our operations, and decreases in lease prepayments for lessor's owned leasehold improvements of \$4.2 million and operating lease liabilities of \$0.9 million.

Net cash provided by operating activities for the year ended December 31, 2021 was \$25.5 million, consisting primarily of net income of \$9.8 million and non-cash charges of \$30.0 million, offset by an increase in net operating assets of \$14.3 million. The change in net operating assets was primarily due to increases in accounts receivable of \$14.3 million and inventories of \$10.5 million to support the growth of our operations, an increase in prepaid and other assets of \$3.4 million primarily from prepaid insurance, which were partially offset by increases in accounts payable of \$3.5 million and accrued liabilities of \$26.0 million due to timing of payments, increased headcount and growth of our operations, lease prepayments for lessor's owned leasehold improvements of \$14.8 million and a decrease in operating lease liabilities of \$0.8 million. The non-cash charges primarily consisted of \$25.4 million in stock-based compensation expense, \$3.0 million in depreciation, and \$1.3 million in amortization of the right-of-use assets.

## [Table of Contents](#)

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

Net cash used in investing activities for the year ended December 31, 2022 was \$195.2 million, consisting of \$489.6 million purchases of marketable securities, \$8.3 million purchases of other investments, and \$10.0 million purchases of property and equipment, offset by maturities of marketable securities of \$312.6 million.

Net cash used in investing activities for the year ended December 31, 2021 was \$51.0 million, consisting of \$134.4 million of purchases of marketable securities coupled with \$13.6 million of purchases of property and equipment, offset by \$97.0 million in maturities of marketable securities.

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

Net cash provided by financing activities for the year ended December 31, 2022 was \$177.1 million, consisting of \$174.4 million net proceeds from the issuance of common stock in the follow-on offering, net of issuance costs of \$11.9 million, \$8.4 million proceeds from the issuance of common stock under our employee stock purchase plan and \$0.8 million of proceeds from exercise of stock options, offset by \$6.5 million of tax payments related to vested restricted stock units ("RSUs").

Net cash provided by financing activities for the year ended December 31, 2021 was \$4.1 million, consisting of \$5.6 million of proceeds from the issuance of common stock under our employee stock purchase plan and \$0.9 million of proceeds from exercise of stock options, offset by \$2.4 million of tax payments related to vested RSU.

### **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 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***

We recognize revenue in accordance with ASC 606, Revenue from Contracts with Customers. Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that are 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.

We sell our products primarily to hospitals in the United States utilizing our direct sales force. We recognize the revenue for arrangements where we have satisfied our performance obligation of shipping

## [Table of Contents](#)

or delivering the products. For sales where our sales representative hand-deliver products directly to the hospitals, control of the product transfers to the customers upon such hand delivery. For sales where our products are shipped, the control of the products transfer either upon shipment or delivery of the products to the customer, depending on the shipping terms and conditions. Revenue from product sales is comprised of product revenue, net of product returns, administrative fees and sales rebates.

**Performance Obligation** — We have revenue arrangements that consist of a single performance obligation, which is the shipping or delivery of our products. The satisfaction of our 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 recognized is based on the transaction price, which represents the invoiced amount, net of administrative fees and sales rebates, where applicable. We provide a standard 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.

As of December 31, 2022 and 2021, we recorded \$1,218,000 and \$448,000, respectively, of unbilled receivables, which are included in accounts receivable, net, in the accompanying consolidated balance sheets.

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 our standard warranty to all customers. We do not sell any warranties on a standalone basis. Our warranty provides that our 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. We estimate warranty liabilities at the time of revenue recognition and record it as a charge to cost of goods sold. The warranty liability as of December 31, 2022 and 2021 were not significant. The warranty costs recognized during December 31, 2022, 2021 and 2020 were \$631,000, \$194,000 and nil, respectively.

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

### ***Cash, Cash Equivalents, and Investments in Debt and Equity Securities***

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 cash and cash equivalent balances with banks. At times, the cash and cash equivalent balances may exceed federally insured limits. We do not believe that this results in any significant credit risk as our policy is to place our cash and cash equivalents in highly-rated financial institutions.

Investments in debt securities 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 available-for-sales debt securities at the time of purchase. Available-for-sale debt securities with maturities greater than 12 months from the balance sheet date are classified as long-term investments on the consolidated balance sheets.

Unrealized gains and losses are excluded from earnings and reported as a component of comprehensive income (loss). We periodically evaluate whether declines in fair values of our marketable securities below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative

## Table of Contents

factors regarding the severity and duration of the unrealized loss as well as our ability and intent to hold the marketable security until a forecasted recovery occurs. Additionally, we assess whether we have plans to sell the security or it is more likely than not that we 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 (expenses), net on the consolidated statements of operations and comprehensive income (loss). The cost of investments sold is based on the specific-identification method. Interest on marketable securities is included in interest income.

We have investments in certain privately held companies, with no readily determinable fair value. We measure these investments at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for an identical or similar investments. We monitor the information that becomes available from time to time and adjust the carrying values of these investments if there are identified events or changes in circumstances that have a significant adverse effect on the fair values or if there are observable changes in fair value. As of December 31, 2022, total other investments of \$8.3 million were included in deposits and other assets in the consolidated balance sheets with no impairment identified.

### ***Accounts Receivable, net***

Trade accounts receivable are recorded at the invoiced amount, net of any allowance for credit losses. We evaluate the expected credit losses of accounts receivable, considering historical credit losses, current customer-specific information and other relevant factors when determining the allowance. An increase to the allowance for credit losses results in a corresponding increase in selling, general and administrative expenses. We charge off uncollectible receivables against the allowance when all attempts to collect the receivable have failed.

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

Upon adoption of Accounting Standard Update ("ASU") 2016-13, we did not recognize an adjustment to the beginning balance of retained earnings as of January 1, 2021, as the impact from the adoption was not material.

### ***Inventories, net***

We value 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. We regularly review inventory quantities in process and on hand, and when appropriate, record a provision for obsolete and excess inventory. We 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 cost of goods sold on the accompanying consolidated statement of operations and comprehensive income (loss).

## [Table of Contents](#)

### ***Right-of-use Assets and Lease Liabilities***

We determine if a contractual arrangement contains a lease at its inception and determine the classification of a lease, as either operating or finance, at commencement.

Right-of-use assets and lease liabilities are recorded based on the present value of future lease payments which factors in certain qualifying initial direct costs incurred as well as any lease incentives received. If an implicit rate is not readily determinable, we utilize inputs from third-party lenders to determine the appropriate discount rate. Lease expense for operating lease payments are recognized on a straight-line basis over the lease term. Lease terms may factor in options to extend or terminate the lease.

We adhere to the short-term lease recognition exemption for all classes of assets (i.e. facilities and equipment). As a result, leases with an initial term of twelve months or less are not recorded on the balance sheet and are recognized on a straight-line basis over the lease term. In addition, for certain equipment leases, we account for lease and non-lease components, such as services, as a single lease component, as permitted.

### ***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 RSU awards is determined based on the number of units granted and the closing price of our 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. We are required to develop an estimate of the number of equity-based awards that will be forfeited due to employee turnover. We estimate and adjust forfeiture rates based on a periodic review of recent forfeiture activity. Adjustments in the estimated forfeiture rates could cause changes in the amount of expense that is recognized in future periods.

### ***Income Taxes***

We use 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. As of December 31, 2022 and 2021, the net deferred tax assets have been fully offset by a valuation allowance.

We recognize 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

## [Table of Contents](#)

measurement are reflected in the period in which judgment occurs. Our policy is to recognize interest and penalties related to the underpayment of income taxes as a component of provision for income taxes.

### **Recent Accounting Pronouncements**

Please refer to Note 2 to our audited 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**

The JOBS Act allows an emerging growth company to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. Effective December 31, 2021, we were no longer an “emerging growth company” within the meaning of the JOBS Act and can no longer take advantage of this extended transition period. Prior to December 31, 2021, we had elected to use this extended transition period and, as a result, our financial statements may not have been comparable to companies that comply with public company effective dates.

## [Table of Contents](#)

### **Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

#### ***Interest Rate Risk***

The risk associated with fluctuating interest rates is primarily limited to our indebtedness. As of December 31, 2022, we 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, 2022, our cash and cash equivalents and investments were maintained with two financial institutions in the United States, and our current deposits are likely in excess of insured limits. We do not believe we are exposed to any significant credit risk. Our cash equivalents are invested in highly rated money market funds.

Our accounts receivable relate to revenue from the sale of our products primarily to hospitals and medical centers in the United States. No customer represented 10% or more of our accounts receivable as of December 31, 2022.

#### ***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 the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934, as amended, or the Exchange Act), as of December 31, 2022. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2022, these disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported, within the time period specified in the Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls

## Table of Contents

and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

### **Management's Annual Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act. Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, to provide reasonable assurance regarding the reliability of financing reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

Under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer and oversight of the board of directors, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2022, based on the criteria set forth in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2022.

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

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(f) and 15d-15(f) under the Exchange Act that occurred during the fourth quarter of our fiscal year ended December 31, 2022. that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## [Table of Contents](#)

### **Attestation Report of the Registered Public Accounting Firm**

BDO USA, LLP, an independent registered public accounting firm that audited our consolidated financial statements as of and for the year ended December 31, 2022, included in this Annual Report, has issued an attestation report on the effectiveness of our internal control over financial reporting, as set forth below:

#### **Report of Independent Registered Public Accounting Firm**

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

#### **Opinion on Internal Control over Financial Reporting**

We have audited Inari Medical, Inc.'s (the "Company's") internal control over financial reporting as of December 31, 2022, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of the Company as of December 31, 2022 and 2021, 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, 2022, and the related notes and our report dated February 27, 2023 expressed an unqualified opinion thereon.

