Table of Contents

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

FORM 10-K

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

For the fiscal year ended **December 31, 2021**

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: **001-34822**

CLEARPOINT NEURO, INC.

(Exact name of registrant as specified in its charter)

Delaware	**58-2394628**
(State or other jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
120 S. Sierra Ave., Suite 100 **Solana Beach, California** *(Address of principal executive offices)*	**92075** *(Zip Code)*

(888) 287-9109
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(g) of the Act: Common Stock, $0.01 par value per share

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value per share	CLPT	Nasdaq Capital Market

Securities registered pursuant to Section 12(b) 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 Section 15(d) of the Exchange 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☑ Yes ☐ No

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

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

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

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

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

As of June 30, 2021, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately **$**61 million based on the closing sale price as reported on the Nasdaq Capital Market.

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date:

Class	Outstanding at March 3, 2022
Common Stock, $.01 par value per share	23,690,218 shares

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III is incorporated by reference from portions of the definitive proxy statement to be filed within 120 days after December 31, 2021, pursuant to Regulation 14A under the Securities Exchange Act of 1934 in connection with the 2022 annual meeting of stockholders.

CLEARPOINT NEURO, INC.

TABLE OF CONTENTS

Trademarks, Trade Names and Service Marks

ClearPoint Neuro®, *ClearPoint*®, *ClearTrace*®, *SmartFlow*®, *SmartFrame*®, *SmartGrid*®, *Inflexion*™, *SmartTwist*™, *SmartTip*™, *ClearPoint Pursuit*®, *ClearPoint Maestro*™, *ClearPoint Revolution*™, *SmartFrame Array*™, *When Your Path is Unclear, We Point The Way*™ , and *MRI Interventions*® are all trademarks of ClearPoint Neuro, Inc. Any other trademarks, trade names or service marks referred to in this Annual Report are the property of their respective owners. As used in this Annual Report, we, us, our, the Company or ClearPoint Neuro refer to ClearPoint Neuro, Inc. and its affiliates, Siemens refers to Siemens Healthineers AG and its affiliates, Boston Scientific refers to Boston Scientific Corporation and its affiliates, Brainlab refers to Brainlab AG and its affiliates, CLS refers to Clinical Laserthermia Systems AB and its affiliates, IMRIS refers to IMRIS, Deerfield Imaging, Inc. and its affiliates, PTC refers to PTC Therapeutics, Inc. and its affiliates, Philips refers to Koninklijke Philips N.V. and its affiliates, Blackrock refers to Blackrock Neurotech, Abbott refers to Abbott Laboratories and its affiliates, Elekta refers to Elekta AB and its affiliates, NeuroPace refers to

Table of Contents

NeuroPace, Inc. and its affiliates, UCSF refers to the University of California, San Francisco, and Johns Hopkins refers to Johns Hopkins University.

PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains "forward-looking statements" as defined under the United States federal securities laws. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements, expressed or implied by the forward-looking statements. Forward-looking statements may include, but are not limited to, statements about:

- the effects of the COVID-19 pandemic and measures taken or that may be taken by federal, state and local governmental authorities to combat the spread of the disease;
- future revenues from sales of ClearPoint system products; and
- our ability to market, commercialize and achieve broader market acceptance for our ClearPoint system products.

In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," and similar expressions intended to identify forward-looking statements, although not all forward-looking statements contain these words. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain.

You should refer to the section of this Annual Report entitled "Risk Factors" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We do not undertake to update any of the forward-looking statements after the date of this Annual Report, except to the extent required by applicable securities laws.

RISK FACTOR SUMMARY

Our business faces many risks and uncertainties. These risks and uncertainties could lead to events or circumstances that have a material adverse effect on our business, financial condition, results of operations and prospects. You should carefully review and consider the full discussion of our risk factors described under Item 1A, Risk Factors of this Annual Report together with other information in this Annual Report and our other filings with the Securities and Exchange Commission ("SEC"), before making an investment decision regarding our common stock.

- COVID-19 could adversely impact our business.
- Our ClearPoint system may not achieve broad market adoption and our future business growth is dependent upon marketing and selling our ClearPoint system, and other new products, in the operating room.
- Our long-term growth depends on our ability to compete effectively in the neurosurgery market by developing and commercializing new products and services through our research and development efforts.
- If coverage and reimbursement from third-party payors for procedures utilizing our products are inadequate, adoption of our products will be adversely affected and our revenues and prospects for profitability will suffer.
- We currently have significant customer concentration, so economic difficulties or changes in the purchasing policies or patterns of our key customers could have a significant impact on our business.
- Our internal manufacturing operations are conducted at a single location, which may limit our ability to provide an adequate supply of our products, and any disruption at our manufacturing facility could render us unable to produce our products, increase our expenses and decrease our revenue.
- Our reliance on single-source suppliers could harm our ability to meet demand for our products.
- To the extent we seek a new indication for use of, or new claims for, our products, the FDA may not grant 510(k) clearance or premarket approval application approval of such new use or claims.
- If we fail to obtain the necessary clearances, certifications or approvals for our new products, our ability to grow our business globally could be harmed.

- The results of our clinical trials may not support our product candidate claims or additional claims we may seek for our products and may result in the discovery of adverse side effects.
- The markets for medical devices are highly competitive, and we may not be able to compete effectively against larger, well-established as well as emerging small innovative competitors.
- We sell our products outside of the United States, and are subject to various economic, political, regulatory and other risks relating to international operations.
- Disruptions of critical information systems or material breaches in the security of our systems could harm us.
- We may acquire other businesses, form joint ventures, or make investments in other companies or technologies that may not result in commercial success and could lead to significant losses.
- We need to hire and retain additional qualified personnel to grow and manage our business.
- We have incurred losses since our inception and we may continue to do so. We may never achieve or sustain profitability.
- We may need additional funding for our business, and we may not be able to raise capital when needed or on terms that are acceptable to us, and raising additional funds may cause dilution, restrict our operations or require us to relinquish proprietary rights.
- If we, or the third parties from whom we license intellectual property, are unable to secure and maintain patent or other intellectual property protection for the intellectual property covering our marketed products or our product candidates, our ability to compete will be harmed.
- If we are subject to third-party claims of intellectual property infringement, we may become engaged in costly disputes.
- If our intellectual property is inadequately protected, our ability to successfully commercialize our marketed products and product candidates will be harmed.
- If we lose access to third-party software that is integrated into our ClearPoint system software, our costs could increase and new installations of our ClearPoint system could be delayed.
- Our rights to develop and commercialize our products are subject, in part, to the terms and conditions of licenses granted to us by others.
- We operate in a highly-regulated industry and any failure to comply with the extensive government regulations may subject us to fines, injunctions and other penalties.
- Federal legislation and other payment and policy changes may have a material adverse effect on our business.
- Our products may be subject to product recalls that could harm our reputation, business operating results and financial condition.
- If our products cause or contribute to a death or a serious injury, or malfunction, we will be subject to Medical Device Reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.
- We may incur significant liability if it is determined that we are promoting off-label uses of our products in violation of federal and state regulations in the United States or elsewhere.
- If we or our third-party suppliers fail to comply with the FDA's QSR or any applicable state equivalent, our manufacturing operations could be interrupted, and our potential product sales and operating results could suffer.
- We are subject to environmental laws and regulations that can impose significant costs and expose us to potential financial liabilities.
- We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.
- We are subject to various laws protecting the confidentiality and security of certain personal information, and our failure to comply could result in penalties and reputational damage.
- Our Third Amended and Restated Bylaws include exclusive forum provisions for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.
- If our common stock becomes subject to the penny stock rules, it may become more difficult to trade our shares. Additionally, the market price of our common stock may be highly volatile and stockholders may not be able to resell shares at or above the purchase price.
- Sales of a substantial number of shares of our common stock in the public market, or the perception that they may occur, may depress the market price of our common stock.
- Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

- We have not paid dividends in the past and do not expect to pay dividends in the future.
- Anti-takeover provisions in our certificate of incorporation, bylaws and Delaware law could prevent or delay a change in control.
- We may fail to meet our publicly announced guidance or other expectations about our business and future operating results, which could cause a decline in our stock price.
- Securities analysts may not continue coverage for our common stock or may issue negative reports.
- We are subject to certain general risks, including, but not limited to, risks related to our dependence on certain employees, damage to our reputation, natural disasters, product and professional liability claims or other lawsuits, and the requirements of being a public company.

ITEM 1. BUSINESS

Overview

We are a commercial-stage medical device company, incorporated in 1998 as a Delaware corporation, that develops and commercializes innovative platforms for performing minimally invasive surgical procedures in the brain. From our inception in 1998, we have deployed significant resources to fund our efforts to develop the foundational capabilities for enabling MRI-guided interventions, building an intellectual property portfolio, and identifying and building out commercial applications for the technologies we develop. In 2021, our efforts expanded beyond the MRI suite to encompass development and commercialization of new neurosurgical device products for the operating room setting, as well as consulting services for pharmaceutical companies. Our products have been used in over 5,000 clinical and clinical trial procedures in the United States, Canada, the European Union (the "EU") and the United Kingdom at approximately 60 neurosurgery centers. We have experienced steady growth since we began commercializing our products and supported 929 procedures in 2021.

Since 2020, we have evolved to become a company comprised of two parts. The first foundational part consists of a business providing medical devices for neurosurgery applications. The second part of our business is focused on partnering with pharmaceutical companies in the biologics and drug delivery space. Currently, we have approximately 40 pharmaceutical company customers who are either evaluating or using our SmartFlow cannula and other products, in trials to inject gene and cell therapies directly into the brain. Our partnership in this space is dependent upon each customer’s stage of product development which ranges from preclinical research to late-stage regulatory trials for over 15 distinct disease states. This part of our business potentially represents the largest opportunity for growth, which we estimate could have an approximately $7 billion market potential; however, our ability to access this market is dependent on our pharmaceutical company customers achieving success in completion of clinical trials and subsequent regulatory approvals of their drugs and biologics.

Our ClearPoint system is in commercial use in the United States, the EU, and the United Kingdom. The primary applications for the ClearPoint system are to target and guide: (a) the insertion of deep brain stimulation electrodes, biopsy needles; and (b) the infusion of pharmaceuticals and laser catheters into the brain. The ClearPoint system was originally designed for use in an MRI setting. In 2021, we launched the SmartFrame Array Neuro Navigation System and Software, which allows for operating room placement of the ClearPoint system.

We are also in the process of developing and commercializing several new technologies and services, including the ClearPoint Maestro Brain Model, a laser ablation system, pre-clinical development services for pharmaceutical partners, and a robotic-assisted navigation system.

We believe that our ClearPoint product platform, subject to appropriate regulatory clearances and approvals we intend to pursue in the expansion of applications and geographic coverage, will provide better patient outcomes, enhance revenue potential for both physicians and hospitals, and reduce costs to the healthcare system, as further discussed:

- Better Patient Outcomes. We believe that if a physician can see the surgical field, the surgical instruments and the patient’s anatomy all at the same time and in the same “imaging space,” the physician can more efficiently and effectively perform a surgical intervention in the brain. We design our product platforms and advanced software with the objective of enabling physicians to see the target site, guide the surgical instrument to the site, deliver therapy, monitor for adverse events and complications, and confirm the desired results of the procedure. We believe that these capabilities will translate directly into better

outcomes for the patients undergoing the procedures due to improved efficiency and the potential for the reduction of adverse events and side effects, as well as the potential for faster recovery times.

- Enhance Revenue Potential. By providing direct, intra-procedural visualization, we believe our ClearPoint system can reduce the amount of time needed to perform the procedures for which it was designed. As a result, we believe that our ClearPoint system may improve the overall economics of the procedures for both the performing physician and the hospital. We believe that our ClearPoint system may also enable a physician to treat more patients in a given period of time and treat patients who would otherwise not be able to be treated utilizing current surgical techniques.

- Reduce Costs to the Healthcare System. We believe that the use of our products may result in more efficient utilization of healthcare resources and physician time. Our product platforms are designed to work in a hospital's existing MRI or operating suite, which facilitates additional utility for an infrastructure investment that has already been made by the hospital. Further, if patient outcomes and procedure efficiencies are improved through use of our products, we believe that the result will be a reduction in overall healthcare costs.

Industry Background

Magnetic Resonance Imaging

MRI is a widely practiced imaging technique that uses spatially varying magnetic fields to produce images of the human anatomy. Hydrogen nuclei, present in molecules throughout the body, are slightly magnetic. When placed in large external magnetic fields, they can be induced to emit or resonate radio frequency signals. These radio frequency signals are used to construct images of human anatomy, including high resolution images of soft tissue.

MRI has important and advantageous properties that differentiate it from other imaging methods. MRI scans can provide images of any part of the body, in any plane of view, and offer more detailed information than other modalities, including fluoroscopy and computed tomography. Some of the unique advantages of MRI include:

- soft tissue imaging that enables superior tissue visualization and enhanced differentiation between healthy and diseased tissues;
- unlimited orientation and positioning of the imaging plane;
- the ability to directly acquire volumetric (three dimensional) data sets;
- the ability to evaluate both the structure and certain functions of internal organs; and
- no harmful ionizing radiation exposure for either the patient or the physician.

Industry sources estimate that there are approximately 400-500 functional neurosurgery centers worldwide with surgeons on staff with the capability to perform the type of MRI-guided minimally invasive neurosurgical procedure described herein. MRI scanners are available in a number of different configurations and field strengths, which refers to the strength of the magnet used to create the magnetic field. Magnetic field strength is measured in Tesla, or T. The most common field strength for MRI scanners is 1.5T. Higher field strength scanners such as 3T MRI scanners are gaining commercial market adoption, offering faster scanner speeds and even higher resolution images than 1.5T MRI scanners.

Minimally Invasive Surgical Procedures in the MRI Suite and the Operating Room

Over the past few decades, one of the most important trends in medicine has been the replacement of open surgical procedures with minimally-invasive approaches. This has taken place in cardiology, where a coronary artery is stented open or a valve is replaced through a small radial incision under x-ray guidance in an angio-suite, instead of in the operating room. Similarly, during surgery, a laminectomy is performed through a small incision instead of a large one, reducing recovery time. As one follows the trajectory of medical innovation throughout the body, we believe two observations may be made when a procedure moves to a minimally-invasive approach: (i) the number of patients who are eligible for these procedures grows significantly; and (ii) surgeons come to rely on an imaging modality to facilitate live image guidance to see inside the body in place of visualizing anatomy in an open procedure. Stereotactic neurosurgery incorporates imaging to help surgeons see through the patient's skull. The modality that best delivers the level of specificity required to delineate different regions of the brain is MRI. MRI allows surgeons to segment the brain into 22 subcortical structures and helps identify the precise target and avoids vasculature and bleeding. In order to facilitate surgery in a large magnet, metal tools that are typically used in the operating room need to be adapted to the MRI suite. ClearPoint

has reduced the size and changed the composition of stereotactic headframes, onsite navigation systems and drills, manufacturing them using MRI-safe materials such as plastics, ceramics and liquids visible under MRI. During an MRI-based ClearPoint procedure, surgeons use our complete navigation system inside an MRI scanner, defining targets in real-time to decide, guide, treat and confirm the procedure with pinpoint accuracy.

In 2021, we launched the SmartFrame Array Neuro Navigation System and Software which allows us to expand our ClearPoint system placement to the operating room. The SmartFrame Array tower can be detected by commonly used operating room imaging modalities such as optical imaging and intra-operative Computed Tomography ("CT"). We believe that a large percentage of neurosurgeons prefer to perform surgery in a traditional operating room. Thus, ClearPoint's expansion into the operating room, where most stereotactic and functional procedures take place today, represents an important growth opportunity.

Our Current Products and Product Candidates

ClearPoint Neuro Navigation System

General

Initially, the ClearPoint software and system was designed to allow minimally invasive procedures in the brain to be performed in a hospital's existing diagnostic MRI suite or in an inter-operative MRI. Our ClearPoint Array Neuro Navigation System, released in 2021, can be used in an MRI suite or in an operating room setting. Both systems provide guidance for the placement and operation of instruments or devices during the planning and operation of neurosurgical procedures and are intended to be used as an integral part of procedures, such as biopsies and the insertion of catheters, electrodes and fiber lasers, which have traditionally been performed using stereotactic methodologies. When deployed in the MRI, our systems are designed to be used with both 1.5T and 3T MRI scanners. Our research efforts for our ClearPoint system began in 2003. In June 2010, we received 510(k) clearance from the FDA to market our ClearPoint system in the United States for general neurosurgical interventional procedures; in February 2011 and May 2018, we also obtained CE marking approval for our ClearPoint system and SmartFlow cannula, respectively. In February 2020, we received 510(k) clearance for our 5 and 7-French Peel-Away Sheath kits, and in June 2020, we obtained CE marking approval for version 2.0 of our ClearPoint software as well as our Inflexion head fixation frame. In January 2021, we received 510(k) clearance for the SmartFrame Array Neuro Navigation System. Today, ClearPoint systems are in clinical use in diagnostic MRI scanners from the three major manufacturers, Siemens, GE Healthcare and Philips Healthcare, an interventional MRI manufactured by IMRIS, and an OR platform, which is manufactured by Brainlab.

The Need for Minimally Invasive Neurosurgical Interventions

Market Overview

Millions of people suffer from neurological diseases including: movement disorders such as Parkinson's disease, essential tremor and dystonia; psychiatric disorders such as major depression, obsessive compulsive disorder and Alzheimer's disease; and brain tumors, such as glioblastoma multiforme. The first line of therapy for most of these conditions is systemic administration of drugs. For example, to treat the early stages of Parkinson's disease, a patient is often prescribed a medication called levodopa. Drugs such as levodopa can be effective in the earlier stages of the disease; however, as the disease progresses, systemic drugs may become less effective, and potentially ineffective, in treating the patient. Given the shortcomings of systemic drugs like levodopa, the medical community has focused significant resources to find new non-systemic or "local" therapies to treat these patients.