#### **Basis for Opinion**

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of internal control over financial reporting in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

#### **Definition and Limitations of Internal Control over Financial Reporting**

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that

[\*\*Table of Contents\*\*](#)

receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ BDO USA, LLP

Costa Mesa, California  
February 27, 2023

**Item 9B. Other Information.**

None.

**Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspection.**

Not applicable.

## [Table of Contents](#)

### **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 2023 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](http://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 Accountant 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.

[Table of Contents](#)

**PART IV**

**Item 15. Exhibits and 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.

## Table of Contents

Exhibit Number	Description	Form	Exhibit Index		
			File Number	Exhibit	Incorporated by reference
3.1	<a href="#">Amended and Restated Certificate of Incorporation</a>	8-K	001-39293	3.1	5/28/2020
3.2	<a href="#">Amended and Restated Bylaws</a>	8-K	001-39293	3.2	5/28/2020
4.1	<a href="#">Form of Certificate of Common Stock</a>	S-1	333-236568	4.1	2/21/2020
4.2	<a href="#">Second Amended and Restated Investors' Rights Agreement by and between Inari Medical, Inc. and certain investors, dated March 29, 2018</a>	S-1	333-236568	4.2	2/21/2020
4.3	<a href="#">Warrant to purchase common stock, issued by Inari Medical, Inc. to Croton Partners, LLC, dated February 19, 2015</a>	S-1	333-236568	4.3	2/21/2020
4.4	<a href="#">Warrant to purchase Series A preferred stock, issued by Inari Medical, Inc. to Silicon Valley Bank, dated December 10, 2014</a>	S-1	333-236568	4.4	2/21/2020
4.5	<a href="#">Warrant to purchase Series B preferred stock, issued by Inari Medical, Inc. to East West Bank dated April 29, 2016</a>	S-1	333-236568	4.5	2/21/2020
4.6	<a href="#">Description of Inari Medical, Inc.'s Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934</a>	10-K	001-39293	4.6	2/23/2022
10.1	<a href="#">Form of Indemnification Agreement between Inari Medical, Inc. and its directors and officers</a>	S-1/A	333-236568	10.1	5/5/2020
10.2#	<a href="#">2011 Equity Incentive Plan</a>	S-1	333-236568	10.3	2/21/2020
10.3#	<a href="#">Form of Stock Option Agreement pursuant to 2011 Equity Incentive Plan</a>	S-1	333-236568	10.4	2/21/2020
10.4#	<a href="#">Form of Restricted Stock Unit Agreement pursuant to 2011 Equity Incentive Plan</a>	S-1	333-236568	10.5	2/21/2020
10.5#	<a href="#">2020 Incentive Award Plan</a>	S-1/A	333-236568	10.6	5/18/2020
10.6#	<a href="#">Form of Option Agreement pursuant to 2020 Incentive Award Plan</a>	S-1/A	333-236568	10.6.1	5/18/2020
10.7#	<a href="#">Form of Restricted Stock Unit Agreement pursuant to 2020 Incentive Award Plan</a>	S-1/A	333-236568	10.6.2	5/18/2020
10.8#	<a href="#">Form of Restricted Stock Unit Award Agreement pursuant to 2020 Incentive Award Plan - International</a>	10-K	001-39293	10.8	3/9/2021
10.9#	<a href="#">Amended and Restated 2020 Employee Stock Purchase Plan</a>	10-Q	001-39293	10.3	11/12/2020
10.10#	<a href="#">Form of Restricted Stock Unit Award Agreement pursuant to 2020 Incentive Award Plan - Non-Employee Director</a>	10-K	001-39293	10.25	2/23/2022
10.11#	<a href="#">Employment Agreement, dated as of March 5, 2020, by and between Inari Medical, Inc. and William Hoffman</a>	S-1/A	333-236568	10.12	5/5/2020
10.12#	<a href="#">Employment Agreement, dated as of March 5, 2020, by and between Inari Medical, Inc. and Mitch Hill</a>	S-1/A	333-236568	10.13	5/5/2020
10.13#	<a href="#">Employment Agreement, dated as of March 5, 2020, by and between Inari Medical, Inc. and Andrew Hykes</a>	S-1/A	333-236568	10.14	5/5/2020
10.14#	<a href="#">Amended and Restated Employment Agreement, effective January 1, 2023, by and between Inari Medical, Inc. and Andrew Hykes</a>	8-K	001-39293	10.1	1/27/2023
10.15#	<a href="#">Employment Agreement, dated as of March 5, 2020, by and between Inari Medical, Inc. and Dr. Thomas Tu</a>	10-K	001-39293	10.13	3/9/2021
10.16#	<a href="#">Amended and Restated Non-Employee Director Compensation Program</a>	10-K	001-39293	10.14	2/23/2022



## Table of Contents

Exhibit Number	Description	Form	Incorporated by reference		
			File Number	Exhibit	Filing Date
10.17	<a href="#"><u>Lease Agreement, dated as of March 6, 2019, by and between Inari Medical, Inc. and Bake Technology Park LLC</u></a>	S-1	333-236568	10.2	2/21/2020
10.18	<a href="#"><u>Lease Agreement, dated as of October 7, 2020, by and between Inari Medical, Inc. and Oak Canyon Creek LLC</u></a>	10-Q	001-39293	10.1	11/12/2020
10.19	<a href="#"><u>Lease Termination Agreement, dated as of October 7, 2020, as modified by that First Amendment to the Lease</u></a> <a href="#"><u>Termination Agreement dated February 3, 2021, by and between Inari Medical, Inc. and Bake Technology Park LLC</u></a>	10-K	001-39293	10.17	3/9/2021
10.20	<a href="#"><u>First Amendment to Lease dated March 3, 2021, by and between Inari Medical, Inc. and Oak Canyon Creek LLC</u></a>	10-K	001-39293	10.18	3/9/2021
10.21	<a href="#"><u>Sublicense Agreement, dated as of August 1, 2019, by and between Inari Medical, Inc. and Inceptus Medical, LLC</u></a>	S-1	333-236568	10.9	2/21/2020
10.22	<a href="#"><u>Amended and Restated Services Agreement, dated as of February 1, 2018, by and between Inari Medical, Inc. and Inceptus Medical, LLC</u></a>	S-1	333-236568	10.10	2/21/2020
10.23	<a href="#"><u>Amended and Restated Technology Agreement, dated as of March 2, 2018, by and between Inari Medical, Inc. and Inceptus Medical, LLC</u></a>	S-1	333-236568	10.11	2/21/2020
10.24	<a href="#"><u>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.</u></a>	8-K	001-39293	10.1	9/11/2020
10.25	<a href="#"><u>First Amendment to Loan, Guaranty and Security Agreement, dated as of March 30, 2021, by and between Inari Medical, Inc., Inari Medical International, Inc. and each of the lenders signatory thereto and Bank of America, N.A. as agent</u></a>	8-K	001-39293	10.1	3/31/2021
10.26	<a href="#"><u>Second Amendment to Loan, Guaranty and Security Agreement, dated as of November 8, 2021</u></a>	10-K	001-39293	10.24	2/23/2022
10.27	<a href="#"><u>Third Amendment and Joinder to the Loan, Guaranty and Security Agreement, dated as of July 21, 2022</u></a>	10-Q	001-39293	10.1	8/3/2022
10.28	<a href="#"><u>Fourth Amendment and Joinder to the Loan, Guaranty and Security Agreement, dated as of December 16, 2022.</u></a>				
10.29	<a href="#"><u>Fifth Amendment and Joinder to the Loan, Guaranty and Security Agreement, dated as of February 6, 2023, by and among Inari Medical, Inc., Inari Medical International, Inc., Inari Medical Latin America, Inc., each of the lenders party thereto, and Bank of America, N.A., as agent for the lenders.</u></a>				
21.1	<a href="#"><u>Subsidiaries of the registrant</u></a>				
23.1	<a href="#"><u>Consent of Independent Registered Public Accounting Firm</u></a>				
31.1	<a href="#"><u>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</u></a>				
31.2	<a href="#"><u>Certification of Principal Accounting 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</u></a>				

**Table of Contents**

- 32.1† [Certification of Principal Executive Officer  
pursuant to 18 U.S.C. Section 1350, as adopted pursuant to  
Section 906 of the Sarbanes-Oxley Act of 2002](#)
- 32.2† [Certification of Principal Accounting Officer  
pursuant to 18 U.S.C. Section 1350, as adopted pursuant to  
Section 906 of the Sarbanes-Oxley Act of 2002](#)

[Table of Contents](#)

Exhibit Number	Description	Form	Incorporated by reference		
			File Number	Exhibit	Filing Date
101.INS	Inline XBRL Instance Document - The instance document does not appear in the interactive data file because its EBRL tags are embedded within the inline XBRL document				
101.SCH	Inline XBRL Taxonomy Extension Schema Document				
101.CAL	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page with Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibit 101).				

# 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: February 27, 2023

By: \_\_\_\_\_ /s/ Andrew Hykes  
**Andrew Hykes**  
**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 Andrew Hykes 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.