The development activity in and the use of local therapies is growing. For example, drug companies and researchers have identified and are investigating various compounds that are delivered directly into the diseased area of the brain, such as directly into the center of a tumor in the brain. Similarly, the medical community has developed a technique commonly referred to as focal ablation or laser interstitial thermal therapy ("LITT"), under which a special laser probe is inserted into a target area of the brain and a small area of diseased brain tissue is then destroyed by applying laser energy or radio frequency energy through the tip of the special probe. Physicians perform this procedure to treat disorders such as Parkinson's disease, drug-resistant epilepsy and brain tumors. Clinical trials for application of LITT to refractory essential tremor are also underway.

The medical community has also developed another local therapy known as deep brain stimulation ("DBS") and responsive neurostimulation ("RNS"). Both DBS and RNS use mild electrical pulses from an implanted device to stimulate

a small target region in the brain. DBS and RNS systems look and operate much like a cardiac pacemaker, except that instead of sending pulses to the heart, it delivers electrical stimulation through the electrodes placed at a precisely targeted area in the brain. The FDA has approved the use of DBS for the treatment of Parkinson's disease, drug-resistant epilepsy, and refractory essential tremor. For dystonia and severe obsessive-compulsive disorder, DBS is currently only available under Humanitarian Device Exemption status. DBS is also being investigated as a therapy for other neurological disorders, such as paralysis, Huntington's disease, auditory nerve implantation, severe major depression disorder, Alzheimer's disease and stroke rehabilitation. The only commercially available RNS system on the market is approved for use in patients with drug resistant epilepsy and refractory idiopathic generalized epilepsy.

These local therapies, among others, involve insertion of a catheter, probe or electrode into a target region of the brain, typically performed as a minimally invasive procedure. Performing these minimally invasive interventions in the brain presents special challenges, including a need to reach a small therapeutic target often located deep within the brain, with a target that is often an area as small as a few millimeters in diameter. To reach these targets, the physician must act with precision to avoid damaging adjacent areas that are responsible for important neurological functions, such as memory or speech, or penetrating blood vessels which can lead to a life-threatening hemorrhage. The medical community developed stereotactic neurosurgery to address these obstacles. However, despite years of development and clinical experience, conventional stereotactic procedures remain complicated and time-consuming for many neurosurgical interventions and can be extremely difficult on the patient.

U.S. Market Opportunities

We believe there are more than 140,000 potential neurosurgical procedures per year in the United States in which our ClearPoint system could be used as a navigational platform for functional stereotactic neurosurgery in indications currently approved by the FDA including Parkinson's disease, drug resistant epilepsy, refractory essential tremor and brain tumors. The potential procedures include:

- *Electrode Placement* – The current standard of care for the placement of the DBS or RNS electrodes in the operating room requires the patient to be awake during surgery in order to verify proper placement. When DBS or RNS is performed in the MRI suite, our ClearPoint system can provide real-time visualization of the placement, which we believe will drive growth in the number of potential procedures. Three manufacturers have received FDA clearances for DBS systems: Medtronic, Boston Scientific and Abbott Laboratories. All three have products that are indicated for Parkinson's disease, essential tremor, and drug resistant epilepsy. DBS is used to treat the symptoms of Parkinson's Disease, a degenerative condition that affects more than one million people in the United States and 10 million people worldwide. DBS works by stimulating a targeted region of the brain through implanted leads that are powered by a device called an implantable pulse generator. We estimate 120,000 Parkinson's disease and essential tremor patients per year are potential candidates for the implantation of deep brain stimulation electrodes utilizing our ClearPoint system. In addition, patients suffering from drug resistant epilepsy, refractory essential tremor, dystonia, severe obsessive compulsion disorder, severe major depressive disorder, paralysis, Huntington's disease, auditory nerve implantation, Alzheimer's disease and stroke rehabilitation may create additional potential procedure opportunities in the future. The only commercially available RNS system on the market is manufactured by NeuroPace. Their brain-responsive neuromodulation system is currently approved for use in patients with drug resistant epilepsy and refractory idiopathic generalized epilepsy.

- *Brain tumor biopsy* – For smaller, harder to reach brain tumors or those near critical structures (the brain stem or large blood vessels), navigating the surgical field so that the biopsy needle reaches the brain tumor and accurately acquires a representative sample of the tumor is paramount. For small, deep-seated tumors, navigating a device to the exact target is challenging and necessary to avoid the inadvertent destruction of healthy brain tissue. We estimate brain tumor applications represent the potential for approximately 15,000 procedures per year.

- *Gene therapy and drug delivery in the brain* – The blood-brain barrier prevents large-molecule, and nearly all small-molecule, neurotherapeutics from reaching the brain. Several pharmaceutical and biotech companies are developing methods to deliver a wide variety of molecules, genes or proteins to targeted brain tissue or structures that would need to bypass the blood-brain barrier. This may enable the development of treatments for rare single-gene pediatric disorders, such as AADC Deficiency, Friedreich's Ataxia and Angelman Syndrome, as well as adult disorders including Parkinson's disease, drug resistant epilepsy, Huntington's disease, Alzheimer's disease and certain types of cancers, such as Glioblastoma.

The potential addressable market by 2025 for these indications is estimated to be a $7 billion dollar market opportunity of more than 600,000 patients in the United States. If our ClearPoint system and SmartFlow cannula become approved and become the standard approach to local drug delivery in the brain, we believe the impact on our financial performance could be significant. However, these treatments are subject to FDA-mandated clinical trial requirements, which are expensive and time consuming to conduct. Nonetheless, several of our biologics and drug delivery customers are pursuing pre-clinical and clinical trials for which we generate revenue through sale of products including our SmartFlow cannula, as well as a growing list of pre-clinical development services that we began offering in 2021, which include protocol consultation, solutions for pre-clinical study design and toxicology support. We believe the first gene therapy submission will be reviewed by regulatory authorities in 2022, which would increase our ability to predict our potential share on this market opportunity.

Challenges with Conventional Stereotactic Neurosurgical Procedures

Conventional stereotactic neurosurgical procedures are performed in a standard operating room. With this method, a large, metal stereotactic frame is typically fixed to the patient's skull, using skull pins, to provide a fixed and common coordinate system. After the frame is attached to the patient's skull, the patient is then imaged pre-operatively, often using MRI, in order to obtain images showing both the stereotactic frame axes and the anatomical structures of the patient's brain. These pre-operative images are then loaded into a surgical planning workstation. Surgical planning software is used to identify the neurosurgical target for the procedure, as well as to define a trajectory path from the skull, through the brain tissue, and to the target. The planned trajectory and target location are then calculated in relation to the frame axes and then used to guide the surgery.

Because conventional stereotaxy relies on pre-operative images, and not intra-procedural images, errors in the alignment of the pre-operative images with the patient's brain anatomy can, and often do, occur as a consequence of brain shift, variation in patient hydration, registration errors or misalignment of the frame. As a result, the physician often must undertake additional steps to further refine the process of locating the patient's neurosurgical target. These steps may include physiological "mapping" of the brain and require an additional procedural step called microelectrode recording, which is a tedious and time-consuming process during which small probes containing microelectrodes are inserted into the deep brain structures, usually multiple times. As these microelectrode recording probes are passed through brain tissue, they pick up electrical activity. The microelectrode recording system then converts the electrical activity into audible tones. In hearing these various audible tones, a trained neurologist or neurophysiologist can distinguish different regions of the brain. Based on these tones, locations are mapped against the pre-operative images and used to refine and adjust the neurosurgical target as depicted on those pre-operative images. New coordinates are then calculated and a new trajectory is planned. To further confirm locations in the brain, various physiologic responses are induced or monitored with the microelectrodes. These physiological mapping steps require the patient to be awake during the surgery and off medications. Given the procedure's complexity, it is not uncommon for the procedure to last six hours or more.

Our ClearPoint Solutions

We believe the design of our ClearPoint system can significantly simplify how stereotactic neurosurgical interventions are performed. Instead of relying on the indirect guidance of pre-operative imaging, our ClearPoint system is based on a direct approach, during which a physician is guided by real-time, high resolution MRI. The procedure performed with our SmartFrame XG and software version 2.0 is designed to take place in a standard hospital-based MRI scanner or intra-operative MRI. In addition, we believe that the introduction of our Smart Frame Array device will allow the physician to perform the procedure in the operating room as well, thus providing the physician and hospital flexibility.

Our ClearPoint system is an integrated system comprised of hardware components, disposable components and intuitive, menu-driven software.

ClearPoint Hardware. Our hardware components consist primarily of a head fixation frame, computer workstation and in-room monitor. The head fixation frame immobilizes the patient's head during the procedure, and it is designed to optimize the placement of an imaging head coil in proximity to the patient's head. When performed in the MRI suite, the ClearPoint system software is installed on a computer workstation networked with an MRI scanner, for which we use a commercially available laptop computer. The in-room monitor allows the physician to view the display of our ClearPoint system workstation from the scanner room while performing the procedure.

ClearPoint Disposables. The disposable components of our ClearPoint system consist primarily of our SmartFrame trajectory device, a hand controller and related accessories, and our SmartFlow Cannula. Our SmartFrame device is an adjustable trajectory guide that attaches to the patient's skull and holds the targeting cannula. The hand controller attaches to our SmartFrame device, and it is used by the physician to adjust the roll, pitch, and X and Y orientation of the targeting cannula while the patient is in the MRI scanner. The accessories include all other components necessary to facilitate the MRI-guided neurosurgical procedure, such as our SmartGrid patch, which is an MRI-visible marking grid that enables rapid localization of the entry position into the brain, and our customized surgical draping, which creates a sterile field within the MRI scanner. For drug delivery procedures, our SmartFlow cannula, which is an MRI-compatible injection and aspiration cannula, serves as the vehicle for the delivery of the compound.

ClearPoint Software. Our ClearPoint system software guides the physician in surgical planning, device alignment, navigation to the target and procedure monitoring. The software uses image segmentation algorithms to help locate and identify our SmartFrame device and its targeting cannula, as well as the anatomical structures of the brain. The software also performs geometric computations to provide the physician with information regarding the positioning of instruments inserted into the patient's brain relative to the target anatomical structures. At the completion of the procedure, the software generates an automated report that includes the key metrics from the procedure.

ClearPoint Services. We provide consultancy to our pharmaceutical and other medical technology partners for on-site clinical support and training, protocol consultation, customized device development, and other solutions to optimize pre-clinical and clinical workflows. Our expertise is concentrated in benchtop testing, pre-clinical studies, clinical trial support, and over-arching translation from the pre-clinical to the clinical setting to enhance accuracy and precision of drug delivery. We have employees and partners who focus on toxicology, pre-clinical testing, and optimizing surgical routes of administration to improve outcome predictability.

Regulatory Status

Our ClearPoint system 510(k) clearance from the FDA permits us to market and promote our ClearPoint system in the United States for use in general neurosurgical procedures, which includes procedures such as biopsies, catheter insertions, and deep brain stimulation lead and electrode insertions. This is the same general indication for use that applies to other devices that have traditionally been used in the performance of stereotactic neurosurgical procedures. In the EU and Israel, our approval carries a similar indication for use.

Our SmartFlow cannula has received 510(k) clearance for injection of Cytarabine or for removal of cerebrospinal fluid from the ventricles. It has also received CE mark for the injection of approved fluids into the brain. Delivery of other therapeutic agents using our SmartFlow cannula is investigational. The SmartFlow cannula is a disposable device intended for single patient use only and is not intended for implant.

Sales and Marketing

Commercializing our ClearPoint system involves marketing primarily to:

- physicians who care for patients suffering from neurological disorders, including stereotactic or functional neurosurgeons, who perform the neurosurgical procedures, and neurologists, who interact with patients prior to and following surgery and who refer patients for surgery; and
- hospitals involved in the treatment of neurological disorders, including the opinion leaders at these hospitals.

Similar to many fields of medicine, some neurosurgeons elect to focus on a particular specialty within the neurosurgery field. For example, some neurosurgeons focus their practice on spine surgeries, while others focus more on open craniotomy surgeries or on minimally invasive approaches, such as functional neurosurgery. We believe our ClearPoint system may be most applicable to functional neurosurgeons, as well as oncologic neurosurgeons, but we also market our ClearPoint system to other neurosurgeons. We believe that our ClearPoint system represents an attractive platform for a neurosurgical team within a hospital to perform various general neurosurgical procedures.

Our business model for the ClearPoint system is focused on producing high margin revenue from sales of the disposable components. Given that focus on disposable product sales, we sell our reusable components at lower margins in order to secure installations of our system within hospitals. In addition, we may install the ClearPoint reusable components at a hospital, but retain title, either for an agreed-upon period of time while the hospital evaluates and processes the

purchase opportunity, or for a rental fee. Our disposable and reusable ClearPoint products are tightly integrated, which allows us to leverage each new installation of a system to generate recurring sales of our disposable products.

As of March 3, 2022, our sales, clinical support and marketing team consisted of 28 employees. We believe that our current sales, clinical support and marketing team is sufficient for our current needs. However, we expect that our sales and marketing team will expand over time as we add new geographies and enter new segments. We expect the size of our clinical support team to increase with the number and locations of the ClearPoint installed base and the volume of procedures utilizing the ClearPoint system.

Research and Development

Continued innovation through research and development is important to our future success. As of March 3, 2022, our research and development team consisted of 21 employees. We have assembled an experienced team with recognized expertise in the development of medical devices, multi-modal software and advanced MRI technologies, including interventional MRI microcoils, robotics and cannula design, the latter with a focus on gene and cell therapies. We believe that our current research and development team is sufficient for our current needs; however, we may increase the size of our team depending on the progress of our ongoing research and development efforts, and we may continue to enter into co-development arrangements as we deem necessary or potentially advantageous in advancing our principal research and development goals, which are to continue to enhance our ClearPoint hardware and software platforms to allow for faster workflows and flexible procedure locations, and to develop devices to facilitate drug delivery directly to the brain.

Manufacturing and Assembly

Our ClearPoint system and SmartFlow cannula include off-the-shelf components, custom-made components produced to our proprietary specifications by various third parties and components that we assemble in our Irvine, California facility. We use third parties to manufacture certain components to utilize their individual expertise, minimize our capital investment and help control costs. We purchase most custom-made components of our ClearPoint system from single-source suppliers due to quality considerations, lower costs and constraints resulting from regulatory requirements; however, we have identified alternative sources for certain components, and believe additional alternative sources are available, if needed, for other components. Generally, we purchase our components through purchase orders and do not have long-term contracts with most of our suppliers.

Our Irvine, California facility is structured to complete component processing, final assembly, packaging and distribution activities for our ClearPoint system. The assembly process is performed in a controlled environment as required by applicable regulation for medical device assembly. Our operations are subject to extensive regulation by the FDA's Quality System Regulation ("QSR"), which requires that manufacturers have a quality management system for the design and production of medical devices. To the extent we conduct such operations outside the United States, we will be subject to international regulatory requirements.

Our Irvine, California facility is FDA-registered, and we believe it is compliant with the FDA's QSR. We are also certified to ISO standard 13485. We have instituted a quality management system, under which we have established policies and procedures that control and direct our operations with respect to design, procurement, manufacture, inspection, testing, installation, data analysis, training and marketing. We review and internally audit our compliance with these policies and procedures, which provides a means for continued evaluation and improvement. As required by our quality management system, we undertake an assessment and qualification process for each third-party manufacturer or supplier that we use. Typically, our third-party manufacturers and suppliers are certified to ISO standard 9001 and/or 13485. We also periodically perform audit procedures on our key third-party manufacturers and suppliers to monitor their activities for compliance with our quality management system. Our facility and the facilities of the third-party manufacturers and suppliers we use are subject to periodic inspections by regulatory authorities, including the FDA and other governmental agencies.

Customers

At March 3, 2022, approximately 60 hospitals in the U.S., Canada, the EU, and the United Kingdom use the ClearPoint system. A small number of these hospital customers account for a substantial portion of our revenues from sales of ClearPoint products. Our five largest hospital customers accounted for approximately 30% of our functional neurosurgery navigation disposable product revenues in 2021.

At March 3, 2022, we had commercial relationships with approximately 40 biologics and drug delivery companies who are either evaluating or using our SmartFlow cannula, depending on each such company's stage of development, which ranges from preclinical research to late-stage regulatory trials. One of these companies, a related party who is a significant stockholder with a Board representative, accounted for approximately 43% of our biologics and drug delivery revenues in 2021.

Intellectual Property

We believe that in order to maintain a competitive advantage in the marketplace, we must develop and maintain the proprietary aspects of our technologies. We rely on a combination of patent, trademark, trade secret, copyright and other intellectual property rights and measures to protect our intellectual property.

Our patent portfolio includes patents and patent applications that we own or that we license from others. We seek patent protection in the United States and internationally for our products and technologies where and when we believe it is appropriate. United States patents are granted generally for a term of 20 years from the earliest effective priority date of the patent application. The actual protection afforded by a foreign patent, which can vary from country to country, depends on the type of patent, the scope of its claims and the availability of legal remedies in the country.

We also rely on other forms of intellectual property rights and measures, including trade secrets and nondisclosure agreements, to maintain and protect proprietary aspects of our products and technologies. We require our employees and consultants to execute confidentiality agreements in connection with their employment or consulting relationships with us. We also require our employees and consultants to disclose and assign to us all inventions conceived during the term of their employment or engagement which relate to our business.

Patents and Patent Applications

We have a significant patent portfolio in the field of MRI-guided interventions. As of March 3, 2022, we own or license over 75 issued United States patents. Our owned, issued patents expire at various dates beginning in 2023. Some of our patents and patent applications are subject to licensing and cross-licensing arrangements in place with third parties.

Certain License and Collaborative Arrangements

Philips

During 2020, we entered into a worldwide license and research agreement with Philips, under which Philips has licensed us to use the technology underlying its Philips Brain Model in our ClearPoint Maestro Brain Model ("Maestro"), the first generation of which we expect to be cleared for a launch in 2022. We believe that Maestro will have use across all our product lines through automatic pathway and trajectory planning, and confirmation of device placement, while identifying eloquent structures of the brain so as to avoid crucial anatomy. In consideration of the foregoing, we paid a fee upon execution of the agreement and are committed to pay royalties based on (a) sales of systems, and (b) procedures in which the licensed technology is used. In early 2022, we expanded our collaboration with Philips to include additional technology to allow use of the Philips Brain Model with Computed Tomography (CT) imaging.

Blackrock

During 2020, we entered into a multi-product development agreement and an option agreement with Blackrock. The objective of these agreements is the incorporation of Blackrock's sensing technologies into certain of our product lines starting with the Microelectric Recording platform and to be followed by offerings including such products as "smart" biopsy needles and other implantable neural electrodes. We believe that the combination of Blackrock's expertise in neuro-electrodes, combined with our ClearPoint navigation technology, will allow us to expand our product offering beyond the MRI suite and into the operating room. In 2021, we entered into a joint development agreement with Blackrock to develop an automated surgical solution, leveraging our technology platform, for implanting Blackrock's brain computer interfaces ("BCIs") into patients with a wide range of neurological disorders.

CLS

In October 2018, and as amended in August 2020, we entered into a license and collaboration agreement, and distribution agreements, with CLS that provides us the exclusive right to distribute and sell CLS's portfolio of products

when used with MRI guidance, including its Tranberg® product line for high precision ablation, in the U.S. and to collaborate with CLS on the development and commercialization of new products in the neurosurgical field.

UCSF

In 2013, we entered into a license agreement with UCSF that provides for our use of design features developed by UCSF, which we incorporated into our SmartFlow cannula, for which we are committed to pay royalties based on our sales of the SmartFlow cannula.

Software License Arrangements

In connection with the development of our software products, which includes ClearPoint Software, ClearPoint Array Software, and ClearPoint Maestro Brain Model Software, we entered into six agreements under which we receive worldwide, non-exclusive licenses to software code related to certain functional elements of these software products, and for which we are committed to pay royalties for each copy of software product sold, or in certain cases, loaned by us to end-users. For one product, the ClearPoint Maestro Brain Model Software, we committed to pay a fee upon execution of the agreement and are committed to pay royalties based on (a) sales of systems, and (b) procedures in which the licensed technology is used.

Competition

General

The medical device industry is highly competitive, subject to rapid technological change and significantly affected by new product introductions and market activities of other participants. Therefore, our currently marketed products are, and future products we commercialize will be, subject to competition.

ClearPoint System

Currently, we are aware of two companies, Monteris Medical, Inc. and Medtronic plc, which offer devices for laser ablation under direct MRI guidance. In addition, companies such as Brainlab, Medtronic plc, Elekta AB, FHC Inc., Integra Life Sciences and Neurologica Corporation, a subsidiary of Samsung Electronics Co., offer devices and systems for use in conventional stereotactic neurosurgical procedures, such as surgical navigation workstations, frame-based and frameless stereotactic systems, portable computer tomography scanners and computer-controlled guidance systems, and these devices and systems are competitive with our ClearPoint system. Also, Zimmer Biomet Holdings, Inc.'s ROSA® robot is an operating room alternative to the ClearPoint system. Additionally, we could also face competition from other medical device, biotechnology and pharmaceutical companies that have the technology, experience and capital resources to develop alternative therapy methods, including MRI-guided technologies. Many of our competitors have substantially greater financial, manufacturing, marketing and technical resources than we have.

Regulatory Requirements of the United States Food and Drug Administration

Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation in the United States and other countries. Most notably, all of our products sold in the United States are subject to regulation as medical devices under the federal Food, Drug, and Cosmetic Act ("FDCA"), as implemented and enforced by the FDA. The FDA regulates the following activities that we perform or that are performed on our behalf, to ensure that the medical devices we manufacture, promote and distribute domestically or export internationally are safe and effective for their intended uses:

- product design, preclinical and clinical development and manufacture;
- product premarket clearance and approval;
- product safety, testing, labeling and storage;
- record-keeping procedures;
- product marketing, sales and distribution; and
- post-marketing surveillance, complaint handling, medical device reporting, reporting of deaths, serious injuries or device malfunctions and repair or recall of products.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either premarket notification, or 510(k) clearance, authorization through the *de novo* classification process, or approval of a PMA from the FDA. The FDA classifies medical devices into one of three classes. Class I devices, considered to have the lowest risk, are those for which safety and effectiveness can be assured by adherence to the FDA's general regulatory controls for medical devices, which include compliance with the applicable portions of the FDA's QSR, facility registration and product listing, medical device reporting (which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur), reports of corrections and removals (which require manufacturers to report recalls or removals and field corrections to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA) and appropriate, truthful and non-misleading labeling (General Controls). Class II devices are subject to the FDA's General Controls, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device (Special Controls). Manufacturers of most Class II and some Class I devices are required to submit to the FDA and obtain clearance for a premarket notification under Section 510(k) of the FDCA prior to commercially distributing the device. This process is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or implantable devices, or devices that are not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA unless they can be reclassified into Class I or II via the *de novo* classification process.

510(k) Clearance Pathway

When a 510(k) clearance is required, we will be required to submit a 510(k) premarket notification demonstrating that our proposed device is substantially equivalent to a legally marketed device, referred to as the "predicate device." A predicate device may be a previously 510(k) cleared device or a Class III device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for PMA applications, or a product previously placed in Class II or Class I through the *de novo* classification process. The manufacturer must show that the proposed device has the same intended use as the predicate device, and it either has the same technological characteristics, or it is shown to be equally safe and effective and does not raise different questions of safety and effectiveness as compared to the predicate device.

The FDA has a user fee goal to apply no more than 90 calendar review days to 510(k) submissions. During the process, the FDA may issue an Additional Information request, which stops the clock. The applicant has 180 days to respond. Therefore, the total review time could be up to 270 days or more.

Any modification to a 510(k)-cleared device that would constitute a major change in its intended use, or any change that could significantly affect the safety or effectiveness of the device, requires a new 510(k) clearance and may even, in some circumstances, require a *de novo* authorization or PMA, if the change raises complex or novel scientific issues or the product has a new intended use. The FDA requires every manufacturer to make the determination regarding the need for a new 510(k) submission in the first instance, but the FDA may review any manufacturer's decision. If the FDA were to disagree with any of our determinations that changes to a device did not require a new 510(k) submission, it could require us to cease marketing and distribution and/or recall the modified device until 510(k) clearance, *de novo* authorization, or PMA approval is obtained. If the FDA requires us to seek 510(k) clearance, *de novo* authorization, or PMA approval for any modifications to a device, we may be required to cease marketing and/or recall the modified device, if already in distribution, until 510(k) clearance, *de novo* authorization, or PMA approval is obtained and we could be subject to significant regulatory fines or penalties.

De Novo Classification

Devices of a new type that the FDA has not previously classified based on risk are automatically classified into Class III regardless of the level of risk they pose. To avoid requiring PMA review of novel low- to moderate-risk devices classified in Class III by operation of law, Congress enacted a provision that allows the FDA to classify a novel low- to moderate-risk device into Class I or II in the absence of a predicate device that would support 510(k) clearance. The FDA evaluates the safety and effectiveness of devices submitted for review under the *de novo* pathway and devices determined

to be Class II through this pathway can serve as predicate devices for future 510(k) applicants. The *de novo* pathway can require clinical data.

The FDA has a user fee goal to review a *de novo* request in 150 calendar review days. During the process, the FDA may issue an Additional Information request, which stops the clock. The applicant has 180 days to respond. Therefore, the total review time could be as long as 330 days or more.

PMA Approval Pathway

A PMA must be submitted to the FDA if the device cannot be cleared through the 510(k) process or classified through the *de novo* process or is not otherwise exempt from the FDA's premarket clearance and approval requirements. A PMA must generally be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. During the review period, the FDA will typically request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of our or our third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the QSR. Once a PMA is approved, the FDA may require that certain conditions of approval be met, such as conducting a post market clinical trial.

The FDA has a user fee goal to review a PMA in 180 calendar review days, if the submission does not require advisory committee input, or 320 review days if the submission does require advisory committee input. During the process, the FDA may issue a major deficiency letter, which stops the review clock. The applicant has up to 180 days to respond. Therefore, the total review time could be up to 360 days or more, if the submission does not require advisory committee input, or 500 days or more if the submission does require advisory committee input.

If the FDA's evaluation of the PMA application is favorable, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the manufacturer. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval and/or placement of restrictions on the sale of the device until the conditions are satisfied.

New PMAs or PMA supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. We could seek to add new indications for use of our existing products that require the approval of a PMA, although we do not have any current plans to do so.

Clinical Trials

Clinical trials are generally required to support a PMA application and also may be required for 510(k) clearance and *de novo* authorization. Such trials generally require an application for an investigational device exemption, or IDE, which is approved in advance by the FDA for a specified number of patients and study sites, unless the product is exempt from the IDE requirements or deemed a non-significant risk device eligible for more abbreviated IDE requirements. 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 application must also include a description of product manufacturing and controls, and a proposed clinical trial protocol. During the study, the sponsor must comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting, and record keeping. The investigators must obtain patient informed consent, follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with reporting and record keeping requirements. Prior to

granting PMA approval, the FDA typically inspects the records relating to the conduct of the study and the clinical data supporting the PMA application for compliance with IDE requirements.

Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard intended to protect the rights and health of patients and to define the roles of clinical trial sponsors, investigators, and monitors; and (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Clinical trials are typically conducted at geographically diverse clinical trial sites and are designed to permit the FDA to evaluate the overall benefit-risk relationship of the device and to provide adequate information for the labeling of the device when considering whether a device satisfies the statutory standard for commercialization.

Clinical trials must be conducted under the oversight of an institutional review board, or IRB, for the relevant clinical trial sites. We, the FDA, or the IRB could suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and effectiveness of the device or may otherwise not be sufficient to obtain FDA clearance, authorization or approval to market the product in the United States. Similarly, in Europe, the clinical study must be approved by a local ethics committee and in some cases, including studies with high-risk devices, by the ministry of health in the applicable country.

Although the QSR does not fully apply to investigational devices, the requirement for controls on design and development does apply. The sponsor also must manufacture the investigational device in conformity with the quality controls described in the IDE application and any conditions of IDE approval that the FDA may impose with respect to manufacturing.

Pervasive and Continuing Regulation

After a device is placed on the market, numerous regulatory requirements continue to apply. In addition to the requirements below, the Medical Device Reporting regulations require that we report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Additional regulatory requirements include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design, manufacturing, and distribution process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance, authorization, or approval of product modifications;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply, when necessary, to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- regulations pertaining to voluntary recalls; and
- notices of corrections or removals.

As a medical device manufacturer, we are subject to announced and unannounced inspections by the FDA to determine our compliance with FDA's QSR and other regulations. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with the QSR and other regulations. We believe that we are in compliance with QSR and other regulations.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the United States Federal Trade Commission, or FTC, and by state regulatory and enforcement authorities. Promotional activities for FDA-regulated products of other companies have been the subject of enforcement actions brought under healthcare reimbursement laws and consumer protection statutes. Furthermore, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. In addition, we are required to meet

regulatory requirements in countries outside the United States, which can change rapidly with relatively short notice. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved or uncleared use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

Failure by us or by our third-party manufacturers and suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities, which may result in sanctions including, but not limited to:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our marketed products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) clearance, *de novo* authorization or PMA approvals of new products or modified products;
- rescinding 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approval for our marketed products; or
- criminal prosecution.

International Marketing Approvals

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ.

The EU has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Each EU member state has implemented legislation applying these directives and standards at a national level. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the EU with respect to medical devices. Devices that comply with the requirements of the laws of the relevant member state applying the applicable EU directive are entitled to bear a CE mark and, accordingly, can be distributed throughout the member states of the EU as well as in other countries, such as Switzerland and Israel, that have mutual recognition agreements with the EU or have adopted the EU's regulatory standards.

The method of assessing conformity with applicable regulatory requirements varies depending on the classification of the medical device, which may be Class I, Class IIa, Class IIb or Class III. Normally, the method involves a combination of self-assessment by the manufacturer of the safety and performance of the device, and a third-party assessment by a Notified Body, usually of the design of the device and of the manufacturer's quality system. A Notified Body is a private commercial entity that is designated by the national government of a member state as being competent to make independent judgments about whether a device complies with applicable regulatory requirements. An assessment by a Notified Body in one country with the EU is required in order for a manufacturer to commercially distribute the device throughout the EU. In addition, compliance with ISO 13485 issued by the International Organization for Standardization, among other standards, establishes the presumption of conformity with the essential requirements for CE marking. Certification to the ISO 13485 standard demonstrates the presence of a quality management system that can be used by a manufacturer for design and development, production, installation and servicing of medical devices and the design, development and provision of related services.

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

The Medical Devices Regulation went into effect as of May 26, 2021. The new regulations:

- Strengthen the rules on placing devices on the market and reinforce surveillance once they are available;

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

Healthcare Laws and Regulations

Third-Party Reimbursement

In the United States and elsewhere, healthcare providers that perform surgical procedures using medical devices such as ours generally rely on third-party payors, including governmental payors such as Medicare and Medicaid and private payors, to cover and reimburse all or part of the cost of the products. Consequently, sales of medical devices are dependent in part on the availability of reimbursement to the customer from third-party payors. The manner in which reimbursement is sought and obtained varies based upon the type of payor involved and the setting in which the product is furnished and utilized. In general, third-party payors will provide coverage and reimbursement for medically reasonable and necessary procedures and tests that utilize medical devices. Third-party payors may provide separate payments for implanted or disposable devices themselves, although no such separate payments are currently provided for our ClearPoint disposable products. Most third-party payors will not pay separately for capital equipment. Instead, payment for the cost of using the capital equipment is considered to be covered as part of payments received for performing the procedure. In determining payment rates, third-party payors are increasingly scrutinizing the prices charged for medical products and services in comparison to other therapies.

In many foreign markets, including the countries in the EU, pricing of medical devices is subject to government reimbursement. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to limit payments by governmental payors for medical devices, and the procedures in which medical devices are used.

Medicare and Medicaid

The Medicare program is a federal health benefit program administered by the Centers for Medicare and Medicaid Services, or CMS, that covers and pays for certain medical care items and services for eligible elderly and certain disabled individuals, and individuals with end stage renal disease. The Medicaid program is a federal-state partnership under which states receive matching federal payments to fund healthcare services for the poor. Because some private commercial health insurers and some state Medicaid programs may follow the coverage and payment policies for Medicare, Medicare's coverage and payment policies are significant to our business.

Medicare coverage for the procedures in which our ClearPoint products are used currently exists in the hospital inpatient setting, which falls under Part A of the Medicare program. Under Medicare Part A, Medicare reimburses acute care hospitals a prospectively determined payment amount for beneficiaries receiving covered inpatient services in an acute care hospital. This method of payment is known as the prospective payment system, or PPS. Under PPS, the prospective payment for a patient's stay in an acute care hospital is determined by the patient's condition and other patient data and procedures performed during the inpatient stay using a classification system known as Medicare Severity Diagnosis Related Groups, or MS-DRGs. Payments also are adjusted to reflect other factors, such as regional variations in labor costs and indirect medical education expenses. Medicare pays a fixed amount to the hospital based on the MS-DRG into which the patient's stay is classified, regardless of the actual cost to the hospital of furnishing the procedures, items and services that the patient's condition requires. Accordingly, acute care hospitals generally do not receive direct Medicare reimbursement under PPS for the specific costs incurred in purchasing medical devices. Rather, reimbursement for these costs is deemed to be included within the MS-DRG-based payments made to hospitals for the services furnished to Medicare-eligible inpatients in which the devices are utilized. For cases involving unusually high costs, a hospital may receive additional "outlier" payments above the pre-determined amount. In addition, there is a mechanism by which new technology services can apply to Medicare for additional payments above the pre-determined amount, although such requests have not been granted frequently.

Because PPS payments are based on predetermined rates and may be less than a hospital's actual costs in furnishing care, and due to payment reforms enacted relatively recently, acute care hospitals have incentives to lower their inpatient operating costs by utilizing products, devices and supplies that will reduce the length of inpatient stays, decrease labor or otherwise lower their costs. For each MS-DRG, a relative weight is calculated representing the average resources required to care for cases grouped in that particular MS-DRG relative to the average resources used to treat cases in all MS-DRGs. MS-DRG relative weights are recalculated every year to reflect changes in technology and medical practice in a budget neutral manner. Under the MS-DRG payment system, there can be significant delays in obtaining adequate reimbursement amounts for hospitals for new technologies such that reimbursement may be insufficient to permit broad acceptance by hospitals.

In addition to payments to hospitals for procedures using our technology, Medicare makes separate payments to physicians for their professional services. The American Medical Association, or AMA, has developed a coding system known as the Current Procedural Terminology, or CPT, codes, which has been adopted by the Medicare program to describe and develop payment amounts for certain physician services.

The Medicare physician fee schedule uses CPT codes (and other codes) as part of the determination of allowable payment amounts to physicians. In determining appropriate payment amounts for surgeons, CMS receives guidance from the AMA regarding the relative technical skill level, level of resources used, and complexity of a new surgical procedure. Generally, the designation of a new procedure code for a new procedure using a new product does not occur until after FDA clearance or approval of the product used in the procedure. Codes are assigned by either the AMA (for CPT codes) or CMS (for Medicare-specific codes), and new codes usually become effective on January 1st of each year.

One result of the current Medicare payment system, which is also utilized by most non-governmental third-party payors, is that a patient's treating physician orders a particular service and the hospital (or other facility in which the procedure is performed) bears the cost of delivery of the service. Hospitals have limited ability to align their financial interests with that of the treating physician because Medicare law generally prohibits hospitals from paying physicians to assist in controlling the costs of hospital services, including paying physicians to limit or reduce services to Medicare beneficiaries even if such services are medically unnecessary. As a result, hospitals have traditionally stocked supplies and products requested by physicians and have had limited ability to restrict physicians' choice of products and services.

Since the enactment of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, together, the Affordable Care Act, there have been a number of legal challenges as well as other legislative and regulatory changes to the healthcare system that could limit the acceptance and availability of our products, which would have an adverse effect on our financial results and business. The full effects of the Affordable Care Act may be unknown until all outstanding legal issues are resolved, the statutory provisions are fully implemented, and CMS, the FDA, and other federal and state agencies issue final applicable regulations or guidance. These developments could result in increased coordination between hospitals and physicians and alignment of financial incentives between hospitals and physicians to control hospital costs. Such payment reform efforts and increased coordination among hospitals and physicians may lead to voluntary reductions in the array of choices currently available to physicians with respect to diagnostic services, medical supplies and equipment, which could result in hospitals reducing the overall number of vendors from which they purchase supplies, equipment and products. The Affordable Care Act remains subject to potential legal and constitutional challenges in the United States Supreme Court.