[Table of Contents](#)

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/ Andrew Hykes <b>Andrew Hykes</b>	Chief Executive Officer (Principal Executive Officer), President and Director	February 27, 2023
/s/ Mitchell Hill <b>Mitchell Hill</b>	Chief Financial Officer (Principal Financial and Principal Accounting Officer)	February 27, 2023
/s/ Donald Milder <b>Donald Milder</b>	Chair of the Board of Directors	February 27, 2023
/s/ Rebecca Chambers <b>Rebecca Chambers</b>	Director	February 27, 2023
/s/ William Hoffman <b>William Hoffman</b>	Director	February 27, 2023
/s/ Cynthia Lucchese <b>Cynthia Lucchese</b>	Director	February 27, 2023
/s/ Dana G. Mead <b>Dana G. Mead, Jr.</b>	Director	February 27, 2023
/s/ Kirk Nielsen <b>Kirk Nielsen</b>	Director	February 27, 2023
/s/ Jonathan Root <b>Jonathan Root, M.D.</b>	Director	February 27, 2023
/s/ Catherine Szyman <b>Catherine Szyman</b>	Director	February 27, 2023
/s/ Robert Warner <b>Robert Warner</b>	Director	February 27, 2023

[Table of Contents](#)

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

<a href="#"><u>Report of Independent Registered Public Accounting Firm</u></a> (BDO USA, LLP; Costa Mesa, California; PCAOB ID#243)	F-2
<a href="#"><u>Consolidated Balance Sheets as of December 31, 2022 and 2021</u></a>	F-4
<a href="#"><u>Consolidated Statements of Operations and Comprehensive Income (Loss) for the Years ended December 31, 2022, 2021, and 2020</u></a>	F-5
<a href="#"><u>Consolidated Statements of Mezzanine Equity and Stockholders' Equity (Deficit) for the Years ended December 31, 2022, 2021 and 2020</u></a>	F-6
<a href="#"><u>Consolidated Statements of Cash Flows for the Years ended December 31, 2022, 2021 and 2020</u></a>	F-7
<a href="#"><u>Notes to Consolidated Financial Statements</u></a>	F-8

---

F-1

## [Table of Contents](#)

### **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, 2022 and 2021, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in *Internal Control – Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") and our report dated February 27, 2023 expressed an unqualified opinion thereon.

#### **Change in Accounting Method Related to Leases**

As discussed in Notes 2 and 7 to the consolidated financial statements, the Company has changed its method of accounting for leases during the year ended December 31, 2021 due to the adoption of the Accounting Standards Codification 842, *Leases*.

#### **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 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.

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.

#### **Critical Audit Matter**

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below,

## Table of Contents

providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

### **Accounting for Income Taxes**

As described in Note 13 to the consolidated financial statements, the Company's consolidated deferred tax assets as of December 31, 2022, includes capitalized research and development expenses of approximately \$14.3 million. For tax years beginning after December 31, 2021, certain research and development expenses are required to be capitalized and amortized over a five year period under the Tax Cuts and Jobs Act, which was signed into law December 22, 2017.

We identified the capitalization of the research and development expenses as a deferred tax asset as a critical audit matter. The principal considerations for our determination are the methodology utilized by management and certain related significant inputs in the calculation of the capitalized research and development expenses. Auditing these elements involved especially challenging auditor judgment due to the nature and extent of audit effort required to address these matters, including the extent of specialized skills and knowledge in taxation.

The primary procedures we performed to address this critical audit matter included:

- Testing of the completeness and accuracy of certain significant inputs used in the calculation by management and agreeing to relevant accounting records or source documents; and
- Utilizing personnel with specialized skill and knowledge in taxation to assist with (i) evaluating the reasonableness of the methodology used in estimating qualified research expenses, (ii) evaluating the reasonableness of certain significant inputs, and (iii) testing the calculations used by management.

/s/ BDO USA, LLP

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

Costa Mesa, California  
February 27, 2023

[Table of Contents](#)

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

	December 31, 2022	December 31, 2021
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 60,222	\$ 92,752
Short-term investments in debt securities	266,179	83,348
Accounts receivable, net	58,611	42,351
Inventories, net	32,581	21,053
Prepaid expenses and other current assets	5,312	5,694
Total current assets	422,905	245,198
Property and equipment, net	21,655	16,471
Operating lease right-of-use assets	50,703	44,909
Deposits and other assets	8,889	981
Long-term investments in debt securities	—	3,983
<b>Total assets</b>	<b>\$ 504,152</b>	<b>\$ 311,542</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 7,659	\$ 6,541
Payroll-related accruals	38,955	24,433
Accrued expenses and other current liabilities	8,249	10,737
Operating lease liabilities, current portion	1,311	802
Total current liabilities	56,174	42,513
Operating lease liabilities, noncurrent portion	30,976	28,404
Other long-term liability	—	1,416
<b>Total liabilities</b>	<b>87,150</b>	<b>72,333</b>
<b>Commitments and contingencies (Note 7)</b>		
<b>Stockholders' equity</b>		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized, no shares issued and outstanding as of December 31, 2022 and 2021	—	—
Common stock, \$0.001 par value, 300,000,000 shares authorized as of December 31, 2022 and 2021; 54,021,656 and 50,313,452 shares issued and outstanding as of December 31, 2022 and 2021, respectively	54	50
Additional paid in capital	462,949	257,144
Accumulated other comprehensive income (loss)	849	(402)
Accumulated deficit	(46,850)	(17,583)
<b>Total stockholders' equity</b>	<b>417,002</b>	<b>239,209</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 504,152</b>	<b>\$ 311,542</b>

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

[Table of Contents](#)

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

	Years Ended December 31,		
	2022	2021	2020
Revenue	\$ 383,471	\$ 276,984	\$ 139,670
Cost of goods sold	44,506	24,757	13,106
Gross profit	338,965	252,227	126,564
Operating expenses			
Research and development	74,221	51,018	18,399
Selling, general and administrative	292,843	190,365	89,746
Total operating expenses	367,064	241,383	108,145
(Loss) income from operations	(28,099 )	10,844	18,419
Other income (expense)			
Interest income	1,852	154	484
Interest expense	(294 )	(295 )	(1,135 )
Change in fair value of warrant liabilities	—	—	(3,317 )
Other income (expense)	356	(18 )	(662 )
Total other income (expense)	1,914	(159 )	(4,630 )
(Loss) income before income taxes	(26,185 )	10,685	13,789
Provision for income taxes	3,082	845	—
Net (loss) income	\$ (29,267 )	\$ 9,840	\$ 13,789
Other comprehensive income (loss)			
Foreign currency translation adjustments	(592 )	(379 )	—
Unrealized gain (loss) on available-for-sale debt securities	1,843	(27 )	4
Total other comprehensive income (loss)	1,251	(406 )	4
Comprehensive (loss) income	\$ (28,016 )	\$ 9,434	\$ 13,793
Net (loss) income per share			
Basic	\$ (0.55 )	\$ 0.20	\$ 0.43
Diluted	\$ (0.55 )	\$ 0.18	\$ 0.27
Weighted average common shares used to compute net (loss) income per share			
Basic	52,837,674	49,815,914	32,033,827
Diluted	52,837,674	55,594,159	51,554,996

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

[Table of Contents](#)

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

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
<b>Balance, December 31, 2019</b>	<b>31,968,570</b>	<b>\$ 54,170</b>	<b>6,720,767</b>	<b>\$ 7</b>	<b>\$ 2,061</b>	<b>\$ -</b>	<b>\$ (41,212)</b>	<b>\$ (39,144)</b>
Conversion of preferred stock to common stock upon initial public offering ("IPO")	(31,968,570)	(54,170)	31,968,570	32	54,138	—	—	54,170
Issuance of common stock in connection with an IPO, 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 IPO	—	—	—	—	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
Other comprehensive income	—	—	—	—	—	4	—	4
Net income	—	—	—	—	—	—	13,789	13,789
<b>Balance, December 31, 2020</b>	<b>49,251,614</b>	<b>49</b>	<b>227,624</b>	<b>4</b>	<b>(27,423)</b>	<b>200,254</b>		
Options exercised for common stock	—	—	806,008	1	868	—	—	869
Issuance of common stock under employee stock purchase plan	—	—	85,049	—	5,558	—	—	5,558
Issuance of common stock upon vesting of restricted stock units, net of shares withheld for taxes	—	—	170,781	—	(2,354)	—	—	(2,354)
Share-based compensation	—	—	—	—	25,448	—	—	25,448
Other comprehensive loss	—	—	—	—	—	(406)	—	(406)
Net income	—	—	—	—	—	—	9,840	9,840
<b>Balance, December 31, 2021</b>	<b>50,313,452</b>	<b>50</b>	<b>257,144</b>	<b>(402)</b>	<b>(17,583)</b>	<b>239,209</b>		
Options exercised for common stock	—	—	1,098,841	1	809	—	—	810
Issuance of common stock under employee stock purchase plan	—	—	133,515	—	8,422	—	—	8,422
Issuance of common stock upon vesting of restricted stock units, net of shares withheld for taxes	—	—	175,848	—	(6,489)	—	—	(6,489)
Issuance of common stock in public offering, net of issuance costs of \$11.9 million	—	—	2,300,000	3	174,392	—	—	174,395
Share-based compensation	—	—	—	—	28,671	—	—	28,671
Other comprehensive income	—	—	—	—	—	1,251	—	1,251
Net loss	—	—	—	—	—	—	(29,267)	(29,267)
<b>Balance, December 31, 2022</b>	<b>54,021,656</b>	<b>\$ 54</b>	<b>\$ 462,949</b>	<b>\$ 849</b>	<b>\$ (46,850)</b>	<b>\$ 417,002</b>		

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

[Table of Contents](#)

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

	Years Ended December 31,		
	2022	2021	2020
<b>Cash flows from operating activities</b>			
Net (loss) income	\$ (29,267 )	\$ 9,840	\$ 13,789
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:			
Depreciation	4,673	3,034	1,385
Amortization of deferred financing costs	143	143	181
Amortization of right-of-use assets	2,446	1,274	—
Share-based compensation expense	28,671	25,448	3,524
Allowance for credit losses, net	736	(22 )	—
Loss on disposal of fixed assets	94	69	237
Loss on extinguishment of debt	—	—	648
Loss on change in fair value of warrant liabilities	—	—	3,317
Changes in:			
Accounts receivable	(17,030 )	(14,361 )	(16,706 )
Inventories	(11,688 )	(10,488 )	(6,644 )
Prepaid expenses, deposits and other assets	580	(3,430 )	(2,458 )
Accounts payable	1,140	3,514	498
Payroll-related accruals, accrued expenses and other liabilities	10,691	25,992	4,141
Operating lease liabilities	(923 )	(772 )	—
Lease prepayments for lessor's owned leasehold improvements	(4,238 )	(14,755 )	—
Net cash (used in) provided by operating activities	<u>(13,972 )</u>	<u>25,486</u>	<u>1,912</u>
<b>Cash flows from investing activities</b>			
Purchases of property and equipment	(9,951 )	(13,645 )	(5,460 )
Purchases of marketable securities	(489,605 )	(134,377 )	(49,977 )
Maturities of marketable securities	312,600	97,000	—
Purchases of other investments	(8,260 )	—	—
Net cash used in investing activities	<u>(195,216 )</u>	<u>(51,022 )</u>	<u>(55,437 )</u>
<b>Cash flows from financing activities</b>			
Proceeds from issuance of common stock in public offering, net of issuance costs	174,395	—	164,361
Proceeds from issuance of common stock under employee stock purchase plan	8,422	5,558	—
Proceeds from exercise of stock options and warrants	810	869	471
Payment of taxes related to vested restricted stock units	(6,489 )	(2,354 )	(25 )
Proceeds from notes payable	—	—	10,000
Repayments of notes payable	—	—	(30,250 )
Debt financing costs	—	—	(442 )
Net cash provided by financing activities	<u>177,138</u>	<u>4,073</u>	<u>144,115</u>
Effect of foreign exchange rate on cash and cash equivalents	(480 )	(402 )	—
<b>Net (decrease) increase in cash</b>	<b><u>(32,530 )</u></b>	<b><u>(21,865 )</u></b>	<b><u>90,590</u></b>
<b>Cash and cash equivalents beginning of period</b>	<b>92,752</b>	<b>114,617</b>	<b>24,027</b>
<b>Cash and cash equivalents end of period</b>	<b><u>\$ 60,222</u></b>	<b><u>\$ 92,752</u></b>	<b><u>\$ 114,617</u></b>
<b>Supplemental disclosures of cash flow information:</b>			
Cash paid for income taxes	\$ 3,417	\$ 472	\$ 154
Cash paid for interest	\$ 151	\$ 151	\$ 999
<b>Noncash investing and financing:</b>			
Lease liabilities arising from obtaining new right-of-use assets	\$ 3,947	\$ 28,648	\$ —
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.

## [Table of Contents](#)

### **INARI MEDICAL, INC. Notes to 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 purpose builds minimally invasive, novel, catheter-based mechanical thrombectomy systems for the unique characteristics of specific disease states.

#### **2. Summary of Significant Accounting Policies**

##### **COVID-19**

From 2020 through 2022, the global healthcare system faced unprecedented challenges as a result of the COVID-19 situation and its impact. Although the lingering effects of COVID-19, many of which are unpredictable and impossible to quantify or measure, may have an adverse impact on the healthcare system generally and certain aspects of the Company specifically, the Company does not expect it to have a material effect on our business going forward.

##### ***Basis of Presentation***

The accompanying consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (“U.S. GAAP”) and include the Company and its wholly owned subsidiaries. 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 may include, but are not limited to, collectability of receivables, recoverability of long-lived assets, valuation of inventory, operating lease right-of-use (“ROU”) assets and liabilities, other investments, fair value of stock options, fair value of common stock warrants, recoverability of net deferred tax assets and related valuation allowance, and certain accruals. Estimates are based on historical experience and on various assumptions that the Company believes are reasonable under current circumstances. Actual results could differ materially from those estimates. Management periodically evaluates such estimates and assumptions, and they are adjusted prospectively based upon such periodic evaluation.

##### ***JOBS Act Accounting Election***

The JOBS Act allows an emerging growth company to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. Effective December 31, 2021, the Company was no longer an “emerging growth company” within the meaning of the JOBS Act and can no longer take advantage of this extended transition period. Prior to December 31, 2021, the Company had elected to use this extended transition period and, as a result, the Company’s financial statements may not have been comparable to companies that comply with public company effective dates.

## [Table of Contents](#)

### **INARI MEDICAL, INC Notes to Consolidated Financial Statements — Continued**

#### **Cash and Cash Equivalents**

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 and cash equivalent balances with banks. At times, the cash and cash equivalent balances may exceed federally insured limits. The Company does not believe that this results in any significant credit risk as the Company's policy is to place its cash and cash equivalents in highly-rated financial institutions.

#### **Investments in Debt and Equity Securities**

Investments in debt securities 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 available-for-sale debt securities at the time of purchase. Available-for-sale securities with maturities less than 12 months at the balance sheet date are considered short-term investments. Available-for-sale debt securities with maturities greater than 12 months from the balance sheet date are classified as long-term investments on the consolidated balance sheets.

Unrealized gains and losses are excluded from earnings and reported as a component of comprehensive income (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 that 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 (expenses), net on the consolidated statements of operations and comprehensive income (loss). The cost of investments sold is based on the specific-identification method. Interest on marketable securities is included in interest income.

As of December 31, 2022, the Company has investments in certain privately held companies, with no readily determinable fair value. The Company measures these investments at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for an identical or similar investments. The Company will monitor the information that becomes available from time to time and adjust the carrying values of these investments if there are identified events or changes in circumstances that have a significant adverse effect on the fair values or if there are observable changes in fair value. As of December 31, 2022, total other investments of \$8.3 million were included in deposits and other assets in the consolidated balance sheets with no impairment or observable changes in fair value identified.

#### **Accounts Receivable, net**

Trade accounts receivable are recorded at the invoiced amount, net of any allowance for credit losses. The Company evaluates the expected credit losses of accounts receivable, considering historical credit losses, current customer-specific information and other relevant factors when determining the allowance. An increase to the allowance for credit losses results in a corresponding increase in selling, general and administrative ("SG&A") expenses. The Company charges off uncollectible receivables against the allowance when all attempts to collect the receivable have failed. The allowance for credit losses was \$776,000 and \$40,000 as of December 31, 2022 and 2021, respectively.

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

## [Table of Contents](#)

### **INARI MEDICAL, INC Notes to Consolidated Financial Statements — Continued**

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 cost of goods sold on the accompanying consolidated statements of operations and comprehensive income (loss).

#### ***Property and Equipment, net***

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 as operating expense in the accompanying consolidated statements of operations and comprehensive income (loss).

#### ***Right-of-use Assets and Lease Liabilities***

The Company determines if an arrangement contains a lease at inception and determines the classification of the lease, as either operating or finance, at commencement.

After the adoption of the new lease standard on January 1, 2021, right-of-use assets and lease liabilities are recorded based on the present value of future lease payments which factors in certain qualifying initial direct costs incurred as well as any lease incentives received. If an implicit rate is not readily determinable, the Company utilizes inputs from third-party lenders to determine the appropriate discount rate. Lease expense for operating lease payments is recognized on a straight-line basis over the lease term. Lease terms may factor in options to extend or terminate the lease.

The Company adheres to the short-term lease recognition exemption for all classes of assets (i.e. facilities and equipment). As a result, leases with an initial term of twelve months or less are not recorded on the balance sheet and are recognized on a straight-line basis over the lease term. In addition, for

## [Table of Contents](#)

### **INARI MEDICAL, INC Notes to Consolidated Financial Statements — Continued**

certain equipment leases, the Company accounts for lease and non-lease components, such as services, as a single lease component as permitted.

#### ***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 and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate their fair value due to their liquidity or short maturities.

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—Adjusted 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. Fair Value Measurements for further information.

#### ***Revenue Recognition***

The Company recognizes revenue in accordance with ASC 606, *Revenue from Contracts with Customers*. Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company 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.

The Company sells its products primarily to hospitals in the United States utilizing the Company's direct sales force. 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 representative hand-deliver products directly to the hospitals, control of the products transfers to the customers 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. Revenue from product sales is comprised of product revenue, net of product returns, administrative fees and sales rebates.

## [Table of Contents](#)

### **INARI MEDICAL, INC Notes to Consolidated Financial Statements — Continued**

**Performance Obligation**—The Company has revenue arrangements that consist of a single performance obligation, the shipping or 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 recognized is based on the transaction price, which represents the invoiced amount, net of administrative fees and sales rebates, where applicable. The Company provides a standard 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.

As of December 31, 2022 and 2021, the Company recorded \$1,218,000 and \$448,000, respectively, of unbilled receivables, which are included in accounts receivable, net, in the accompanying consolidated balance sheets.

The Company disaggregates revenue by product. Revenue from ClotTriever and other systems and FlowTriever system as a percentage of total revenue is as follows:

	Years Ended December 31,		
	2022	2021	2020
ClotTriever and other systems	32 %	32 %	37 %
FlowTriever system	68 %	68 %	63 %

Revenue from the Company's products by geographic area, based on the location where title transfers, is as follows (in thousands):

	Years Ended December 31,		
	2022	2021	2020
United States	\$ 374,040	\$ 274,402	\$ 139,670
International	9,431	2,582	-
Total revenue	<u>\$ 383,471</u>	<u>\$ 276,984</u>	<u>\$ 139,670</u>

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. The warranty liability as of December 31, 2022 and 2021 were not significant. The warranty costs recognized during December 31, 2022, 2021 and 2020 were \$631,000, \$194,000 and nil, respectively.