On April 16, 2015, President Obama signed into law, the Medicare Access and CHIP Reauthorization Act, or the Medicare Access Act, which removed the sustainable growth rate or SGR, methodology applicable to fees for physician services. The Medicare Access Act replaced the previous fee-for-service payment system with a more value-based system. As a result, reimbursements from the Medicare program may be reduced. As noted above, failure by hospitals and physicians to receive an amount that they consider to be adequate reimbursement for procedures in which our products are used may deter them from purchasing or using our products and will limit our sales growth.

Commercial Insurers

In addition to the Medicare program, many private payors look to CMS policies as a guideline in setting their coverage policies and payment amounts. The current coverage policies of these private payors may differ from the Medicare program, and the payment rates they make may be higher, lower, or the same as the Medicare program. If CMS or other agencies decrease or limit reimbursement payments for hospitals and physicians, this may affect coverage and reimbursement determinations by many private payors. Additionally, some private payors do not follow the Medicare

guidelines, and those payors may reimburse only a portion of the costs associated with the use of our products, or none at all.

Fraud and Abuse Laws

Because of the significant federal funding involved in Medicare and Medicaid, Congress and the states have enacted, and actively enforce a number of laws whose purpose is to eliminate fraud and abuse in federal healthcare programs. Our business is subject to compliance with these laws.

Anti-Kickback Laws

In the United States, there are federal and state anti-kickback laws that generally prohibit the payment or receipt of kickbacks, bribes or other remuneration in exchange for the referral of patients or other health-related business. The United States federal healthcare programs' Anti-Kickback Statute makes it unlawful for individuals or entities to knowingly and willfully solicit, offer, receive or pay any kickback, bribe or other remuneration, directly or indirectly, in exchange for or to induce the purchase, lease or order, or arranging for or recommending purchasing, leasing, or ordering, any good, facility, service, or item for which payment may be made in whole or in part under a federal healthcare program such as Medicare or Medicaid. The Anti-Kickback Statute covers "any remuneration," which has been broadly interpreted to include anything of value, including for example gifts, certain discounts, the furnishing of free supplies, equipment or services, credit arrangements, payments of cash and waivers of payments. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the arrangement can be found to violate the statute. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. In addition, several courts have permitted kickback cases brought under the federal False Claims Act to proceed, as discussed in more detail below.

Because the Anti-Kickback Statute is broadly written and encompasses many harmless or efficient arrangements, Congress authorized the Office of Inspector General of the United States Department of Health and Human Services, or OIG, to issue a series of regulations, known as "safe harbors." For example, there are regulatory safe harbors for payments to bona fide employees, properly reported discounts, and payments for certain investment interests. Although an arrangement that fits into one or more of these exceptions or safe harbors is immune from prosecution, arrangements that do not fit squarely within an exception or safe harbor do not necessarily violate the statute. The failure of a transaction or arrangement to fit precisely within one or more of the exceptions or safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that arguably implicate the Anti-Kickback Statute but do not fully satisfy all the elements of an exception or safe harbor may be subject to increased scrutiny by government enforcement authorities such as the OIG. The Affordable Care Act increased the investigatory authority of the OIG, clarified that Anti-Kickback Statute claims can be brought under the federal civil False Claims Act, and provided for enhanced civil monetary penalties and expanded permissible exclusion authority.

Many states have laws that implicate anti-kickback restrictions similar to the federal Anti-Kickback Statute. Some of these state prohibitions apply regardless of whether federal healthcare program business is involved, such as for self-pay or private pay patients.

Government officials have focused their enforcement efforts on marketing of healthcare services and products, among other activities, and recently have brought cases against companies, and certain sales, marketing and executive personnel, for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business.

Federal Civil False Claims Act and State False Claims Laws

The federal civil False Claims Act imposes liability on any person or entity that, among other things, knowingly and willfully presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program, including Medicare and Medicaid. The "qui tam" or "whistleblower" 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. Medical device companies, like us, can be held liable under false claims laws, even if they do not submit claims to the government where they are deemed to have caused

submission of false claims by, among other things, providing incorrect coding or billing advice about their products to customers that file claims, or by engaging in kickback arrangements with customers that file claims.

The False Claims Act also has been used to assert liability on the basis of misrepresentations with respect to the services rendered and in connection with alleged off-label promotion of products. Our activities relating to the manner in which we sell our products and document our prices such as the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our products, and the sale and marketing of our products, may be subject to scrutiny under these laws.

The Affordable Care Act may increase the number of cases asserting civil False Claims Act violations since it removes a significant defense to such claims and clarifies that a violation of the Anti-Kickback Statute and the retention of a federal healthcare program overpayment are both actionable under the civil False Claims Act.

When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. There are many potential bases for liability under the False Claims Act. A number of states have enacted false claim laws analogous to the federal civil False Claims Act and many of these state laws apply where a claim is submitted to any state or private third-party payor.

HIPAA Fraud and Other Regulations

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, created a class of federal crimes known as the "federal healthcare offenses," including 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 or artifice to defraud any healthcare benefit program, or to obtain by means of false of fraudulent pretenses, any money under the control of 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 Affordable Care Act also provides for civil monetary penalties for knowingly participating in certain federal healthcare offenses and enhances sentences under the Federal Sentencing Guidelines for such offenses. The HIPAA false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines and/or imprisonment. Entities that are found to have aided or abetted in a violation of the HIPAA federal healthcare offenses are deemed by statute to have committed the offense and are punishable as a principal.

We are also subject to the United States Foreign Corrupt Practices Act and similar anti-bribery laws applicable in non-United States jurisdictions that generally prohibit companies and their intermediaries from making improper payments to non-United States government officials for the purpose of obtaining or retaining business. Because of the predominance of government sponsored healthcare systems around the world, we expect that many of our customer relationships outside of the United States will be with governmental entities and therefore subject to such anti-bribery laws.

HIPAA and Other Privacy & Security Laws

As a part of HIPAA, Congress enacted the Administrative Simplification provisions, which are designed to require the establishment of uniform standards governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of individually identifiable health information maintained or transmitted by healthcare providers, health plans and healthcare clearinghouses, which are referred to as "covered entities." Several regulations have been promulgated under HIPAA, including: the Standards for Privacy of Individually Identifiable Health Information, or the Privacy Rule, which restricts the use and disclosure of certain individually identifiable health information; the Standards for Electronic Transactions, which establishes standards for common healthcare transactions, such as claims information, plan eligibility, payment information and the use of electronic signatures; and the Security Standards for the Protection of Electronic Protected Health Information, or the Security Rule, which requires covered entities to implement and maintain certain security measures to safeguard certain electronic health information. Although we do not believe we are a covered entity and therefore are not currently subject to these standards directly, we expect that our customers generally will be covered entities and may ask us to contractually comply with certain aspects of these standards by entering into confidentiality agreement or, when appropriate, business associate agreements. While the government intended this legislation to reduce administrative expenses and burdens for the healthcare industry, our compliance with certain provisions of these standards could entail significant costs for us.

The Health Information Technology for Economic and Clinical Health Act, or HITECH, which was enacted in February 2009, strengthened and expanded the HIPAA Privacy and Security Rules and the restrictions on use and disclosure of patient identifiable health information. HITECH also fundamentally changed a business associate's obligations by imposing a number of Privacy Rule requirements and a majority of Security Rule provisions directly on business associates that were previously only directly applicable to covered entities. HITECH includes, but is not limited to, prohibitions on exchanging patient identifiable health information for remuneration (directly or indirectly), restrictions on marketing to individuals and obligations to agree to provide individuals an accounting of virtually all disclosures of their health information. Moreover, HITECH requires covered entities to report any unauthorized use or disclosure of patient identifiable health information that compromises the security or privacy of the information, known as a breach, to the affected individuals, the United States Department of Health and Human Services, or HHS, and depending on the size of any such breach, the media for the affected market. Business associates are similarly required to notify covered entities of a breach.

HITECH has increased civil penalty amounts for violations of HIPAA by either covered entities or business associates up to an annual maximum of $1.5 million for each uncorrected violation based on willful neglect. HITECH requires HHS to conduct periodic audits to confirm compliance and to investigate any violation that involves willful neglect. Additionally, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations of HIPAA Privacy and Security Rules that threaten the privacy of state residents.

In addition to federal regulations issued under HIPAA, some states have enacted privacy and security statutes or regulations that, in some cases, are more stringent than those issued under HIPAA. Further, the majority of states have enacted state data breach laws, which also require notification of certain alleged breaches of the privacy or security of personal information.

Federal and state consumer protection laws are being applied increasingly by the FTC and state attorneys general to regulate the collection, use, storage and disclosure of personal or patient information, through websites or otherwise, and to regulate the presentation of web site content. Courts may also adopt the standards for fair information practices promulgated by the FTC, which concern consumer notice, choice, security and access. Numerous other countries have or are developing laws governing the collection, use, disclosure and transmission of personal or patient information.

HIPAA, as well as other federal and state laws, will apply to our receipt of patient identifiable health information in connection with any clinical trials we conduct. In addition, we collaborate with other individuals and entities in conducting research and all involved parties must comply with applicable laws. Therefore, the compliance of the physicians, hospitals or other providers or entities with which we collaborate affects our company.

Human Capital Resources

As of March 3, 2022, we had 80 full time employees, of whom 21 were engaged primarily in research and development, 22 in manufacturing and quality assurance, 28 in sales, clinical support and marketing, and 9 in administrative and finance functions. None of our employees are covered by a collective bargaining agreement, and we consider our relationship with our employees to be good.

We recruit employees with the skills and training relevant to functional responsibilities. As a small, innovative company focused on the development and commercialization of technology, we believe that cultural fit and energy are important considerations. We assess the likelihood that a particular candidate will contribute to our overall goals, and beyond their specifically assigned tasks. Depending on the position, our recruitment reach can be national as well as local. We aim to provide market-based compensation and to retain our employees. New employees are provided industry-relevant compliance training and are introduced to our Code of Business Conduct and Ethics. During 2021, as we worked to manage through the effects of the COVID-19 pandemic, all employees based in our facilities were retained at full salary and, where possible, were provided the option of working remotely or at such facilities with appropriate safeguards.

ITEM 1A. RISK FACTORS

Any investment in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below and all information contained in this Annual Report before you decide whether to purchase our common stock. If any of the following risks or uncertainties actually occurs, our business, financial condition, results of operations and prospects would likely suffer, possibly materially. In addition, the trading price of our common stock could decline due to any of these risks or uncertainties, and you may lose part or all of your investment.

Risks Related to Our Business and Industry

COVID-19 could adversely impact our business.

In March 2020, the World Health Organization characterized the spread of a novel strain of coronavirus ("COVID-19") as a global pandemic, and the President of the United States later proclaimed that the COVID-19 outbreak in the United States constituted a national emergency. Extraordinary actions were taken by federal, state and local governmental authorities to combat the spread of COVID-19, including issuances of "stay-at-home" directives and similar mandates that substantially restricted daily activities and for many businesses curtailed or ceased normal operations. These measures led to reduced economic activity, including the postponement or cancellation of elective surgical procedures, which historically have represented approximately 80% of the number of surgical procedures using our ClearPoint system. Although economic activity is returning to normalized levels, new variants of COVID-19, such as Delta and Omicron, continue to spread in the United States and across the globe. The ultimate impact of the COVID-19 pandemic cannot be predicted at this time, and could depend on numerous factors, including vaccination rates among the population, the effectiveness of vaccines against different variants and the response by governmental bodies and regulators. We are unable to determine the timing and extent to which the vaccination process will affect the progression of the virus; the timing, adoption or viability of periodic resumption, if any, of elective procedures; and the resulting length of time that the COVID-19 pandemic will adversely affect our product revenues.

Furthermore, the recessionary conditions on the global economy caused by the COVID-19 pandemic could have a material adverse effect on our business. Although most segments of the United States economy have reopened, the effects of the COVID-19 pandemic remain intense in many areas of the country, and many public health experts continue to anticipate future surges of COVID-19 due to new variants. Accordingly, reinstatement of directives and mandates requiring businesses to again curtail or cease normal operations, including the postponement or cancellation of elective surgeries, remains a possibility. The continuing uncertainty as to whether the federal government will address the resulting fiscal condition in both the near- and long-term with measures such as additional fiscal stimulus, as well as other geopolitical issues relating to the global economic slowdown, has increased domestic and global instability. Additionally, global economic and supply chain disruptions, labor shortages, which may affect our ability to retain and attract new talent, and inflationary conditions caused by the COVID-19 pandemic could have a material adverse effect on the Company's business. The rapid development and fluidity of the situation precludes any prediction as to the ultimate impact COVID-19 will have on our business, financial condition, results of operation and cash flows, which will depend largely on future developments directly or indirectly relating to the duration and scope of the COVID-19 outbreak in the United States.

Our ClearPoint system may not achieve broad market adoption.

To date, a substantial majority of the sales of our ClearPoint System have been derived from a limited number of hospitals.Our future growth depends on our ability to increase physician and patient awareness of our products, and on the willingness of hospitals to adopt our products for their neurosurgical procedures. Our ClearPoint system may not gain broad market adoption unless we continue to convince physicians, hospitals and patients of its benefits. Moreover, even if physicians and hospitals understand the benefits of our ClearPoint system, they still may elect not to use our ClearPoint system for a variety of reasons, such as:

- the shift in location of the procedure from the operating room to the MRI suite;
- demand for the MRI suite within the hospital, which may result in limited or no MRI scanner availability for procedures in which our ClearPoint system would be used;
- the familiarity of the established physician with other devices and surgical approaches;
- lack of exposure to the ClearPoint system in the fellowship training period where preferences for surgical methods are formed;
- the physician's perception that there are insufficient benefits of our ClearPoint system relative to those other devices and surgical approaches;
- budgetary constraints with respect to the purchase of our ClearPoint system hardware and software;
- hospital infection control procedures;
- the price of our ClearPoint system disposable products, which may be higher than devices used with other surgical approaches; and
- the physician's perception that there is a lack of clinical data on the use of our ClearPoint system.

Our ability to execute our growth strategy and become profitable depends upon the adoption by physicians and hospitals of the ClearPoint system for use in neurosurgical procedures. Historically, a substantial portion of our revenue is generated from sales of the disposable products utilized with our ClearPoint system, and we are therefore highly dependent on growing the installed base of the ClearPoint system for our success. We cannot provide assurance that our ClearPoint system will achieve broad market acceptance among hospitals, physicians, or patients. Any failure of the ClearPoint system to achieve meaningful market acceptance and penetration will harm our future prospects and have a material adverse effect on our business, financial condition and results of operations.

A portion of our future business growth is dependent upon marketing and selling our ClearPoint system, and other new products, in the operating room, and if we are unable to expand, manage and maintain our marketing and sales capabilities in this environment, we may be unable to generate significant growth in our product revenues.

We started selling our ClearPoint system in August 2010, and to date, sales of the ClearPoint system have been focused on its use for neurosurgical procedures in the MRI suite. In 2021, we launched the SmartFrame Array Neuro Navigation System and Software, which allows for operating room placement of our technology. We have relatively limited experience marketing and selling our ClearPoint system for use with neurosurgical procedures in the operating room. If our team fails to adequately promote, market and sell the ClearPoint system, and other new products that we may develop in the future, in this new environment, our sales could suffer.

Additionally, our future revenue and operating results will depend on our ability to manage the anticipated growth of our business. To achieve our business objectives, we must continue to grow. However, continued growth presents numerous challenges, including:

- expanding our sales, clinical support, product development and marketing infrastructure and capabilities;
- expanding our assembly capacity and increasing production;
- implementing appropriate operational and financial systems and controls;
- improving our information systems;
- identifying, attracting and retaining qualified personnel in our areas of activity; and
- hiring, training, managing and supervising our personnel.

We cannot be certain that our systems, controls, infrastructure and personnel will be adequate to support our future operations. Any failure to effectively manage our growth could impede our ability to successfully develop, market and sell our products and our business will be harmed.

Our long-term growth depends on our ability to compete effectively in the neurosurgery market by developing and commercializing new products and services through our research and development efforts, independently and through third-party collaborations.

Our future business prospects depend in part on our ability to develop and commercialize new products and services, such as the Maestro Brain Model, the Laser Ablation System, Pre-Clinical Development Services for Pharmaceutical Partners, and the Robotic-Assisted Navigation system. New technologies, techniques or products could emerge from competitors that might offer better combinations of price and performance than our products and services. It is important that we anticipate changes in technology and market demand, as well as customer preferences and practices, to successfully commercialize new technologies to meet our prospective customers' needs on a timely and cost-effective basis.

We might be unable to successfully commercialize our marketed products or services, or obtain authorization to market new products. The success of any new product offering will depend on numerous factors, including our ability to:

- properly identify and anticipate customer needs;
- identify, retain, and manage third-party design and development firms, where appropriate, to accelerate development;
- develop and introduce new products or services in a timely manner;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;

- obtain and retain third-party licenses required for the development, commercialization, and/or utilization of new products;
- demonstrate the safety and efficacy of new products;
- obtain the necessary regulatory authorizations to market new products or product enhancements;
- deliver products and services at a price point that is both profitable and acceptable to the market; and
- secure our supply chain to ensure we can continue to deliver products in a timely fashion to all geographies.

If we do not develop and obtain regulatory authorization to market new products in time to meet market demand, or if there is insufficient demand for these products, our results of operations will suffer. Our internal research and development efforts and our outsourced third-party design and development initiatives may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology, material or other innovation. In addition, even if we are able to develop enhancements or new generations of our products successfully, these enhancements or new generations of products may not produce sales in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features.

In the ordinary course of our development and commercialization of new products and services, we may enter into collaborations, in-licensing arrangements, joint development, distribution, or other commercial arrangements. Proposing, negotiating and implementing such arrangements may be a lengthy, expensive, 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 arrangements may not result in the development of products or services that achieve commercial success or result in significant revenues and could be terminated prior to achieving their desired objectives.