Costs associated with product sales include commissions and are recorded in SG&A expenses. The Company applies the practical expedient and recognizes commissions as an 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

## [Table of Contents](#)

### **INARI MEDICAL, INC Notes to Consolidated Financial Statements — Continued**

stock-based compensation. Cost of goods sold also includes depreciation expense for production equipment, inventory impairment charges, and certain direct costs such as shipping and handling costs and royalty expense.

#### ***Advertising Costs***

Advertising costs are charged to operations as incurred. Advertising costs were \$957,000, \$344,000 and \$333,000 for the years ended December 31, 2022, 2021 and 2020, respectively. Advertising costs are included in SG&A expenses in the accompanying consolidated statements of operations and comprehensive income (loss).

#### ***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 the purchase of intellectual property relating to a particular research and development project that has no alternative future uses, clinical studies, registries and sponsored researches. 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 consolidated statements of operations and comprehensive income (loss).

#### ***Stock-based Compensation***

The Company's 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. The Company estimates and adjusts forfeiture rates based on a periodic review of recent forfeiture activity. Adjustments in the estimated forfeiture rates could cause changes in the amount of expense that is recognized in future periods.

#### ***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. As of December 31, 2022 and 2021, 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 Translation***

When the functional currencies of the Company's foreign subsidiaries are currencies other than the U.S. dollar, the assets and liabilities of the foreign subsidiaries are translated into U.S. dollars at the exchange

## [Table of Contents](#)

### **INARI MEDICAL, INC Notes to Consolidated Financial Statements — Continued**

rate in effect on the balance sheet date. Income and expense items of the subsidiaries are translated into U.S. dollars at the average exchange rates prevailing 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 subsidiaries, at which time the gains or losses will be realized and included in consolidated net income (loss). Transaction gains and losses are included in other income (expense) and have not been significant for the periods presented.

The Company's intercompany accounts are denominated in the functional currencies of the foreign subsidiaries. Gains and losses resulting from the remeasurement of intercompany transactions that the Company considers to be of a long-term investment nature are recorded in accumulated other comprehensive income (loss) as a separate component of stockholders' equity, while gains and losses resulting from the remeasurement of intercompany transactions from those foreign subsidiaries for which the Company anticipates settlement in the foreseeable future are recorded in the consolidated statements of operations and comprehensive income (loss).

#### ***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 debt securities 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, shares from redeemable convertible preferred stock and warrants, common stock options, RSUs and ESPP 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.

#### ***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, which is the development and commercialization of minimally invasive, novel, catheter-based mechanical thrombectomy systems for the unique characteristics of specific disease states. Geographically, the Company sells primarily 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 February 2017, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASC 842"), 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. ASC 842 requires additional quantitative and qualitative financial statement note disclosures about the leases, significant judgments made in accounting for those leases and amounts recognized in the financial statements about those leases.

## [Table of Contents](#)

### **INARI MEDICAL, INC Notes to Consolidated Financial Statements — Continued**

The Company adopted the requirement of ASC 842 effective January 1, 2021 and elected the modified retrospective method for all lease arrangements with a cumulative-effect adjustment as of January 1, 2021. Results for reporting periods beginning on or after January 1, 2021 are presented under ASC 842, while prior period amounts were not adjusted and are reported in accordance with the Company's historic accounting under ASC 840, Leases. For leases that commenced before the effective date of ASC 842, the Company elected the transition package of three practical expedients permitted within ASC 842, which eliminates the requirements to reassess prior conclusions about lease identification, lease classification, and initial direct costs. The Company also elected the hindsight practical expedient, which permits the use of hindsight when determining lease term and impairment of right-of-use assets. Further, the Company elected a short-term lease exception policy, permitting the Company to not apply the recognition requirements of this standard to short-term leases (i.e., leases with terms of 12 months or less) and an accounting policy to account for lease and non-lease components as a single component for certain classes of assets.

As a result of adopting ASC 842 as of January 1, 2021, the Company recorded an operating lease right-of-use asset of approximately \$1.2 million and related operating lease liability of approximately \$1.3 million based on the present value of the future lease payments on the date of adoption. There was no cumulative-effect adjustment recorded to retained earnings upon adoption. Adopting ASC 842 did not have a material impact on the Company's consolidated statements of operations and comprehensive income (loss) and consolidated statements of cash flows. See Note 7, Commitments and Contingencies, for further discussion of the Company's adoption of ASC 842 and related disclosures.

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 adopted this guidance effective January 1, 2021 and the adoption of this standard did not have a material impact on its consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*, which changes the impairment model for most financial assets. The new model uses a forward-looking expected loss method, which will generally result in earlier recognition of allowances for losses. 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. This standard provides guidance regarding methodologies and disclosures related to expected credit losses. The guidance became effective for the Company on December 31, 2021 when the Company no longer qualified for emerging growth company status. The Company adopted this guidance effective January 1, 2021. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

[Table of Contents](#)

**INARI MEDICAL, INC**  
**Notes to Consolidated Financial Statements — Continued**

**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, 2022 and 2021 (in thousands):

	December 31, 2022			Aggregate Fair Value	
	Level 1	Level 2	Level 3		
<b>Financial Assets</b>					
<b>Cash and cash equivalents:</b>					
Money market mutual funds	\$ 20,329	\$ —	\$ —	\$ 20,329	
Total included in cash and cash equivalents	20,329	—	—	20,329	
<b>Investments:</b>					
U.S. Treasury securities	172,088	—	—	172,088	
U.S. Government agencies	—	47,131	—	47,131	
Corporate debt securities and commercial paper	—	46,960	—	46,960	
Total included in short-term investments	172,088	94,091	—	266,179	
Total assets	<u>\$ 192,417</u>	<u>\$ 94,091</u>	<u>\$ —</u>	<u>\$ 286,508</u>	

	December 31, 2021			Aggregate Fair Value	
	Level 1	Level 2	Level 3		
<b>Financial Assets</b>					
<b>Cash and cash equivalents:</b>					
Money market mutual funds	\$ 48,595	\$ —	\$ —	\$ 48,595	
Total included in cash and cash equivalents	48,595	—	—	48,595	
<b>Investments:</b>					
U.S. Treasury securities	44,322	—	—	44,322	
Corporate debt securities and commercial paper	—	39,026	—	39,026	
Total included in short-term investments	44,322	39,026	—	83,348	
U.S. Treasury securities included in long-term investments	3,983	—	—	3,983	
Total assets	<u>\$ 96,900</u>	<u>\$ 39,026</u>	<u>\$ —</u>	<u>\$ 135,926</u>	

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

## [Table of Contents](#)

### INARI MEDICAL, INC Notes to Consolidated Financial Statements — Continued

#### 4. Cash Equivalents and Investments

The following is a summary of the Company's cash equivalents and investments in debt securities as of December 31, 2022 and 2021 (in thousands):

	December 31, 2022			
	Amortized Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
<b>Financial Assets</b>				
<b>Cash and cash equivalents:</b>				
Money market mutual funds	\$ 20,329	\$ —	\$ —	\$ 20,329
Total included in cash and cash equivalents	<u>20,329</u>	<u>—</u>	<u>—</u>	<u>20,329</u>
<b>Investments:</b>				
U.S. Treasury securities	171,006	1,120	(38)	172,088
U.S. Government agencies	46,777	354	—	47,131
Corporate debt securities and commercial paper	46,576	397	(13)	46,960
Total included in short-term investments	<u>264,359</u>	<u>1,871</u>	<u>(51)</u>	<u>266,179</u>
Total assets	<u>\$ 284,688</u>	<u>\$ 1,871</u>	<u>\$ (51)</u>	<u>\$ 286,508</u>

	December 31, 2021			
	Amortized Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
<b>Financial Assets</b>				
<b>Cash and cash equivalents:</b>				
Money market mutual funds	\$ 48,595	\$ —	\$ —	\$ 48,595
Total included in cash and cash equivalents	<u>48,595</u>	<u>—</u>	<u>—</u>	<u>48,595</u>
<b>Investments:</b>				
U.S. Treasury securities	44,349	—	(27)	44,322
Corporate debt securities and commercial paper	39,012	14	—	39,026
Total included in short-term investments	<u>83,361</u>	<u>14</u>	<u>(27)</u>	<u>83,348</u>
U.S. Treasury securities included in long-term investments	3,993	—	(10)	3,983
Total assets	<u>\$ 135,949</u>	<u>\$ 14</u>	<u>\$ (37)</u>	<u>\$ 135,926</u>

The Company regularly reviews the changes to the rating of its debt securities and reasonably monitors the surrounding economic conditions to assess the risk of expected credit losses. As of December 31, 2022, the risk of expected credit losses was not significant.

#### 5. Inventories, net

Inventories, net of reserves, consist of the following (in thousands):

	December 31, 2022	December 31, 2021
Raw materials	\$ 13,943	\$ 5,763
Work-in-process	3,396	1,490
Finished goods	15,242	13,800
Total inventories, net	<u>\$ 32,581</u>	<u>\$ 21,053</u>

## Table of Contents

### INARI MEDICAL, INC Notes to Consolidated Financial Statements — Continued

#### **6. Property and Equipment, net**

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

	<b>December 31, 2022</b>	<b>December 31, 2021</b>
Manufacturing equipment	\$ 13,585	\$ 7,408
Computer hardware	5,123	2,864
Leasehold improvements	5,040	4,712
Furniture and fixtures	4,119	3,044
Assets in progress	2,516	3,124
Computer software	100	100
<b>Total property and equipment, gross</b>	<b>30,483</b>	<b>21,252</b>
Accumulated depreciation	(8,828)	(4,781)
<b>Total property and equipment, net</b>	<b>\$ 21,655</b>	<b>\$ 16,471</b>

Depreciation expense of \$3,780,000, \$2,367,000 and \$1,039,000 was included in SG&A expenses and \$893,000, \$667,000 and \$346,000 was included in cost of goods sold for the years ended December 31, 2022, 2021 and 2020, respectively.

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

The Company has software systems that are cloud-based hosting arrangements with service contracts. The Company accounts for costs incurred in connection with the implementation of these various software systems under 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. The Company expenses all costs (internal and external) that are incurred in the planning and post-implementation operation stages.

As of December 31, 2022, the Company has capitalized approximately \$1,047,000 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. As of December 31, 2022 and 2021, approximately \$137,000 and \$391,000, respectively, of the capitalized costs were included in prepaid expenses and other current assets and \$53,000 and \$55,000, respectively, were included in deposits and other assets. The Company starts amortizing capitalized implementation costs when the systems are placed in production and ready for their intended use. For the years ended December 31, 2022, 2021 and 2020, amortization expense, which was included in SG&A expenses, was \$518,000, \$222,000 and \$100,000, respectively.

#### **7. Commitments and Contingencies**

##### ***Operating Leases***

The Company has operating leases for facilities and certain equipment. Leases with an initial term of 12 months or less are not recorded on the consolidated balance sheet. Lease expense for operating leases is recognized on a straight-line basis over the lease term. For lease agreements, other than long-term real estate leases, entered into or reassessed after the adoption of ASC 842 on January 1, 2021, the Company combines lease and non-lease components (see Note 2. Summary of Significant Accounting Policies).

In March 2019, the Company executed a five-year lease for a facility in Irvine, California, where substantially all operations of the Company had been located from September 2019 to September 2021. This lease was originally set to expire in September 2024. Concurrent with the execution of the Oak Canyon lease in October 2020 (see below), the Company entered into a termination agreement (as amended) that would have released the Company from the obligations under the lease effective July 2022 and contained options to extend the lease term for up to three periods of an additional 30 days

## [Table of Contents](#)

### **INARI MEDICAL, INC Notes to Consolidated Financial Statements — Continued**

each, which the Company had exercised as of September 30, 2022. In October 2022, the Company amended the lease agreement to cancel the termination agreement and revert the lease termination date back to September 2024. The amended lease also contains two optional extension periods of 6 month each. The Company has determined that it is reasonably certain to exercise one of the 6 months extension, which is included in the calculation of the ROU asset and lease liability. The amendment of this lease resulted in an increase in the ROU asset and lease liability of \$1.7 million during 2022.

In October 2020, the Company entered into a ten-year lease for a facility located in Irvine, California (the "Oak Canyon lease") with two option extension periods of five years each, which the Company has determined that it is reasonably certain to exercise. The Oak Canyon lease requires the Company to make variable lease payments, which are not included in the lease liability due to the amounts not being fixed, for property taxes, insurance, maintenance, repair costs, and certain improvements deemed to be assets of the lessor. The Oak Canyon lease includes scheduled payment escalation clauses over the lease term. The Oak Canyon lease also requires the Company to maintain 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 determined the lease commencement date to be September 30, 2021. On the commencement date, the Company recorded approximately \$42.2 million and \$28.6 million of ROU asset and lease liability, respectively. The ROU asset included approximately \$13.5 million, net of \$3.7 million tenant allowance, related to prepaid lease payments for the lessor's owned leasehold improvements. Subsequent to the commencement date, the Company made additional prepaid lease payments for lessor's owned leasehold improvements, which are also included in the ROU asset as of December 31, 2022, amounting to approximately \$2.8 million and \$4.2 million for the years ended December 31, 2022 and 2021, respectively.

In July 2022, the Company entered into a five-year commercial lease agreement for office space located in Basel, Switzerland (the "Basel lease"). The lease commenced on July 1, 2022, with an option to extend for a period of five years, which the Company has determined that it is reasonably certain to exercise and is, therefore, included in the calculation of the ROU asset and lease liability. The lease payment is also indexed to the Switzerland national consumer price index, which may be adjusted once per calendar year. The Basel lease also requires the Company to maintain a bank guarantee for the benefit of the landlord in the amount of approximately \$0.2 million, which is secured by two letters of credit issued under the Company's Credit Agreement. The addition of this lease resulted in an increase in the ROU asset and lease liability of \$2.2 million during 2022.

As of December 31, 2022, the aggregate operating lease right-of-use assets and lease liabilities were \$50.7 million and \$32.3 million, respectively, with the weighted average remaining lease term of 17.1 years. As of December 31, 2021, the aggregate operating lease right-of-use assets and lease liabilities were \$44.9 million and \$29.2 million, respectively, with the weighted average remaining lease term of 19.2 years.

As of December 31, 2022 and 2021, the weighted average incremental borrowing rate used to measure all operating lease liabilities was approximately 6.1% and 6.0%, respectively. During the years ended December 31, 2022 and 2021, cash paid for amounts included in the measurement of operating lease liabilities was \$2.7 million and \$14.6 million, respectively.

Total lease cost for the years ended December 31, 2022 and 2021 are as follows (in thousands):

	Years Ended December 31,	
	2022	2021
Operating lease cost	\$ 4,276	\$ 1,568
Short-term lease cost	240	200
Variable lease cost	622	473
<b>Total lease costs</b>	<b>\$ 5,138</b>	<b>\$ 2,241</b>

## [Table of Contents](#)

### **INARI MEDICAL, INC Notes to Consolidated Financial Statements — Continued**

The rent expense for year ended December 31, 2020 was \$790,000.

Future minimum lease payments under operating leases liabilities as of December 31, 2022 are as follows (in thousands):

<b>Year ending December 31:</b>	<b>Amount</b>
2023	\$ 3,237
2024	3,333
2025	2,812
2026	2,683
2027	2,741
Thereafter	38,504
Total lease payments	53,310
Less imputed interest	(21,023)
Total lease liabilities	32,287
Less: lease liabilities - current portion	(1,311)
Lease liabilities - noncurrent portion	<u>\$ 30,976</u>

In February 2023, the Company entered into a lease agreement to lease additional space in its facility located in Irvine, California. The estimated minimum lease payments for the lease are approximately \$1.1 million in aggregate, which are not included in the table above for the future minimum lease payments as of December 31, 2022.

#### ***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.

#### ***Licensed Technology***

In December 2021, the Company entered into an exclusive, perpetual, royalty free, technology license agreement (the "Licensed Technology") for use in a particular research and development project that requires total payments of approximately \$4.2 million payable in three installments due in 2022 and 2023. The Company accounted for the purchase as a research and development expense as it was determined to have no future alternative uses. As of December 31, 2021, the Company recorded \$4.2 million on its consolidated balance sheet, of which \$2.8 million was included in accrued expenses and other current liabilities, and the remaining was included in other long-term liability. As of December 31, 2022, the

## [Table of Contents](#)

### **INARI MEDICAL, INC Notes to Consolidated Financial Statements — Continued**

outstanding balance was approximately \$1.3 million, which was included in accrued expenses and other current liabilities on the consolidated balance sheets.

#### ***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. Certain stockholders of the Company were stockholders of Inceptus. As of the completion of the Company's IPO in 2020, Inceptus is no longer considered a related party.

Under the sublicense agreement, the Company is required to pay an ongoing quarterly administration fee, which amounted to \$116,000, \$116,000, and \$95,000 for the years ended December 31, 2022, 2021 and 2020, respectively. Additionally, the Company is obligated to pay 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 \$1,500. The Company recorded royalty expense to cost of goods sold of \$215,350, \$769,000, and \$488,000 for the years ended December 31, 2022, 2021, and 2020, respectively.

#### **8. Concentrations**

The Company's revenue is derived primarily from the sale of catheter-based therapeutic devices in the United States. For the years ended December 31, 2022, 2021 and 2020, 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, 2022 and 2021.

No vendor accounted for more than 10% of the Company's purchases for the years ended December 31, 2022, 2021 and 2020. There were no vendors which accounted for more than 10% of the Company's accounts payable as of December 31, 2022 and 2021.

#### **9. Related Party**

The Company utilizes MRI The Hoffman Group ("MRI"), a recruiting services company owned by the brother of the former Chief Executive Officer and President and current member of the board of directors of the Company. The Company paid for recruiting services provided by MRI amounting to \$320,000, \$369,000, and \$427,000 for the years ended December 31, 2022, 2021, and 2020, respectively, which was included in SG&A expenses on the consolidated statements of operations and comprehensive income (loss). As of December 31, 2022 and 2021, there was no balance payable to MRI.

#### **10. Credit Facility**

##### ***Bank of America Credit Facility***

On December 16, 2022, the Company amended its senior secured revolving credit facility with Bank of America (the "Amended Credit Agreement") under which the Company may borrow loans up to a maximum principal amount of \$40.0 million and increases the optional accordion to \$120.0 million. The Amended Credit Agreement matures on December 16, 2027. The amount available to borrow under the Amended Credit Agreement as of December 31, 2022 is approximately \$38.0 million, comprised of: a) 90% of eligible accounts receivable, plus b) eligible inventory plus c) pledged cash (up to \$10.0 million).

Advances under the Amended 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 Bloomberg Short-Term Bank Yield Index ("BSBY") rate based upon an interest period of one month plus 1.00%

## [Table of Contents](#)

### **INARI MEDICAL, INC Notes to Consolidated Financial Statements — Continued**

. The Margin ranges from 0.50% to 1.00% in the case of Base Rate loans and 1.50% and 2.00% in the case of BSBY Rate loans depending on average daily availability, in each case with a floor of 0%. As a condition to entering into the Amended Credit Agreement, the Company was obligated to pay a nonrefundable fee of \$10,000. The Company is also required to pay an unused line fee at an annual rate of 0.25% per annum of the average daily unused portion of the aggregate revolving credit commitments under the Amended Credit Agreement.