A growing part of our revenue from the biologics and drug delivery business is derived from providing consultancy to our pharmaceutical and other medical technology partners for on-site clinical support and training, protocol consultation, customized device development, and other solutions to optimize pre-clinical and clinical workflows. In certain cases, these services support a novel area in which commercialization must be preceded by FDA-mandated clinical trials, which are expensive and time consuming to conduct, and for which the commercial success is uncertain, pending, in part, the outcome of those trials. The continuation and growth of our revenue from our biologics and drug delivery services is dependent on our pharmaceutical and other medical technology partners achieving commercial success with their therapeutic products.

If coverage and reimbursement from third-party payors for procedures utilizing our products are inadequate, adoption of our products will be adversely affected and our revenues and prospects for profitability will suffer.

Our products are purchased primarily by hospitals, which bill various third-party payors, including governmental healthcare programs, such as Medicare, and private insurance plans, for procedures in which our products are used. Reimbursement is a significant factor considered by hospitals in determining whether to acquire and utilize medical devices. Therefore, our ability to successfully commercialize our products depends significantly on the adequacy of coverage and reimbursement from these third-party payors.

Third-party payors, whether foreign or domestic, governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for medical device products and services exists among third-party payors. Therefore, coverage and reimbursement for medical device products and services can differ significantly from payor to payor. In addition, payors continually review new technologies for possible coverage and can, without notice, deny coverage for these new products and procedures. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained or maintained if obtained.

Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In many international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Further, many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures. In most markets, there are private insurance systems as well as government-managed systems.

Because in most cases, hospitals are reimbursed for the procedures in which our products are used and our products are not separately reimbursed, the additional cost associated with the use of our products could impact hospital profit margins. Some hospitals could believe third-party reimbursement levels are not adequate to cover the cost of our products. Furthermore, some physicians could believe third-party reimbursement levels are not adequate to compensate them for performing the procedures in which our products are used. Failure by hospitals and physicians, whether in the United States or abroad, to receive an amount that they consider to be adequate reimbursement for procedures in which our products are used will deter them from purchasing or using our products and will limit our revenues and prospects for profitability.

We currently have significant customer concentration, so economic difficulties or changes in the purchasing policies or patterns of our key customers could have a significant impact on our business and operating results.

A small number of our customers account for a substantial portion of our revenues. In 2021, one pharmaceutical customer, a related party as described in Note 2 to the consolidated financial statements included elsewhere in this Annual Report, for whom we provide clinical services in support of the customer's clinical trials and earn a quarterly fee, accounted for 18% of our total revenues, and 43% of our biologics and drug delivery revenue. Our five largest hospital customers account for approximately 30% of our functional neurosurgery navigation revenues. Revenues from almost all our customers are not based on long-term, committed volume purchase contracts, and we may not continue to generate a similar level of revenues from our largest customers, or any other customer. Because of our current customer concentration, our revenues could fluctuate, possibly significantly, due to a reduction or delay in our biotechnology and pharmaceutical customers' clinical trials, or in orders from any of our significant hospital customers, which could harm our business and results of operations.

Our internal manufacturing operations are conducted at a single location, which may limit our ability to provide an adequate supply of our products, and any disruption at our manufacturing facility could render us unable to produce our products, increase our expenses and decrease our revenue.

Final assembly of many of our products' components occurs at our Irvine, California facility, in an area that is at risk of experiencing serious fires and power outages and is considered to lie in an earthquake risk zone. If our facility experiences a disruption, we would have no other means of assembling those components until we are able to restore the manufacturing capability at our current facility or develop the same capability at an alternative facility. We do not maintain a backup manufacturing facility, making us dependent on our current facility for the continued operation of our business. A natural or other disaster could damage or destroy our manufacturing equipment and cause substantial delays in our manufacturing operations, which could lead to additional expense and decreased revenue due to lack of supply. The insurance we maintain may not be adequate to cover our losses in any particular case. With or without insurance, damage to our facility or our other property due to a natural disaster or casualty event could have a material adverse effect on our business, financial condition and results of operations.

In connection with the continued commercialization of our products, we expect that we will need to increase, or "scale up," the production process of our components over the current level of production. While we have taken steps in anticipation of growth, manufacturers often encounter difficulties in scaling up production, such as problems involving yields, quality control and assurance, and shortages of qualified personnel. If the scaled-up production process is not efficient or produces a product that does not meet quality and other standards, we may be unable to meet market demand and our revenues, business and financial prospects would be adversely affected.

Our reliance on single-source suppliers could harm our ability to meet demand for our products in a timely manner or within budget.

Many of the components and component assemblies of our products are provided to us by single-source suppliers. We generally purchase components and component assemblies through purchase orders rather than long-term supply agreements and generally do not maintain large volumes of inventory. While alternative suppliers exist and have been identified for substantially all components, the disruption or termination of the supply of components and component assemblies could cause a significant increase in the cost of these components, which could affect our operating results. Our dependence on a limited number of third-party suppliers and the challenges we may face in obtaining adequate supplies involve several risks, including limited control over pricing, availability, quality and delivery schedules. A disruption or termination in the supply of components could also result in our inability to meet demand for our products, which could harm our ability to generate revenues, lead to customer dissatisfaction and damage our reputation. Disruptions in the global supply chain, such as those caused by the COVID-19 pandemic, could negatively affect our single-source suppliers and

could further exacerbate the risk that we are unable to meet the demand for our products. Furthermore, if we are required to change the supplier of a key component or component assembly of our products, we may be required to verify that the new supplier maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new supplier could also adversely affect our ability to meet demand for our products.

To the extent we seek a new indication for use of, or new claims for, our products, the FDA may not grant 510(k) clearance or premarket approval application ("PMA") approval of such new use or claims, which may affect our ability to grow our business.

We received 510(k) clearance to market our ClearPoint system for use in general neurosurgery interventional procedures, including DBS. We could seek to obtain additional, more specific indications for use of our ClearPoint system beyond the general neurosurgical intervention claim. To the extent we seek expanded claims for our ClearPoint system, such claims could, depending on their nature, require 510(k) clearance or FDA approval of a PMA. Moreover, some specific ClearPoint system claims could require clinical trials to support regulatory clearance or approval. In the event we seek a new indication for use of, or new claims for, the ClearPoint system that we believe are necessary or desirable for successful commercialization, the FDA may refuse our requests for 510(k) clearance or PMA approval. Likewise, to the extent clinical trials are necessary, we may not successfully complete or have the funds to initiate such clinical trials.

Our SmartFlow Cannula has received 510(k) clearance from the FDA for use in the United States for the aspiration of cerebrospinal fluid ("CSF"), or injection of Cytarabine into the ventricles. It has also been CE marked for use in Europe for the delivery of approved fluids into the brain or aspiration of CSF. The SmartFlow Cannula is being utilized in approved combination product clinical and preclinical studies by pharmaceutical companies and academic research customers for various research and clinical trials in connection with delivery of therapeutic agents. The growth of our drug delivery and biologics business is dependent upon our pharmaceutical company customers' ability to obtain regulatory approval for the use of the SmartFlow Cannula for delivery of their therapeutic agent, and/or our ability to expand the cleared indications for our SmartFlow Cannula to include delivery of our pharmaceutical company customers' therapeutic agents. To the extent that our pharmaceutical partners are not successful in obtaining regulatory approval, or if we are unable to expand the cleared indications for use of our SmartFlow Cannula, we may not be able to grow our business.

Clinical trials necessary to support 510(k) clearance or PMA approval for any new indications for use of our products would be expensive and could require the enrollment of large numbers of suitable patients, who could be difficult to identify and recruit. Delays or failures in any necessary clinical trials would prevent us from commercializing any modified product or new product candidate and could adversely affect our business, operating results and prospects.

Initiating and completing clinical trials necessary to support 510(k) clearance or PMA approval for our existing products or any other product candidates that we may develop, or additional safety and efficacy data that the FDA may require for 510(k) clearance or PMA approval for any new specific indications of our products that we may seek, would be time consuming and expensive with an uncertain outcome. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product candidate we advance into clinical trials may not have favorable results in later clinical trials.

Conducting successful clinical trials could require the enrollment of large numbers of patients, and suitable patients could be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators and support staff, the proximity to clinical sites of patients that are able to comply with the eligibility and exclusion criteria for participation in the clinical trial, and patient compliance. For example, patients could be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our product candidates or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. In addition, patients participating in clinical trials may die before completion of the trial or suffer adverse medical events unrelated to our product candidates.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy will be required and we may not adequately develop such protocols to support clearance or approval. Further, the FDA could require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of

patients to continue to participate in a clinical trial could cause an increase in costs and delays in the approval and attempted commercialization of our product candidates or result in the failure of the clinical trial. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

If we fail to obtain the necessary clearances, certifications or approvals for our new products, our ability to grow our business globally could be harmed.

Our business growth is dependent upon our ability to market and sell new products, including new therapy devices and devices to allow us to expand our business into the operating room. Unless and until we obtain FDA clearance, authorization or approval for the new products in our pipeline, we will not be able to sell or promote them in the United States. Under FDA regulations, unless exempt, a new medical device may only be commercially distributed after it has received 510(k) clearance, is authorized through the *de novo* classification process, or is the subject of an approved PMA. The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to another legally marketed product not subject to a PMA. Sometimes, premarket submissions must be supported by clinical data. Clinical trials are expensive, time consuming, and their outcomes are uncertain. Our ability to enroll patients in clinical trials could be impacted by the COVID-19 outbreak, as many patients are electing or being asked to delay procedures at this time. The PMA process typically is more costly, lengthy and stringent than the 510(k) process and usually requires more substantial clinical studies.

The FDA may not authorize marketing via *de novo* classification or clear our 510(k) applications on a timely basis or at all. For example, the COVID-19 outbreak could affect the FDA's ability to review applications or supplements. Such delays or refusals, regardless of the cause, could have a material adverse effect on our business, financial condition, and results of operations. The FDA may also change its clearance and authorization policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay authorization or clearance of our products. Similar restrictions exist outside of the United States.

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

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

There is no assurance that future clearance or approval of our new products will be granted, or that we will be able to continue selling our products in any geography. Such failures could hurt our ability to maintain and grow our business.

The results of our clinical trials may not support our product candidate claims or any additional claims we may seek for our products and may result in the discovery of adverse side effects.

Even if any clinical trial that we need to undertake is completed as planned, we cannot be certain that its results will support our product candidate claims or any new indications that we may seek for our products or that the FDA or foreign authorities will agree with our conclusions regarding the results of those trials. The clinical trial process may fail to

demonstrate that our products or a product candidate is safe and effective for the proposed indicated use, which could cause us to stop seeking additional clearances or approvals for our products or abandon or delay development of other product candidates. Any delay or termination of our clinical trials will delay the filing of our regulatory submissions and, ultimately, our ability to commercialize a product candidate. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile.

The markets for medical devices are highly competitive, and we may not be able to compete effectively against the larger, well-established companies in our markets or emerging and small innovative companies that may seek to obtain or increase their share of the market.

We will face competition from products and techniques already in existence in the marketplace. The markets for medical devices used in neurosurgical procedures is intensely competitive, and many of our competitors are much larger and have substantially more financial and human resources than we do. Many have long histories and strong reputations within the industry, and a relatively small number of companies dominate these markets. Examples of such large, well-known companies include Medtronic, Abbott, Elekta and Brainlab.

These companies enjoy significant competitive advantages over us, including:

- broad product offerings, which address the needs of physicians and hospitals in a wide range of procedures and allow for price bundling;
- greater experience in, and resources for, launching, marketing, distributing and selling products, including strong sales forces and established distribution networks;
- existing relationships with physicians and hospitals;
- more extensive intellectual property portfolios and resources for patent protection;
- greater financial and other resources for product research and development;
- greater experience in obtaining and maintaining FDA and other regulatory clearances or approvals for products and product enhancements;
- established manufacturing operations and contract manufacturing relationships; and
- significantly greater name recognition and more recognizable trademarks.

We may not succeed in overcoming the competitive advantages of these large and established companies. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies may introduce products that compete effectively against our products in terms of performance, price or both.

We sell our products outside of the United States, and we are subject to various economic, political, regulatory, and other risks relating to international operations, which could harm our revenue and profitability.

As of December 31, 2021, we have sold our products in several countries outside of the United States. Our business strategy includes plans for expansion in countries where we currently operate as well as introducing our products to other international markets. Doing business outside of the United States exposes us to risks distinct from those we face in our domestic operations. For example, our operations outside of the United States are subject to different regulatory requirements in each jurisdiction where we operate or have sales. Our failure, or the failure of our distributors, to comply with current or future foreign regulatory requirements, or the assertion by foreign authorities that we or our distributors have failed to comply, could result in adverse consequences, including enforcement actions, fines and penalties, recalls, cessation of sales, civil and criminal prosecution, and the consequences could be disproportionate to the relative contribution of our international operations to our results of operations.

Engaging in business outside of the United States inherently involves a number of other difficulties and risks, including, but not limited to:

- export restrictions and controls relating to technology;
- pricing pressure that we may experience internationally;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability;
- consequences arising from natural disasters and other similar catastrophes, such as hurricanes, tornados, earthquakes, floods and tsunamis;
- potentially adverse tax consequences, tariffs and other trade barriers;

- the need to hire additional personnel to promote our products outside of the United States;
- international terrorism and anti-American sentiment;
- fluctuations in exchange rates for future sales denominated in foreign currency, which represent a majority of our sales outside of the United States;
- difficulty in obtaining and enforcing intellectual property rights; and
- changing regulatory environments such as the European Medical Device Regulation.

In addition, our business practices in foreign countries must comply with U.S. laws, including the Foreign Corrupt Practices Act ("FCPA"). We have a compliance program in place designed to reduce the likelihood of potential violations of the FCPA and other U.S. and foreign anti-bribery and anti-corruption laws. If violations were to occur, they could subject us to fines and other penalties as well as increased compliance costs.

Our exposure to each of these risks may increase our costs and require significant management attention. We cannot assure you that one or more of these factors will not harm our business.

Disruptions of critical information systems or material breaches in the security of our systems could harm our business, customer relations and financial condition.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our customers, suppliers and business partners, and personally identifiable information of our customers and employees in our data centers, on our networks, and on third party-controlled applications. The secure processing, maintenance and transmission of this information is critical to our operations and business strategy. The information technology and infrastructure which we rely upon may be vulnerable to attacks by hackers or breached due to human error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, regulatory penalties, disrupt our operations and the services we provide to customers, and damage our reputation and cause a loss of confidence in our products and services, which could adversely affect our business, operating margins, revenues and competitive position.

We also rely in part on information technology to store information, interface with customers, maintain financial accuracy, secure our data and accurately produce our financial statements. If our information technology systems do not effectively and securely collect, store, process and report relevant data for the operation of our business, whether due to equipment malfunction or constraints, software deficiencies, human error or cyber incident, our ability to effectively plan, forecast and execute our business plan and comply with applicable laws and regulations would be materially impaired. Any such impairment could have a material adverse effect on our results of operations, financial condition and the timeliness with which we report our operating results.

We may acquire other businesses, form joint ventures, or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt, or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions or investments in other companies or technologies. We also may pursue strategic alliances and joint ventures that leverage our core technology and industry experience to expand our offerings or distribution. We have no experience with acquiring or investing in other companies and limited experience with forming strategic alliances and joint ventures. We may not be able to find suitable partners or acquisition or investment candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, or joint venture.

To finance any investments, acquisitions or joint ventures, it may be necessary for us to raise additional funds through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

We need to hire and retain additional qualified personnel to grow and manage our business. If we are unable to attract and retain qualified personnel, our business and growth could be seriously harmed.

Our performance depends on the talents and efforts of our employees. Our future success will depend on our ability to attract, retain and motivate highly skilled personnel in all areas of our organization, but particularly as part of our sales, clinical support, product development and marketing teams. We plan to continue to grow our business and will need to hire additional personnel to support this growth. It is often difficult to hire and retain these persons, and we may be unable to replace key persons if they leave or fill new positions requiring key persons with appropriate experience. If we experience difficulties locating and hiring suitable personnel in the future, our growth may be hindered. Qualified individuals are in high demand, particularly in the medical device industry, and we may incur significant costs to attract and retain them. If we are unable to attract and retain the personnel we need to succeed, our business and growth could be harmed.

Risks Related to Our Financial Position

We have incurred losses since our inception and we may continue to incur losses. If we fail to generate significant revenue from sales of our products and services, we may never achieve or sustain profitability.

We have incurred losses in each year since our inception in 1998 that have resulted principally from costs incurred in connection with our sales and marketing activities, research and development efforts, manufacturing activities and other general and administrative expenses associated with our operations, and we may continue to incur losses as we continue to invest capital in the sales and marketing of our ClearPoint platform products and services, and growth of our business generally.

As a result of the numerous risks and uncertainties associated with developing medical devices and with our biologic and drug delivery customers' development of safe and effective drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Our profitability will depend on revenues from the sale of our products and services. Additionally, increases in our various costs that may be the result of inflationary pressures could further reduce our sales and profitability. We cannot provide any assurance that we will ever achieve profitability and, even if we achieve profitability, that we will be able to sustain or increase profitability on a quarterly or annual basis. Further, because of our relatively limited commercialization history, we have limited insight into the trends that may emerge and affect our business. We may make errors in predicting and reacting to relevant business trends, which could harm our business and financial condition. Any failure to achieve and maintain profitability would continue to have an adverse effect on our stockholders' equity and working capital and could result in a decline in our stock price or cause us to cease operations.

We may need additional funding for our business, and we may not be able to raise capital when needed or on terms that are acceptable to us, which could force us to delay, reduce or eliminate our commercialization efforts or our product development programs.

The cumulative net loss from our inception through December 31, 2021 was approximately $134 million. Net cash used in operations was $12.7 million for the year ended December 31, 2021. Since our inception, we have financed our operations principally from the sale of equity securities and the issuance of notes payable. At December 31, 2021, we had cash and cash equivalent balances aggregating $54.1 million, resulting primarily from the 2021 public offering and note issuances pursuant to the 2020 Financing Transaction as discussed in Notes 8 and 6, respectively, to the consolidated financial statements included elsewhere in this Annual Report.