The Amended Credit Agreement also includes the LC Facility of up to \$5.0 million. In February 2023, the Company amended the LC Facility to increase the limit to up to \$10.0 million. The aggregate stated amount outstanding of letter of credits reduces the total borrowing base available under the Amended 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 BSBY 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, 2022, the Company had three letters of credit in the aggregated amount of \$2.0 million outstanding under the LC Facility.

The Amended Credit Agreement contains certain customary covenants subject to certain exceptions, including, among others, the following: a fixed charge coverage ratio covenant, and limitations of indebtedness, liens, investments, asset sales, mergers, consolidations, liquidations, dispositions, restricted payments, transactions with affiliates and prepayments of certain debt. The Amended Credit Agreement also contains certain events of default subject to certain customary grace periods, including, among others, payment defaults, breaches of any representation, warranty or covenants, judgment defaults, cross defaults to certain other contracts, bankruptcy and insolvency defaults, material judgment defaults and a change of control default.

As of December 31, 2022, there was no principal amount outstanding, and no cash was pledged under the Amended Credit Agreement, and the Company was in compliance with its covenant requirements. Obligations under the Amended Credit Agreement are secured by substantially all of the Company's assets, excluding intellectual property.

## **11. Stockholder's Equity**

### ***Redeemable Convertible Preferred Stock***

In connection with the IPO in May 2020, the 31,968,570 shares of redeemable convertible preferred stock then outstanding were converted into 31,968,570 shares of common stock.

### ***Accumulated Other Comprehensive Income (Loss)***

The following table summarizes the changes in accumulated balances of other comprehensive income (loss), net of tax, for the years ended December 31, 2022, 2021 and 2020 (in thousands):

	Unrealized Gain (Loss) on Investments	Foreign Currency Translation	Accumulated Other Comprehensive Income (Loss)
Balance, December 31, 2019	\$ —	\$ —	\$ —
Other comprehensive income	4	—	4
Balance, December 31, 2020	4	—	4
Other comprehensive loss	(27 )	(379 )	(406 )
Balance, December 31, 2021	(23 )	(379 )	(402 )
Other comprehensive income	1,843	(592 )	1,251
Balance, December 31, 2022	<u>\$ 1,820</u>	<u>\$ (971 )</u>	<u>\$ 849</u>

## [Table of Contents](#)

### **INARI MEDICAL, INC Notes to Consolidated Financial Statements — Continued**

#### **Common Stock**

In March 2022, the Company completed an underwritten public offering (“Follow-On Offering”) of 2,300,000 shares of its common stock, including 300,000 shares sold pursuant to the underwriters’ exercise of their option to purchase additional shares, at a public offering price of \$81.00 per share. The Company received net proceeds of approximately \$174.4 million, after deducting underwriters’ discounts and commissions of \$11.2 million and offering costs of \$0.7 million.

#### **Warrants**

There were no warrants outstanding as of December 31, 2022 and 2021. The Company had previously issued common stock warrants and redeemable convertible preferred stock warrants (“Preferred Warrants”) allowing 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 in the Company’s consolidated 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 liabilities to additional paid-in capital. Warrant expense of \$3.3 million relating to the change in fair value was recognized during the year ended December 31, 2020.

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)	
	Series A	Series B
Expected volatility	51.10 %	50.00 %
Preferred stock fair value (per share)	\$ 19.00	\$ 19.00
Dividend yield	0.00 %	0.00 %
Risk free interest rates	0.17 %	0.53 %
Expected remaining term in years	1.55	5.94-6.86

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

#### **12. Equity Incentive Plans**

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 and directors. 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,

## [Table of Contents](#)

### INARI MEDICAL, INC Notes to Consolidated Financial Statements — Continued

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, 2022, there were 5,635,200 shares available for issuance under the 2020 Plan, including 1,509,404 additional shares reserved effective January 1, 2022.

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

##### **Stock Options**

A summary of stock option activities under the 2011 Plan is as follows (intrinsic value in thousands):

	<b>Number of Awards</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Fair Value</b>	<b>Remaining Contractual Life (in years)</b>	<b>Weighted Average Remaining Contractual Life (in years)</b>	<b>Intrinsic Value</b>
<b>Outstanding, December 31, 2019</b>	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			
<b>Outstanding, December 31, 2020</b>	3,436,785	\$ 1.36	\$ 0.98	8.05	\$ 295,331	
Exercised	(806,008)	\$ 1.08	\$ 0.83			\$ 73,299
Cancelled	(56,423)	\$ 2.17	\$ 1.36			
<b>Outstanding, December 31, 2021</b>	2,574,354	\$ 1.43	\$ 1.02	7.07	\$ 231,286	
Exercised	(1,098,841)	\$ 0.74	\$ 0.59			\$ 80,830
Cancelled	(19,185)	\$ 2.64	\$ 1.57			
<b>Outstanding, December 31, 2022</b>	<u>1,456,328</u>	<u>\$ 1.93</u>	<u>\$ 1.34</u>	6.20	\$ 89,749	
Vested and exercisable at December 31, 2022	<u>1,220,470</u>	<u>\$ 1.62</u>	<u>\$ 1.15</u>	6.11	\$ 75,602	
Vested and expected to vest at December 31, 2022	<u>1,450,206</u>	<u>\$ 1.92</u>	<u>\$ 1.33</u>	6.20	\$ 89,388	

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 options granted under the 2011 Plan was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	<b>Year Ended December 31, 2020</b>
Expected volatility	40.60%
Weighted-average volatility	40.60%
Common stock fair value (per share)	\$7.88 - \$9.05
Expected dividends	0.00%
Risk free interest rates	1.46% - 1.68%
Expected term	5.90 - 6.07

**Expected volatility.** The expected volatility is derived from an average of the historical volatilities of the common stock of the Company and several other entities with characteristics similar to those of the Company, such as the size and operational and economic similarities to the Company's principal business operations.

**Common Stock fair value.** The Company uses the market closing price of its Class A common stock, as reported on the NASDAQ Global Select Market, for the fair value. Prior to the IPO, the fair value of the Company's common stock was determined by the board of directors with assistance from management. The board of directors determined the fair value of common stock by considering independent valuation



## [Table of Contents](#)

### **INARI MEDICAL, INC Notes to Consolidated Financial Statements — Continued**

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.

*Expected dividends.* The Company has not declared or paid any dividends.

*Risk-free interest rates.* The Company applies the risk-free interest rate based on the U.S. 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.

In 2021, the Company accelerated the vesting of 4,993 stock options for an employee and accounted for the vesting acceleration as a modification under ASC 718. The Company recognized additional stock-based compensation expense as a result of this modification of approximately \$0.5 million, which was determined using the Black-Scholes option pricing model with a weighted average volatility of 51.90%, common stock value of \$105.54, dividend yield of 0.00% and risk free interest rate of 0.10% and was included in SG&A expenses on the consolidated statements of operations and comprehensive income (loss).

#### **Restricted Stock Units**

Under the 2011 Plan, the Company granted 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. The 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.

In 2021, the Company accelerated the vesting of 96,658 RSUs for an employee and accounted for the vesting acceleration as a modification under ASC 718. The Company recognized a one-time stock-based compensation expense as a result of this modification of approximately \$8.3 million, which was determined based on the fair value of the Company's shares of common stock at the time of the modification, and was included in SG&A expenses on the consolidated statements of operations and comprehensive income (loss).

RSU activities under the 2011 Plan is set forth below:

	Number of Awards	Weighted Average Fair Value
Outstanding, December 31, 2020	2,867,326	\$ 0.17
Vested	(96,658)	0.17
Cancelled	(57,994)	0.17
Outstanding, December 31, 2021 and 2022	<u>2,712,674</u>	<u>\$ 0.17</u>

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.

## [Table of Contents](#)

### **INARI MEDICAL, INC Notes to Consolidated Financial Statements — Continued**

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 Incentive Award Plan**

##### **Restricted Stock Units**

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 activities under the 2020 Plan is set forth below:

	Number of Awards	Weighted Average Fair Value
Outstanding, December 31, 2019	-	\$ -
Granted	227,963	58.68
Vested	(1,199)	51.41
Cancelled	(4,200)	51.41
Outstanding, December 31, 2020	<u>222,564</u>	<u>58.86</u>
Granted	515,880	98.98
Vested	(99,758)	78.15
Cancelled	(27,481)	86.41
Outstanding, December 31, 2021	<u>611,205</u>	<u>88.34</u>
Granted	696,111	73.22
Vested	(257,198)	84.15
Cancelled	(50,903)	82.92
Outstanding, December 31, 2022	<u>999,215</u>	<u>\$ 79.16</u>

In 2021, the Company accelerated the vesting of 8,947 RSUs for a director and accounted for the vesting acceleration as a modification under ASC 718. The Company recognized a one-time stock-based compensation expense as a result of this modification of approximately \$0.4 million, which was determined based on the fair value of the Company's shares of common stock at the time of the modification and was included in SG&A expenses on the consolidated statements of operations and comprehensive income (loss).

The total fair value of RSUs vested under both the 2011 Plan and 2020 Plan during the years ended December 31, 2022, 2021 and 2020, was \$20.2 million, \$17.7 million and \$80,000, respectively.

#### **Stock-based Compensation Expense**

[Table of Contents](#)

**INARI MEDICAL, INC**  
**Notes to Consolidated Financial Statements — Continued**

Total compensation cost for all share-based payment arrangements recognized, including \$3.3 million, \$2.4 million and \$560,000 of stock-based compensation expense related to the ESPP for the years ended December 31, 2022, 2021 and 2020, respectively, was as follows (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Cost of goods sold	\$ 1,510	\$ 815	\$ 155
Research and development	4,255	2,214	592
Selling, general and administrative	22,906	22,419	2,777
	<u>\$ 28,671</u>	<u>\$ 25,448</u>	<u>\$ 3,524</u>

Total compensation costs as of December 31, 2022 related to all non-vested awards to be recognized in future periods was \$66.0 million and is expected to be recognized over the remaining weighted average period of 2.8 years.

The income tax benefit from the exercises of stock options before valuation allowance was \$7.6 million, \$10.3 million and \$4.9 million for the years ended December 31, 2022, 2021 and 2020, respectively.

***Employee Stock Purchase Plan***

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. 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. 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.

The fair value of the ESPP shares is estimated using the Black-Scholes option pricing model with the following assumptions:

	Years Ended December 31,		
	2022	2021	2020
Expected term (in years)	0.5	0.5	0.5
Expected volatility	56.09% - 72.78%	51.47% - 51.91%	49.23%
Dividend yield	0.00%	0.00%	0.00%
Risk free interest rate	0.48% - 2.96%	0.06% - 0.08%	0.11%

Total shares of common stock purchased under the ESPP for the years as of December 31, 2022, 2021, and 2020 were 133,515, 85,049 and nil, respectively. As of December 31, 2022 and 2021, there were 1,767,957 and 1,398,337 shares, respectively, reserved for future purchases.

## [Table of Contents](#)

### INARI MEDICAL, INC Notes to Consolidated Financial Statements — Continued

#### 13. Income Taxes

The Company's income tax provision is summarized as follows (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Income (loss) before provision for income taxes:			
United States	\$ (15,787)	\$ 18,301	\$ 14,541
Foreign	(10,398)	(7,616)	(752)
(Loss) income before income taxes	<u>\$ (26,185)</u>	<u>\$ 10,685</u>	<u>\$ 13,789</u>
Current tax expense:			
Federal	\$ 826	\$ —	\$ —
State	1,997	832	—
Foreign	259	13	—
Total current tax expense	<u>3,082</u>	<u>845</u>	—
Total provision for income taxes	<u>\$ 3,082</u>	<u>\$ 845</u>	\$ —
Provision for income taxes as a percentage of income (loss) before taxes	<u>(11.8 %)</u>	<u>7.9 %</u>	0.0 %

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 are as follows (in thousands):

	December 31,	
	2022	2021
<b>Deferred tax assets</b>		
Capitalized R&D Expenses	\$ 14,250	\$ -
Credit carryforwards	10,298	7,750
Operating leases	7,587	7,432
Net operating losses and capital loss carryforwards	6,038	8,918
Equity compensation	2,307	1,511
Intangible asset basis	2,008	2,390
Accrued employee compensation	1,321	1,028
Inventory	1,207	778
Other	—	44
<b>Total deferred tax assets</b>	<u>\$ 45,016</u>	<u>\$ 29,851</u>
<b>Deferred tax liabilities</b>		
Right-of-use assets	\$ (10,390)	\$ (9,138)
Fixed asset basis	(3,980)	(2,810)
Other liabilities	(325)	(7)
<b>Total deferred tax liabilities</b>	<u>\$ (14,695)</u>	<u>\$ (11,955)</u>
Valuation allowance	\$ (30,321)	\$ (17,896)
<b>Net deferred tax assets</b>	<u>\$ —</u>	<u>\$ —</u>

ASC 740 requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is "more likely than not". Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward periods. Based on its evaluation, including projected taxable losses, management believes that recognition of the deferred tax

assets arising from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly has provided for a valuation allowance. The Company will continue to assess its position on the realizability of its deferred

## Table of Contents

### INARI MEDICAL, INC Notes to Consolidated Financial Statements — Continued

tax assets, until such time as sufficient positive evidence may become available to allow the Company to reach a conclusion that a significant portion of the valuation allowance will no longer be needed. Any release of the valuation allowance will result in a material benefit recognized in the quarter of release. The valuation allowance increased by approximately \$12.4 million during the year ended December 31, 2022.

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

	Years Ended December 31,		
	2022	2021	2020
Statutory rate	\$ (5,499)	\$ 2,244	\$ 2,896
State taxes, net of federal benefit	(1,060)	(317)	—
Foreign rate differential	1,982	1,181	—
Meals and entertainment	37	14	213
Equity compensation	(9,351)	(8,387)	(3,576)
162(m) Limitation	8,242	4,162	197
Return to provision	105	(1,127)	258
Permanent adjustments	103	104	827
General business credits	(4,709)	(3,761)	(1,621)
Change in valuation allowance	12,891	6,031	110
Intercompany Profit in Inventory	341	701	—
Stock warrants	—	—	696
Total	<u>\$ 3,082</u>	<u>\$ 845</u>	<u>\$ —</u>

For tax years beginning after December 31, 2021, certain research and development expenses are required to be capitalized and amortized over a five year period under the Tax Cuts and Jobs Act, which was signed into law December 22, 2017. The Company has reviewed and incorporated this change which impacts the expected U.S. federal and state tax expense and cash taxes to be paid for the tax year ending December 31, 2022.

As a result of losses incurred in the past, the Company has net operating loss ("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, which is, generally, the three-year period preceding a testing date.

Net operating losses and tax credit carryforwards as of December 31, 2022 are as follows (in thousands):

	Amount	Expiration Years
Net operating losses, federal - Expiring	\$ 8,706	2032 - 2037
Net operating losses, federal - Indefinite	1,774	Indefinite
Net operating losses, state	20,487	2031-2041
Net operating losses, foreign	26,554	2028-2029
Net operating losses, foreign - Indefinite	720	Indefinite
Tax credits, federal	9,046	2040 - 2042
Tax credits, state	8,005	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 and December 31, 2021. Usage of NOL's generated prior to March 29, 2018 will be limited to \$3.0 million for calendar years 2019 through 2022, \$0.7 million for 2023, \$0.6 million from 2024 through

2039, and \$0.2 million for 2040 for both federal and state purposes. The IRC §382 ownership change that occurred on December 31, 2021 did not further limit t

## [Table of Contents](#)

### **INARI MEDICAL, INC Notes to Consolidated Financial Statements — Continued**

he use of the Company's NOL's generated prior to December 31, 2021. Of the federal net operating loss and the state net operating loss carryforward amounts, \$10.5 million and \$19.7 million are subject to the IRC §382 limitation, respectively.

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, 2022 and 2021, the Company has total uncertain tax positions of \$5.5 million and \$2.7 million respectively. The Company estimates that these liabilities would be reduced by \$5.5 million and \$2.7 million, 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 (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Balance at the beginning of the year	\$ 2,679	\$ 882	\$ 1,091
Additions based on tax positions related to the current year	2,348	1,352	287
Additions based on tax provisions related to prior years	499	445	—
Deductions based on tax positions related to prior years	—	—	(496)
Balance at the end of the year	<u>\$ 5,526</u>	<u>\$ 2,679</u>	<u>\$ 882</u>

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 December 31, 2019, December 31, 2018, and December 31, 2017 are open for federal, state, and foreign tax purposes, respectively.

On August 9, 2022, President Biden signed the Creating Helpful Incentives to Produce Semiconductors (CHIPS) Act into law, which includes an advanced manufacturing investment tax credit, among other provisions. Additionally, on August 16, 2022, President Biden signed the Inflation Reduction Act (the IRA) into law, which includes implementation of a new alternative minimum tax, an excise tax on stock buybacks, and significant tax incentives for energy and climate initiatives, among other provisions. The Company has reviewed these changes and determined that they do not have a material impact on the Company's December 31, 2022 U.S. income tax positions.

#### **14. 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 Trust Company. Beginning in January 2021, the Company contributes 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's contributions becoming fully vested immediately. For the years ended December 31, 2022 and 2021, the Company recognized \$7.5 million and \$3.3 million, respectively, in matching contributions expense. During the year ended December 31, 2022, the Company recorded an out-of-period adjustment resulting in additional matching contribution expense of \$0.8

[Table of Contents](#)

**INARI MEDICAL, INC**  
**Notes to Consolidated Financial Statements — Continued**

million. The out-of-period adjustment was not considered material to the fiscal 2021 or fiscal 2022 annual consolidated financial statements.

**15. Net Income (Loss) Per Share**

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

	Years Ended December 31,		
	2022	2021	2020
<b>Numerator:</b>			
Net (loss) income (in thousands)	\$ (29,267)	\$ 9,840	\$ 13,789
<b>Denominator:</b>			
Weighted average number of common shares outstanding - basic	52,837,674	49,815,914	32,033,827
Common stock equivalents from convertible preferred stock	—	-	12,490,452
Common stock equivalents from outstanding common stock options	—	2,842,938	3,856,222
Common stock equivalents from unvested RSUs	—	2,929,524	2,858,224
Common stock equivalents from ESPP	—	5,783	-
Common stock equivalents from outstanding warrants	—	-	191,194
Common stock equivalents from restricted stock	—	-	125,077
Weighted average number of common shares outstanding - diluted	<u>52,837,674</u>	<u>55,594,159</u>	<u>51,554,996</u>
<b>Net (loss) income per share:</b>			
Basic	\$ (0.55)	\$ 0.20	\$ 0.43
Diluted	<u>\$ (0.55)</u>	<u>\$ 0.18</u>	<u>\$ 0.27</u>

The Company did not have any anti-dilutive common stock equivalents for the years ended December 31, 2021 and 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 below due to their anti-dilutive effect:

	For the Year Ended December 31, 2022
Common stock options	1,456,328
RSUs	3,711,889
Total potentially dilutive common stock equivalents excluded from calculation due to anti-dilutive effect	<u>5,168,217</u>