Our plans for the next twelve months reflect our anticipation of increases in revenues from sales of the ClearPoint system and related disposable products as a result of greater utilization at existing installed sites and the installation of the ClearPoint system at new sites, as well as from consulting services and sales of systems and disposables to our pharmaceutical partners for gene and stem cell therapy trials. We also anticipate increases over the next twelve months in operating expenses to support the expected increase in revenues, with resulting decreases in loss from operations and in cash flow used in operations. However, there is no assurance that we will be able to achieve anticipated results, and even in the event such results are achieved, we expect to continue to consume cash in operations over at least the next twelve months.

As a result of the foregoing, we believe it may be necessary to seek additional sources of funds from the sale of equity or other debt securities, which likely would result in dilution to existing ownership interests, from the establishment

of a credit facility, or from entry into an agreement with a strategic partner or some other form of collaborative relationship. There is no assurance, however, that we will be able to obtain such additional financing on commercially reasonable terms, if at all, and there is no assurance that any additional financing we do obtain will be sufficient to meet our needs. If we are not able to obtain the additional financing on a timely basis, we may be unable to achieve anticipated results, and may not be able to meet other obligations as they become due. An inability to obtain a sufficient amount of additional funding would create substantial doubt as to our ability to continue as a going concern.

The funding requirements for our business will depend on many factors, including:

- the timing of broader market acceptance and adoption of our ClearPoint platform products and services;
- the scope, rate of progress and cost of our ongoing product development activities relating to our ClearPoint system;
- the cost and timing of expanding our sales, clinical support, marketing and distribution capabilities and other corporate infrastructure;
- the cost and timing of establishing inventories at levels sufficient to support our sales;
- the scope, rate of progress and cost of our research and development activities relating to new products;
- the effect of competing technological and market developments;
- the terms and timing of any future collaborative, licensing or other arrangements that we may establish;
- the cost and timing of any clinical trials;
- the cost and timing of regulatory filings, clearances and approvals; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Raising additional funds may cause dilution to existing stockholders, restrict our operations or require us to relinquish proprietary rights.

To the extent we raise additional capital through the sale of equity or convertible debt securities, existing ownership interests will be diluted, and the terms may include liquidation or other preferences that adversely affect such existing stockholders' rights. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we secure additional funds through arrangements with a strategic or other collaboration partner, we may have to relinquish valuable rights to our technologies, products or product candidates or grant licenses on terms that are not favorable to us. Any of these events could adversely affect our ability to achieve our commercialization and/or product development goals and have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Intellectual Property

If we, or the third parties from whom we license intellectual property, are unable to secure and maintain patent or other intellectual property protection for the intellectual property covering our marketed products or our product candidates, our ability to compete will be harmed.

Our commercial success depends, in part, on obtaining patent and other intellectual property protection for the technologies contained in our products and product candidates. The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. Our patent position is uncertain and complex, in part, because of our dependence on intellectual property that we license from others. If we, or the third parties from whom we license intellectual property, fail to obtain adequate patent or other intellectual property protection for intellectual property covering our products or product candidates, or if any protection is reduced or eliminated, others could use the intellectual property covering our products or product candidates, resulting in harm to our competitive business position. In addition, patent and other intellectual property protection may not provide us with a competitive advantage against competitors that devise ways of making competitive products without infringing any patents that we own or to which we have rights.

United States patents and patent applications may be subject to interference proceedings and United States patents may be subject to inter partes proceedings ("IPRs"), reissue and reexamination proceedings in the United States Patent and Trademark Office. Foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent offices. Any of these proceedings could result in either loss of the patent or denial of the patent application, or loss or reduction in the scope of one or more of the claims of the patent or patent application. Changes in either patent laws or

in interpretations of patent laws may also diminish the value of our intellectual property or narrow the scope of our protection. Interference, IPRs, reexamination and opposition proceedings may be costly and time consuming, and we, or the third parties from whom we license intellectual property, may be unsuccessful in such proceedings. Thus, any patents that we own or license may provide limited or no protection against competitors. In addition, our pending patent applications and those we may file in the future may not result in patents being issued or may have claims that do not cover our products or product candidates. Even if any of our pending or future patent applications are issued, they may not provide us with adequate protection or any competitive advantages. Our ability to develop additional patentable technology is also uncertain.

Non-payment or delay in payment of patent fees or annuities, whether intentional or unintentional, may also result in the loss of patents or patent rights important to our business. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States, particularly in the field of medical devices and procedures.

Others may assert that our products infringe their intellectual property rights, which may cause us to engage in costly disputes and, if we are not successful in defending ourselves, could also cause us to pay substantial damages and prohibit us from selling our marketed products.

There may be United States and foreign patents issued to third parties that relate to our business. Some of these patents may be broad enough to cover one or more aspects of our present technologies and/or may cover aspects of our future technologies. We do not know whether any of these patents, if they exist and if asserted, would be held valid, enforceable and infringed. We cannot provide any assurance that a court or administrative body would agree with any arguments or defenses we may have concerning invalidity, unenforceability or non-infringement of any third-party patent. The medical device industry has been characterized by extensive litigation and administrative proceedings regarding patents and other intellectual property rights, and companies have employed such actions to gain a competitive advantage. If third parties assert infringement or other intellectual property claims against us, our management personnel will experience a significant diversion of time and effort and we will incur large expenses defending our company. If third parties in any patent action are successful, our patent portfolio may be damaged, we may have to pay substantial damages and we may be required to stop selling our products or obtain a license which, if available at all, may require us to pay substantial royalties. We cannot be certain that we will have the financial resources or the substantive arguments to defend our products from infringement or our patents from claims of invalidity or unenforceability, or to defend our products against allegations of infringement of third-party patents. In addition, any public announcements related to litigation or administrative proceedings initiated by us, or initiated or threatened against us, could negatively impact our business.

If the combination of patents, trade secrets and contractual provisions that we rely on to protect our intellectual property is inadequate, our ability to successfully commercialize our marketed products and product candidates will be harmed, and we may not be able to operate our business profitably.

Our success and ability to compete is dependent, in part, upon our ability to maintain the proprietary nature of our technologies. We rely on a combination of patent, copyright, trademark and trade secret law and nondisclosure agreements to protect our intellectual property. However, such methods may not be adequate to protect us or permit us to gain or maintain a competitive advantage. Our patent applications may not issue as patents in a form that will be advantageous to us, or at all. Our issued patents, and those that may issue in the future, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products.

To protect our proprietary rights, we may in the future need to assert claims of infringement against third parties to protect our intellectual property. There can be no assurance that we will be successful on the merits in any enforcement effort. In addition, we may not have sufficient resources to litigate, enforce or defend our intellectual property rights. Litigation to enforce our intellectual property rights in patents, copyrights or trademarks is highly unpredictable, expensive and time consuming and would divert human and monetary resources away from managing our business, all of which could have a material adverse effect on our financial condition and results of operations even if we were to prevail in such litigation. In the event of an adverse judgment, a court could hold that some or all of our asserted intellectual property rights are not infringed, or that they are invalid or unenforceable, and could award attorney fees.

Despite our efforts to safeguard our unpatented and unregistered intellectual property rights, we may not be successful in doing so or the steps taken by us in this regard may not be adequate to detect or deter misappropriation of our technologies or to prevent an unauthorized third party from copying or otherwise obtaining and using our products, technologies or other information that we regard as proprietary. Additionally, third parties may be able to design around our patents. Furthermore, the laws of foreign countries may not protect our proprietary rights to the same extent as the laws of the United States. Our inability to adequately protect our intellectual property could allow our competitors and others to produce products based on our technologies, which could substantially impair our ability to compete.

We have entered into confidentiality and intellectual property assignment agreements with our employees and consultants as one of the ways we seek to protect our intellectual property and other proprietary technologies. However, these agreements may not be enforceable, or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements.

Our employees and consultants may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party illegally obtained and is using our proprietary know-how is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect know-how than courts in the United States. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Failure to obtain or maintain intellectual property protection could adversely affect our competitive business position.

If we lose access to third-party software that is integrated into our ClearPoint system software, our costs could increase and new installations of our ClearPoint system could be delayed, potentially hurting our competitive position.

We have received non-exclusive, non-transferable, worldwide licenses from third parties to certain software, in source code form, that is integrated into the software component of our ClearPoint system. In return, we agreed to pay one such third party a one-time license fee, as well as a license fee for each copy of the ClearPoint system software that we distribute, subject to certain minimum license purchase commitments which we already have satisfied, and we have agreed to pay royalties to other third parties based on our placements of new ClearPoint system installations. A loss of any of the licenses could impede our ability to install our ClearPoint system at new sites until equivalent software could be identified, licensed or developed, and integrated into the software component of our ClearPoint system. These delays, if they occur, would harm our business, operating results and financial condition.

Our rights to develop and commercialize our products are subject, in part, to the terms and conditions of licenses granted to us by others.

We rely, in part, upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of our products and technology. These and other licenses may not provide exclusive rights to use such intellectual property and technology, and we may not have intellectual property rights through such licenses in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not in sole and exclusive control or may not be the sole owners of the patents we in-license. This could materially and adversely affect our business, financial condition and results of operations.

The agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the

relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement. In spite of our best efforts, our licensors might also conclude that we have materially breached our license agreements and terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to larger financial commitments. Any of these events could materially and adversely affect our business, financial condition and results of operations.

Risks Related to Legal and Regulatory Compliance

We operate in a highly-regulated industry and any failure to comply with the extensive government regulations may subject us to fines, injunctions and other penalties that could harm our business.

We are subject to extensive regulation by the FDA and various other federal, state and foreign governmental authorities. Government regulations and foreign requirements specific to medical devices are wide ranging and govern, among other things:

- design, development and manufacturing;
- testing, labeling and storage;
- product safety;
- marketing, sales and distribution;
- premarket clearance, authorization, or approval;
- recordkeeping procedures;
- advertising and promotions;
- recalls and field 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; and
- product export.

We are subject to ongoing regulatory requirements, including: required submissions of safety and other post-market information; manufacturing facility registration and device listing requirements; compliance with medical device current Good Manufacturing Practice regulations, as codified in the QSR; requirements regarding field corrections and removals of our marketed products; reporting of adverse events and certain product malfunctions to regulatory bodies; and numerous recordkeeping requirements. If we or any of our collaborators or suppliers fail to comply with applicable regulatory requirements, a regulatory agency may take action against us, including any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or orders for the repair or replacement of our products or refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for regulatory approvals of new products or modified products;
- withdrawing regulatory submissions that have already been granted; or
- refusing to grant export approval for our products.

We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation, administrative, or executive action, either in the United States or abroad. For example, the Biden administration has taken and will continue to take executive actions, some of which could impact us and our business. The implementation of new policies and priorities by the Biden administration are unknown and could materially impact the regulation of our products. If executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Federal legislation and other payment and policy changes may have a material adverse effect on our business.

Since enactment of the Affordable Care Act in 2010, there have been a number of legal challenges as well as other legislative and regulatory changes to the healthcare system that could limit the acceptance and availability of our products, which would have an adverse effect on our financial results and business. The full effects of the Affordable Care Act may be unknown until all outstanding legal issues are resolved, the statutory provisions are fully implemented, and CMS, the

FDA, and other federal and state agencies issue final applicable regulations or guidance. These developments could result in increased coordination between hospitals and physicians and alignment of financial incentives between hospitals and physicians to control hospital costs. Such payment reform efforts and increased coordination among hospitals and physicians may lead to voluntary reductions in the array of choices currently available to physicians with respect to diagnostic services, medical supplies and equipment, which could result in hospitals reducing the overall number of vendors from which they purchase supplies, equipment and products. The Affordable Care Act may continue to be periodically subject to legal challenges or a continuing political effort to limit its scope. While we do not expect the Biden Administration to modify or repeal the Affordable Care Act, we cannot offer assurances that the political situation regarding the Affordable Care Act will not change in the future in ways that could have a material adverse effect on our business or results of operations.

On April 16, 2015, President Obama signed into law, the Medicare Access and CHIP Reauthorization Act, or the Medicare Access Act, which removed the sustainable growth rate or SGR, methodology applicable to fees for physician services. The Medicare Access Act replaced the previous fee-for-service payment system with a more value-based system. As a result, reimbursements from the Medicare program may be reduced. As noted above, failure by hospitals and physicians to receive an amount that they consider to be adequate reimbursement for procedures in which our products are used may deter them from purchasing or using our products and will limit our sales growth.

The Affordable Care Act also imposes, among other things, an annual excise tax on any entity that manufactures or imports medical devices offered for sale in the United States. In December 2019, President Trump signed into law a permanent repeal of the medical device tax under the Affordable Care Act, but there is no guarantee that Congress or President Biden will not reverse course in the future. If such an excise tax on sales of our products in the United States is enacted, it could have a material adverse effect on our business, results of operations and financial condition.

Various healthcare reform proposals have also emerged at the state level. We cannot predict what healthcare initiatives will be implemented at the federal or state level, or the effect any recently promulgated or future legislation or regulation will have on us. However, an expansion in government's role in the United States healthcare industry may lower reimbursements for our products, reduce medical procedure volumes and adversely affect our business, possibly materially.

Our products may be subject to product recalls that could harm our reputation, business operating results and financial condition. Likewise, products that are manufactured and sold by third parties and that are needed for procedures in which physicians use our products also may be subject to recalls, which could adversely impact our business, operating results and financial condition.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design, manufacture or labeling. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. We may initiate certain voluntary recalls involving our products in the future. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. If we determine that certain of those recalls do not require notification to the FDA, the FDA may disagree with our determinations and require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement actions against us, which could impair our ability to produce our products in a cost-effective and timely manner to meet our customers' demands. Regulatory investigations or product recalls could also result in our incurring substantial costs, losing revenues and implementing a change in the design, manufacturing process or the indications for which our products may be used, each of which would harm our business.

In addition, products that are manufactured and sold by other companies and that are needed for procedures in which physicians use ClearPoint devices also could become subject to a recall. ClearPoint devices are designed to enable a range of minimally-invasive procedures in the brain. Those procedures involve insertion of a catheter, probe, electrode or other similar device into a target region of the brain, and most of those devices are manufactured and sold by other companies. Any of those devices may become the subject of a recall, whether required by the FDA or a foreign governmental body or initiated by the third-party manufacturer. The shortage or absence of any of those devices in the

marketplace could adversely impact the number of procedures performed by physicians using our ClearPoint devices, which would adversely impact our financial condition and results of operations.

If our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to Medical Device Reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA's Medical Device Reporting regulations, we are required to report to the FDA any incident in which our products may have caused or contributed to a death or serious injury or in which our products malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. In the future, we may experience events that may require reporting to the FDA pursuant to the medical device reporting regulations. In addition, all manufacturers placing medical devices in EU markets are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the relevant authority in whose jurisdiction the incident occurred. Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. 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 may harm our reputation and financial results. In addition, failure to report such adverse events to appropriate government authorities on a timely basis, or at all, could result in an enforcement action against us.

We may incur significant liability if it is determined that we are promoting off-label uses of our products in violation of federal and state regulations in the United States or elsewhere.

We obtained 510(k) clearance of our ClearPoint system from the FDA for a general neurosurgical intervention claim. This general neurosurgical intervention indication is the same indication for use that applies to other devices that have traditionally been used in the performance of stereotactic neurosurgery procedures. Unless and until we receive regulatory clearance or approval for use of our ClearPoint system in specific procedures, uses in procedures other than general neurosurgical interventional procedures may be considered off-label uses of our ClearPoint system.

Under the federal Food, Drug, and Cosmetic Act and other similar laws, we are prohibited from labeling or promoting our ClearPoint system, or training physicians, for such off-label uses. The FDA defines labeling to include not only the physical label attached to the product, but also items accompanying the product. This definition also includes items as diverse as materials that appear on a company's website. As a result, we are not permitted to promote off-label uses of our products, whether on our website, in product brochures or in customer communications. However, although manufacturers are not permitted to promote for off-label uses, in their practice of medicine, physicians may lawfully choose to use medical devices for off-label uses. Therefore, a physician could use our ClearPoint system for uses not covered by the cleared labeling.

The FDA and other regulatory agencies actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance or approval has not been obtained. If the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, warning letter, injunction, seizure, civil fine and criminal penalties. We could be enjoined from selling some or all of our products for any unapproved uses. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and market adoption of our products would be impaired. In addition, the off-label use of our products may increase the risk of injury to patients, and, in turn, the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention and result in substantial damage awards against us.

If we or our third-party suppliers fail to comply with the FDA's QSR or any applicable state equivalent, our manufacturing operations could be interrupted, and our potential product sales and operating results could suffer.

We and some of our third-party suppliers are required to comply with the FDA's QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products and product candidates. We and our suppliers will also be subject to the regulations of foreign jurisdictions regarding the manufacturing process to the extent we market our products in these jurisdictions. The FDA

enforces the QSR through periodic and unannounced inspections of manufacturing facilities. Our facilities were last inspected by the FDA for QSR compliance in July 2018. We anticipate that we and certain of our third-party suppliers will be subject to future inspections. The failure by us or one of our third-party suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations, could result in enforcement actions against us, which could impair our ability to produce our products in a cost-effective and timely manner to meet our customers' demands. If we fail to comply with the FDA's QSR or any applicable state equivalent, we would be required to incur the costs and take the actions necessary to bring our operations into compliance, which may have a negative impact on our future sales and our ability to generate a profit.

We are subject to environmental laws and regulations that can impose significant costs and expose us to potential financial liabilities.

The manufacture of certain of our products and the handling of materials used in the product testing process involve the use of biological, hazardous and/or radioactive materials and wastes. Our business and facilities and those of our suppliers are subject to foreign, federal, state, and local laws and regulations relating to the protection of human health and the environment, including those governing the use, manufacture, storage, handling, and disposal of, and exposure to, such materials and wastes. In addition, under some environmental laws and regulations, we could be held responsible for costs relating to any contamination at our past or present facilities and at third-party waste disposal sites even if such contamination was not caused by us. A failure to comply with current or future environmental laws and regulations could result in severe fines or penalties. Any such expenses or liability could have a significant negative impact on our business, results of operations, and financial condition.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.

Although we do not provide healthcare services or receive payments directly from Medicare, Medicaid or other third-party payors for our products or the procedures in which our products may be used, many state and federal healthcare laws and regulations governing financial relationships between medical device companies and healthcare providers apply to our business and we could be subject to enforcement by both the federal government, private whistleblowers and the states in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include:

- The federal healthcare programs' Anti-Kickback Statute, which prohibits, among other things, individuals or entities from knowingly and willfully soliciting, receiving, offering or providing any kickback, bribe or other remuneration, directly or indirectly, in exchange for or to induce the purchase, lease or order, or arranging for or recommending of, any item or service for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs.
- Federal false claims laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment to Medicare, Medicaid or other federally-funded healthcare programs that are false or fraudulent, or are for items or services not provided as claimed, and which may apply to entities like us to the extent that our interactions with customers may affect their billing or coding practices. Changes to the federal false claims law enacted as part of the Affordable Care Act will likely increase the number of whistleblower cases brought against providers and suppliers of health care items and services.
- The federal Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA, which established new federal crimes for knowingly and willfully executing a scheme to defraud any healthcare benefit program or making false statements in connection with the delivery of or payment for healthcare benefits, items or services.
- State and foreign law equivalents of each of the above federal laws, such as: (i) anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; and (ii) the Foreign Corrupt Practices Act, which may apply to interactions with foreign government officials, including physician employees of a foreign government entity, by our employees and third-party business partners.
- The Affordable Care Act, which imposes certain reporting obligations on manufacturers of drugs, devices and biologics. Specifically, such manufacturers are required to report payments or other transfers of value to or on behalf of physicians, physician assistants, certain types of advance care nurses or teaching hospitals by such manufacturers, as well as any ownership or investment interest held by physicians in such manufacturers. Violations of the reporting requirements are subject to civil monetary penalties.

- The Affordable Care Act also grants the Office of Inspector General additional authority to obtain information from any individual or entity to validate claims for payment or to evaluate the economy, efficiency or effectiveness of the Medicare and Medicaid programs, expands the permissible exclusion authority to include any false statements or misrepresentations of material facts, enhances the civil monetary penalties for false statements or misrepresentation of material facts, and enhances the Federal Sentencing Guidelines for those convicted of federal healthcare offenses.

The medical device industry has been under heightened scrutiny as the subject of government investigations and government enforcement or private whistleblower actions under the Anti-Kickback Statute and the False Claims Act involving manufacturers who allegedly offered unlawful inducements to potential or existing customers in an attempt to procure their business, including specifically arrangements with physician consultants.

We may from time to time have agreements with physicians that could be scrutinized or could be subject to reporting requirements in the future, including consulting contracts in which we compensate physicians for various services, which could include:

- providing training and other similar services on the proper use of our products;
- advising us with respect to the commercialization of products in their respective fields;
- keeping us informed of new developments in their respective fields of practice;
- advising us on our research and development projects related to their respective fields;
- advising us on improvements to methods, processes and devices related to their respective fields (such as advice on the development of prototype devices); and
- assisting us with the technical evaluation of our methods, processes and devices related to their respective fields.

The Affordable Care Act mandates increased transparency of arrangements between physicians and medical device companies. We believe that this increased transparency may also result in a heightened level of government scrutiny of the relationships between physicians and medical device companies. While we believe that all of our arrangements with physicians comply with applicable law, the increased level of scrutiny, coupled with the expanded enforcement tools available to the government under the Affordable Care Act, may increase the likelihood of a governmental investigation. If we become subject to such an investigation, our business and operations would be adversely affected even if we ultimately prevail because the cost of defending such investigation would be substantial. Moreover, companies subject to governmental investigations could lose both overall market value and market share during the course of the investigation.

In addition, we may provide customers with information on products that could be deemed to influence their coding or billing practices, and may have sales, marketing or other arrangements with hospitals and other providers that could also be the subject of scrutiny under these laws. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations. Any penalties, damages, fines, exclusions, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of these laws are broad and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, 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 the physicians or other providers or entities with which we do business are found to be non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on our business.

We are subject to various laws protecting the confidentiality and security of certain personal information, and our failure to comply could result in penalties and reputational damage.

We are subject to various laws and regulations protecting the confidentiality and security of certain patient health information, and our failure to comply with such laws and regulations could result in penalties and reputational damage.

Within the United States, numerous federal and state laws governing the collection, use, disclosure and storage of personal information may apply to us, including, without limitation, HIPAA, state data privacy laws (for example, the California Consumer Privacy Act and the California Privacy Rights Act), state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws. In addition, in certain cases, we may be a business associate of our HIPAA covered entity customers by virtue of receiving individually identifiable health

information (referred to as "Protected Health Information" or "PHI") from these customers. In these business associate relationships, we must comply with applicable HIPAA requirements, state data privacy and security requirements, and the contractual terms of our business associate agreements that govern its permitted uses and disclosures of PHI received from the covered entity counterparty. Our failure to comply with any of these laws may result in criminal and civil liability. Enforcement actions can be costly and interrupt regular operations which may adversely affect our business.

Outside the United States, numerous countries in which we operate, manufacture and sell our products have, or are developing, laws protecting data privacy and the confidentiality of certain personal data. For example, the EU General Data Protection Regulation ("GDPR"), which became effective on May 25, 2018, introduced new data protection requirements in the European Economic Area and substantial fines for violations of the data protection rules. The GDPR applies extraterritorially, and we may be subject to the GDPR because of our potential data processing activities that involve the personal data of individuals located in the EU, such as in connection with any EU customers, EU clinical trials or related to any employees in the EU. The GDPR imposes strict obligations and restrictions on controllers and processors of personal data, which could cause our costs of compliance to increase, potentially leading to harm to our business and financial condition.

Globally, 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 that may affect our business. There is a degree of uncertainty associated with the legal and regulatory environment around privacy and data protection laws, which continue to develop in ways we cannot predict. Privacy and data protection laws may be interpreted and applied inconsistently from country to country and impose inconsistent or conflicting requirements. Varying jurisdictional requirements could increase the costs and complexity of compliance or require us to change our business practices in a manner adverse to our business. A determination that we have violated privacy or data protection laws could result in significant damage awards, fines and other penalties that could, individually or in the aggregate, materially harm our business and reputation.

Our Third Amended and Restated Bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Third Amended and Restated Bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) is the exclusive forum (to the fullest extent permitted by law, and subject to applicable jurisdictional requirements) for claims in the right of the corporation that are based upon a violation of a duty by a current or former director, officer, employee or stockholder in such capacity, or as to which the Delaware General Corporation Law confers jurisdiction upon the Court of Chancery of the State of Delaware.

Our Third Amended and Restated Bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive-forum provision in our Third Amended and Restated Bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

Risks Related to Our Common Stock

If our common stock becomes subject to the penny stock rules, it may become more difficult to trade our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00, other than securities registered on certain

national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. While our common stock currently trades in excess of $5.00, our common stock has traded below $5.00 in the recent past. If we do not retain a listing on The Nasdaq Capital Market, and if the price of our common stock is less than $5.00, our common stock will be deemed a penny stock and be subject to the following requirements:

- a broker-dealer must deliver, prior to the transaction, a disclosure schedule prepared by the SEC relating to the penny stock market;
- a broker-dealer must disclose the commissions payable to the broker-dealer and its registered representative;
- a broker-dealer must disclose current quotations for the securities; and
- a broker-dealer must furnish its customers with monthly statements disclosing recent price information for all penny stocks held in the customer's account and information on the limited market in penny stocks.

Additional sales practice requirements are imposed on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. For these types of transactions, the broker-dealer must make a special suitability determination for the purchaser and must have received the purchaser's written consent to the transaction prior to sale. If our common stock becomes subject to these penny stock rules these disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for our common stock. As a result, fewer broker-dealers may be willing to make a market in our stock, which could affect our stockholders' ability to sell their shares.

The market price of our common stock may be highly volatile, and a stockholder may not be able to resell their shares at or above the price at which the shares were purchased.

Companies trading in the stock market in general have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The market price of our common stock may be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- Failure to successfully develop our products;
- Changes in laws or regulations applicable to future products;
- Inability to obtain adequate product supply for our product candidates or the inability to do so at acceptable prices;
- Adverse regulatory decisions;
- Introduction of new products, services or technologies by our competitors;
- Failure to meet or exceed financial projections we may provide to the public;
- Inability to obtain additional funding;
- Failure to meet or exceed the financial projections of the investment community;
- Disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- Additions or departures of key personnel;
- Significant lawsuits, including patent or stockholder litigation;
- Changes in the market valuations of similar companies;
- Purchases and sales of our common stock resulting from, related to or arising out of (i) recent stock run-ups or recent divergences in valuations relative to those seen during traditional markets, (ii) high short interest or reported short squeezes, or (iii) reports of strong and atypical retail investor interest (whether on social media or otherwise);
- Sales of our common stock by us or our stockholders in the future; and
- Trading volume of our common stock.

Sales of a substantial number of shares of our common stock in the public market, or the perception that they may occur, may depress the market price of our common stock.

As of March 3, 2022, almost all of our outstanding shares were freely transferable or could be publicly resold pursuant to Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. In general, under Rule 144 as currently in effect, a person (or persons whose shares are aggregated) who has beneficially owned unregistered restricted securities for at least six months, including our affiliates, would be entitled to sell such securities, subject to the availability

of current public information about the Company. A person who has not been our affiliate at any time during the three months preceding a sale, and who has beneficially owned his shares for at least one year, would be entitled under Rule 144 to sell such shares without regard to any limitations under Rule 144. Under Rule 144, sales by our affiliates are subject to volume limitations, manner of sale provisions and notice requirements. Any substantial sale of common stock may have an adverse effect on the market price of our common stock by creating an excessive supply. Likewise, the availability for sale of substantial amounts of our common stock could reduce the prevailing market price.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, to offset future taxable income. Our existing NOLs may be subject to substantial limitations arising from previous ownership changes. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Section 382 of the Code. Our NOLs may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs. Furthermore, our ability to utilize our NOLs is conditioned upon our attaining profitability and generating U.S. federal taxable income. We have incurred net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; thus, we do not know whether or when we will generate the U.S. federal taxable income necessary to utilize our NOLs.

We have not paid dividends in the past and do not expect to pay dividends in the future.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all future earnings for the operation and expansion of our business and, therefore, do not anticipate declaring or paying cash dividends in the foreseeable future. The payment of dividends will be at the discretion of our Board of Directors and will depend on our results of operations, capital requirements, financial condition, prospects, contractual arrangements, any limitations on payments of dividends present in any of our future debt agreements and other factors our Board of Directors may deem relevant. If we do not pay dividends, a return on our stockholders' investment will only occur if our stock price appreciates.

Anti-takeover provisions in our certificate of incorporation, bylaws and Delaware law could prevent or delay a change in control.

We have 200,000,000 shares of common stock authorized, and 23,690,218 shares outstanding as of March 3, 2022. As a result, our Board will be able to issue a substantial number of additional shares of common stock, without seeking stockholder approval. In addition, provisions in our certificate of incorporation and bylaws, as well as provisions of Delaware law, may discourage, delay or prevent a merger, acquisition or change of control. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors and take other corporate actions. These provisions:

- permit our Board of Directors to issue shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in our control;
- provide that the authorized number of directors may be changed only by resolution of the Board of Directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the chairman of the Board of Directors, our Chief Executive Officer or by the Board of Directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and

- provide that stockholders will be permitted to amend our bylaws only upon receiving at least 66 2/3% of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any broad range of business combinations with any stockholder who owns, or at any time in the last three years owned, 15% or more of our outstanding voting stock, for a period of three years following the date on which the stockholder became an interested stockholder. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders.

We may fail to meet our publicly announced guidance or other expectations about our business and future operating results, which could cause a decline in our stock price.

We provide financial guidance about our business and future operating results. In developing this guidance, our management makes certain assumptions and judgments about our future operating performance, including projected hiring of personnel, continued increase of our revenue, and continued stability of the macro-economic environment in our key markets. Furthermore, analysts and investors may develop and publish their own projections of our business, which may form a consensus about our future performance. Our business results may vary significantly from such guidance or that consensus due to a number of factors, many of which are outside of our control, and which could adversely affect our operations and operating results. Furthermore, if we make downward revisions of our previously announced guidance, or if our publicly announced guidance of future operating results fails to meet expectations of securities analysts, investors, or other interested parties, the market price of our common stock could decline.

Securities analysts may not continue, or additional securities analysts may not initiate, coverage for our common stock or may issue negative reports. This may have a negative impact on the market price of our common stock.

Securities analysts provide research coverage of our common stock. Some analysts may publish statements that do not portray our technology, products or procedures using our product in a positive light. If we are unable to educate those who publicize such reports about the benefits we believe our business provides, or if one or more of the analysts who elects to cover us downgrades our stock, our stock price would likely decline rapidly. If one or more of these analysts ceases coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline. The trading market for our common stock may be affected in part by the research and reports that industry or financial analysts publish about us or our business. If sufficient securities analysts do not cover our common stock, the lack of research coverage may adversely affect the market price of our common stock. It may be difficult for companies such as ours, with smaller market capitalizations, to attract and maintain sufficient independent financial analysts that will cover our common stock. This could have a negative effect on the market price of our stock. We may fail to meet our publicly announced guidance or other expectations about our business and future operating results, which could cause a decline in our stock price.

General Risk Factors

We are dependent on our senior management team, our sales, clinical support and marketing team and our engineering team, and the loss of any of them could harm our business.

All our employees, including the members of our senior management team, are at-will employees, and therefore they may terminate employment with us at any time. Accordingly, there are no assurances that the services of any of our employees will be available to us for any specified period of time. The loss of members of our senior management team, our sales, clinical support and marketing team or our engineering team, or our inability to attract or retain other qualified personnel, could have a material adverse effect on our business, financial condition and results of operations. If the need to replace any of our key employees arises, the replacement process likely would involve significant time and costs, and may significantly delay or prevent the achievement of our business objectives.

Damage to our reputation could harm our businesses, including our competitive position and business prospects.

Our ability to attract and retain customers, suppliers, investors and employees is impacted by our reputation. Harm to our reputation can arise from various sources, including employee misconduct, security breaches, unethical behavior,

litigation or regulatory outcomes, the suitability or harm, which could, among other consequences, increase the size and number of litigation claims and damages asserted or subject us to enforcement actions, fines and penalties and cause us to incur related costs and expenses.

We could become subject to product liability or professional liability claims that could be expensive, divert management's attention and harm our business.

Our business exposes us to potential product liability risks that are inherent in the manufacturing, marketing and sale of medical devices. We may be held liable if our products cause injury or death or are found otherwise unsuitable or defective during usage. Our ClearPoint system and other products may incorporate mechanical and electrical parts, complex computer software and other sophisticated components, any of which can have defective or inferior parts or contain defects, errors or failures. Complex computer software is particularly vulnerable to errors and failures, especially when first introduced.

Because our products are designed to be used to perform complex surgical procedures, defects could result in a number of complications, some of which could be serious and could harm or kill patients. The adverse publicity resulting from any of these events could cause physicians or hospitals to review and potentially terminate their relationships with us.

We may also be subject to professional liability for errors in the clinical support that we provide to clinicians in connection with our products or for a misunderstanding of, or inappropriate reliance upon, the information we provide.

The medical device industry has historically been subject to extensive litigation over product liability and professional liability claims. A product liability or professional liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs. Although we maintain liability insurance that we believe is appropriate, this insurance coverage is subject to deductibles and coverage limitations, and may not be adequate to protect us against any future liability claims. Additionally, we may be unable to maintain our existing liability insurance in the future at satisfactory rates or in adequate amounts. A liability claim, regardless of its merit or eventual outcome, could result in:

- decreased demand for our products;
- injury to our reputation;
- diversion of management's attention;
- significant costs of related litigation;
- payment of substantial monetary awards by us;
- product recalls or market withdrawals;
- a change in the design, manufacturing process or the indications for which our marketed products may be used;
- loss of revenue; and
- an inability to commercialize product candidates.

Our operations are vulnerable to interruption or loss due to natural disasters, power loss and other events beyond our control, which would adversely affect our business.

We do not have redundant facilities. We conduct many of our activities, including research and development, component processing, final assembly, packaging and distribution activities for our ClearPoint system, at our facility located in Irvine, California, which is a seismically active area that has experienced major earthquakes in the past, as well as other natural disasters, including wildfires. We have taken precautions to safeguard our facility, including obtaining business interruption insurance. However, any future natural disaster, such as an earthquake or a wildfire, pandemics, such as the COVID-19 pandemic, or other unanticipated catastrophes, such as telecommunications failures, cyberattacks, or terrorist attacks, at any of the locations in which we or our key partners, suppliers and customers do business, could significantly disrupt our operations, and delay or prevent product assembly and shipment during the time required to repair, rebuild or replace our facility, which could be lengthy and result in significant expenses. Furthermore, the insurance coverage we maintain may not be adequate to cover our losses in any particular case or continue to be available at commercially reasonable rates and terms. In addition, our facility may be subject to shortages of electrical power, natural gas, water and other energy supplies. Any future shortage or conservation measure could disrupt our operations and cause expense, thus adversely affecting our business and financial results.

The requirements of being a public company may strain our resources and distract management.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended ("Exchange Act"), and the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley Act"). We are also subject to certain provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 ("Dodd-Frank Act"). The Exchange Act requires that we file annual, quarterly and current reports with respect to our business and financial condition. The Dodd-Frank Act requires the SEC to adopt certain rules and regulations relating to our public disclosures, corporate governance and executive compensation, among other things, and such rules and regulations require significant attention from management. Compliance with all of these laws, rules and regulations may from time to time divert management's attention from other business concerns, which could have a material adverse effect on our business, financial condition, results of operations and cash flows.

The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal controls over financial reporting and management is required to evaluate the effectiveness of our internal control over financial reporting as of the end of each fiscal year. To maintain the effectiveness of our disclosure controls and procedures and internal control over financial reporting, significant resources and management oversight is required. If we are not successful in maintaining effective internal control over financial reporting, there could be inaccuracies or omissions in the consolidated financial information we are required to file with the SEC. Additionally, even if there are no inaccuracies or omissions, we will be required to publicly disclose the conclusion of our management that our internal control over financial reporting or disclosure controls and procedures are not effective.

These events could cause investors to lose confidence in our reported financial information, adversely impact our stock price, result in increased costs to remediate any deficiencies, or attract regulatory scrutiny or lawsuits that could be costly to resolve and distract management's attention.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

Not applicable.

ITEM 2. PROPERTIES.

We lease approximately 7,500 square feet of space in Solana Beach, California, which serves as our corporate headquarters and houses certain management and research and development personnel. We also lease approximately 7,400 square feet of space in Irvine, California, which houses office space and a manufacturing facility. We believe that these facilities are sufficient to meet our current and near-term needs.

ITEM 3. LEGAL PROCEEDINGS.

In the ordinary course of our business, we may be subject to various claims, pending and potential legal actions for damages, investigations relating to governmental laws and regulations and other matters arising out of the normal conduct of our business. We are not aware of any material pending legal proceedings to which we are a party or of which any of our properties is the subject.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the Nasdaq Capital Market under the symbol "CLPT."

Holders

As of March 3, 2022, we had 23,690,218 shares of common stock outstanding and no shares of preferred stock outstanding. As of March 3, 2022, we had approximately 225 stockholders of record. In addition, as of March 3, 2022, options and warrants to purchase 2,012,922 shares of common stock were outstanding.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all future earnings for the operation and expansion of our business and, therefore, do not anticipate declaring or paying cash dividends in the foreseeable future. The payment of dividends will be at the discretion of our Board of Directors and will depend on our results of operations, capital requirements, financial condition, prospects, contractual arrangements, any limitations on payments of dividends present in any of our future debt agreements and other factors our Board of Directors may deem relevant.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by stockholders[(1)]	838,098	$ 10.14	718,384
Equity compensation plans not approved by stockholders[(1)(2)(3)(4)(5)(6)(7)]	512,375	$ 10.03	—
Total	1,350,473	$ 10.10	718,384

(1) The information presented in this table is as of December 31, 2021.

(2) In December 2013, we adopted our 2013 Non-Employee Director Equity Incentive Plan. The plan provides for the issuance of awards with respect to an aggregate of 14,250 shares of our common stock. As of December 31, 2021, awards with respect to 7,375 shares of our common stock were outstanding under the 2013 Non-Employee Director Equity Incentive Plan.

(3) In October 2014, we entered into a written compensatory contract with Francis P. Grillo, our then-Chief Executive Officer, pursuant to which we awarded Mr. Grillo non-qualified stock options to purchase 60,000 shares of our common stock.

(4) In December 2014, we entered into a written compensatory contract with Wendelin C. Maners, our then-Vice President, Marketing, pursuant to which we awarded Ms. Maners non-qualified stock options to purchase 8,750 shares of our common stock.

(5) In March 2015, we entered into a written compensatory contract with Harold A. Hurwitz, our then-Chief Financial Officer, pursuant to which we awarded Mr. Hurwitz non-qualified stock options to purchase 11,250 shares of our common stock.

(6) In November 2017, we entered into a written compensatory contract with Joseph M. Burnett, our Chief Executive Officer, pursuant to which we awarded Mr. Burnett a non-qualified stock option to purchase 350,000 shares of our common stock.

(7) In September 2020, we entered into a written compensatory contract with Danilo D'Alessandro, our Chief Financial Officer, pursuant to which we awarded Mr. D'Alessandro a non-qualified stock option to purchase 75,000 shares of our common stock.

ITEM 6. SELECTED FINANCIAL DATA.

Reserved.

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 related notes thereto included elsewhere in this Annual Report. This discussion and analysis contains forward-looking statements that are based upon current expectations and involve risks, assumptions and uncertainties. You should review the "Risk Factors" section of this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements described in the following discussion and analysis.

Overview

We are a commercial-stage medical device company that develops and commercializes innovative platforms for performing minimally invasive surgical procedures in the brain. We have deployed significant resources to fund our efforts to develop the foundational capabilities for enabling MRI-guided interventions, building an intellectual property portfolio, and identifying and building out commercial applications for the technologies developed by our company. In 2021, our efforts expanded beyond the MRI suite to encompass development and commercialization of new neurosurgical device products for the operating room, as well as consulting services for pharmaceutical companies.

Starting in 2020, ClearPoint Neuro has evolved to become a company comprised of two parts. The first foundational part is a medical device company providing medical devices for neurosurgery applications. The second part is focused on pharmaceutical companies in the biologics and drug delivery space, approximately 40 of whom are either evaluating or using our SmartFlow cannula and, in certain cases, in conjunction with our full ClearPoint Neuro Navigation platform.

Our ClearPoint system is in commercial use in the United States, the EU, and the United Kingdom. The primary applications for the ClearPoint system are to target and guide the insertion of deep brain stimulation electrodes, biopsy needles and laser catheters into the brain. The ClearPoint system was originally designed for use in an MRI setting. In 2021, we launched the SmartFrame Array Neuro Navigation System and Software, which allows for operating room placement of the ClearPoint system.

Our revenue is comprised primarily of: (1) product revenue resulting from the sale of functional neurosurgery, navigation, therapy, and biologics and drug delivery disposable products; (2) product revenue resulting from the sale of ClearPoint capital equipment and software; (3) revenue resulting from the service, installation, training and shipping related to ClearPoint capital equipment and software; and (4) consultation revenue and clinical case support revenue in connection with customer-sponsored clinical trials.

We have financed our operations and internal growth primarily through the sale of equity securities and the issuance of convertible and other secured notes. We have incurred significant losses since our inception in 1998 as we have devoted substantial efforts to research and development. As of December 31, 2021, we had accumulated losses of approximately $134 million. We may continue to incur operating losses as we expand our ClearPoint system platform and our business generally.

Factors Which May Influence Future Results of Operations

The following is a description of factors which may influence our future results of operations, and which we believe are important to an understanding of our business and results of operations.

COVID-19

In March 2020, the World Health Organization characterized the spread of a novel strain of coronavirus ("COVID-19") as a global pandemic, and the President of the United States later proclaimed that the COVID-19 outbreak in the United States constituted a national emergency. Extraordinary actions were taken by federal, state and local governmental authorities to combat the spread of COVID-19, including issuances of "stay-at-home" directives and similar mandates that substantially restricted daily activities and for many businesses curtailed or ceased normal operations. These measures led to reduced economic activity, including the postponement or cancellation of elective surgical procedures, which historically have represented approximately 80% of the number of surgical procedures using our ClearPoint system. Although economic activity is returning to normalized levels, new variants of COVID-19, such as Delta and Omicron, continue to spread in the United States and across the globe. The ultimate impact of the COVID-19 pandemic cannot be predicted at this time, and could depend on numerous factors, including vaccination rates among the population, the effectiveness of vaccines against different variants and the response by governmental bodies and regulators. We are unable to determine the timing and extent to which the vaccination process will affect the progression of the virus; the timing, adoption or viability of periodic resumption, if any, of elective procedures; and the resulting length of time that the COVID-19 pandemic will adversely affect our product revenues.

Furthermore, the recessionary conditions on the global economy caused by the COVID-19 pandemic could have a material adverse effect on our business. Although most segments of the United States economy have reopened, the effects of the COVID-19 pandemic remain intense in many areas of the country, and many public health experts continue to anticipate future surges of COVID-19 due to new variants. Accordingly, reinstatement of directives and mandates requiring businesses to again curtail or cease normal operations, including the postponement or cancellation of elective surgeries, remains a possibility. Additionally, global economic and supply chain disruptions, labor shortages, which may affect our ability to retain and attract new talent, and inflationary conditions caused by the COVID-19 pandemic could have a material adverse effect on our business. The rapid development and fluidity of the situation precludes any prediction as to the ultimate impact COVID-19 will have on our business, financial condition, results of operation and cash flows, which will depend largely on future developments directly or indirectly relating to the duration and scope of the COVID-19 outbreak in the United States.

Key Performance Indicators

The key performance indicators we utilize on a tactical basis are integrated into our longer-term strategic plan within the following categories:

- Functional neurosurgery navigation
    - Case volume – Underlying the revenue from sales of our functional neurosurgical navigation products reflected in the accompanying consolidated financial statements appearing elsewhere in this Annual Report are the procedures, or cases, performed in hospitals or at customer-sponsored contract research organizations utilizing one or more of our products or our clinical services. Case volume data is not influenced by variations in pricing or quantities of product used on a per case basis, and thus provide a more reliable indicator of the growth of our functional neurosurgery navigation line of business. Management analyzes case volume by customer and by type of procedure to gain information that informs targeted sales and marketing activities. During the year ended December 31, 2021, the ClearPoint system was used in 929 cases, as compared to 682 cases during 2020, representing an increase of 36%. Consistent with the discussion in the section "Results of Operations –Revenues," we attribute this increase primarily to the reduced levels of elective procedures resulting from the initial onset and progression of the COVID-19 pandemic during 2020.
    - Number of "Active Surgery Centers" – For purposes of analyzing this performance indicator, an Active Surgery Center is a hospital or customer-sponsored research organization that has purchased products from us or has performed procedures utilizing our ClearPoint system within a rolling 24-month period, and includes sites having purchased the ClearPoint system, as well as sites in which the ClearPoint system is being used on an evaluation basis. The justification for including "evaluation sites" is that our disposable neurosurgery product is sold to such sites for their use in cases. In addition to signifying growth, the number of Active Surgery Centers, when analyzed in conjunction with case volume data, further informs targeted sales and marketing activities and confirms where these activities have led to increased penetration of our product lines. As of December 31, 2021, the ClearPoint system was used in approximately 60 Active Surgery Centers, which is comparable to the number of such centers in 2020.

- Biologics and drug delivery
    - Number of "Partners" – Underlying the revenue from sales of products and services to our biologics and drug delivery customers is the number of customers, or "Partners." Our Partners consist of pharmaceutical and biotech companies, academic institutions, or customer-sponsored contract research organizations that are developing methods to deliver a wide variety of molecules, genes or proteins to targeted brain tissue or structures that would need to bypass the blood-brain barrier for the treatment of a variety of disorders. This business is a novel area in which commercialization must be preceded by FDA-mandated clinical trials, which are expensive and time consuming to conduct, and for which the commercial success is uncertain, pending, in part, the outcome of those trials. While our revenues from sales of products and services to these Partners in support of their clinical trials are indicative of growth, the number of such relationships is also of importance as we recognize the possibility that some Partners' research will reach commercial success, and others may not. To the extent our Partners achieve commercial success, our expectation is that we will share in such success through our Partners' use of our products and services in their delivery of therapies. At December 31, 2021, we had commercial relationships with approximately 40 Partners, as compared with approximately 25 Partners at December 31, 2020.

- Therapy products – We do not expect meaningful revenue from therapy products insofar as we are targeting a limited market release of such products in 2022. As a result, our milestones in the therapy space are focused on refining the product and obtaining regulatory clearance. Should we be successful in achieving these milestones, we believe our initial performance indicators will focus on case volume and number of Active Surgical Centers, as are currently used in measuring our performance in functional neurosurgery navigation.

- Global scale and efficiency – We have been cautious in setting our goals for operations beyond the U.S. so as to conserve our resources and not establish a foreign presence in advance of being assured of a corresponding revenue stream. In late 2020 we took the first steps in leveraging the CE Marks we have for our ClearPoint system and SmartFlow cannula by establishing an initial presence in Europe for product sales and clinical advisory services. From this initial presence, we believe that future global key performance indicators will be similar to those described above for our U.S. business: case volume, number of Active Surgery Centers and number of biologics and drug delivery Partners.

Revenues

In 2010, we received 510(k) clearance from the FDA to market our ClearPoint system in the U.S. for general neurosurgical procedures; in February 2011 and May 2018, we also obtained CE marketing approval for our ClearPoint system and SmartFlow cannula, respectively; and in June 2020 we obtained CE marking approval for version 2.0 of our ClearPoint software and our Inflexion head fixation frame. In January 2021, we received 510(k) clearance for the SmartFrame Array Neuro Navigation System. Future revenue from sales of our ClearPoint platform products and services is difficult to predict and may not be sufficient to offset our continuing research and development expenses and our increasing selling, general and administrative expenses.

Generating recurring revenue from the sale of products is an important part of our business model for our ClearPoint system. Our product revenue was approximately $11.9 million and $8.8 million for the years ended December 31, 2021 and 2020, respectively, and was almost entirely related to our ClearPoint system. Our service revenue was approximately $4.4 million and $4.0 million for the years ended December 31, 2021 and 2020, respectively.

Our revenue recognition policies are more fully described in the "Critical Accounting Estimates" section below.

Cost of Revenues

Cost of revenue includes the direct costs associated with the assembly and purchase of components for functional neurosurgery navigation products, biologics and drug delivery products, non-neurosurgery therapy products, and ClearPoint capital equipment which we have sold, and for which we have recognized the revenue in accordance with our revenue recognition policy. Cost of revenue also includes the allocation of manufacturing overhead costs and depreciation of loaned systems installed under our ClearPoint placement program, as well as provisions for obsolete, impaired, or excess inventory.

Research and Development Costs

Our research and development costs consist primarily of costs associated with the conceptualization, design, testing, and prototyping of our ClearPoint system products and enhancements. Such costs include salaries, travel, and benefits for research and development personnel, including related share-based compensation; materials and laboratory supplies in research and development activities; consultant costs; and licensing costs related to technology not yet commercialized. We anticipate that, over time, our research and development costs may increase as we: (i) continue to develop enhancements to our ClearPoint system; and (ii) seek to expand the application of our technological platforms. From our inception through December 31, 2021, we have incurred approximately $70 million in research and development expenses.

Product development timelines, likelihood of success, and total costs can vary widely by product candidate. There are also risks inherent in the regulatory clearance and approval process. At this time, we are unable to estimate with any certainty the costs that we will incur in our efforts to expand the application of our technological platforms.

Sales and Marketing, and General and Administrative Expenses

Our sales and marketing, and general and administrative expenses consist primarily of salaries, incentive-based compensation, travel and benefits, including related share-based compensation; marketing costs; professional fees, including fees for outside attorneys and outside accountants; occupancy costs; insurance; and other general and administrative expenses, which include, but are not limited to, corporate licenses, director fees, hiring costs, taxes, postage, office supplies and meeting costs. Our sales and marketing expenses are expected to increase due to costs associated with the commercialization of our ClearPoint system and the increased headcount necessary to support growth in operations.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the consolidated financial statements as well as the reported expenses during the reporting periods. The accounting estimates that require our most significant, difficult and subjective judgments are discussed below. We evaluate our estimates and judgments on an ongoing basis. Actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements included elsewhere in this Annual Report, we believe that the following accounting policies and estimates are most critical to a full understanding and evaluation of our reported financial results.

Revenue Recognition. Our revenue is comprised primarily of: (1) product revenue resulting from the sale of functional neurosurgery, navigation, therapy, and biologics and drug delivery disposable products; (2) product revenue resulting from the sale of ClearPoint capital equipment and software; (3) revenue resulting from the service, installation, training and shipping related to ClearPoint capital equipment and software; and (4) consultation revenue and clinical case support revenue in connection with customer-sponsored clinical trials. We recognize revenue when control of our products and services is transferred to its customers in an amount that reflects the consideration we expect to receive from our customers in exchange for those products and services, in a process that involves identifying the contract with a customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. When a contract calls for the satisfaction of multiple performance obligations for a single contract price, we allocate the contract price among the performance obligations based on the relative stand-alone prices for each such performance obligation we customarily charge. We consider a performance obligation satisfied once it has transferred control of a good or service to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service. We recognize revenue for satisfied performance obligations only when we determine there are no uncertainties regarding payment terms or transfer of control.

Lines of Business; Timing of Revenue Recognition

- *Functional neurosurgery navigation product, biologics and drug delivery systems product, and therapy product sales:* Revenue from the sale of functional neurosurgery navigation products (consisting of disposable products sold commercially and related to cases utilizing our ClearPoint system), biologics and drug delivery systems (consisting primarily of disposable products related to customer-sponsored clinical trials utilizing the ClearPoint system), and therapy products (consisting primarily of disposable laser-related products used in non-neurosurgical procedures) is generally based on customer purchase orders, the predominance of which require delivery within one week of the order having been placed, and are recognized at the point in time of delivery to the customer, which is the point at which legal title, and risks and rewards of ownership, along with physical possession, transfer to the customer.

- *Capital equipment and software sales:*

    - *Capital equipment and software sales preceded by evaluation periods:* The predominance of capital equipment and software sales (consisting of integrated computer hardware and software that are integral components of our ClearPoint system) are preceded by customer evaluation periods. During these evaluation periods, installation of, and training of customer personnel on, the systems have been completed and the systems have been in operation. Accordingly, revenue from capital equipment and software sales following such evaluation periods is recognized at the point in time that we are in receipt of an executed purchase agreement or purchase order.

    - *Capital equipment and software sales not preceded by evaluation periods:* Revenue from sales of capital equipment and software not having been preceded by an evaluation period is recognized at the point in time that the equipment and software has been delivered to the customer.

For both types of capital equipment and software sales described above, our determination of the point in time at which to recognize revenue represents that point at which the customer has legal title, physical possession, and the risks and rewards of ownership, and we have a present right to payment.

- *Functional neurosurgery navigation and therapy services:* We recognize revenue for such services at the point in time that the performance obligation has been satisfied.

- *Biologics and drug delivery services:*

    - *Consultation Services:* We recognize consultation revenue at the point in time such services are performed.

    - *Clinical Service Access Fees:* For contracts in which we receive a periodic fixed fee, irrespective of the number of cases attended by our personnel during such periods, revenue is recognized ratably over the period covered by such fees. A time-elapsed output method is used for such fees because we transfer control evenly by providing a stand-ready service.

    - *Clinical Service Procedure-Based Fees:* We recognize revenue at the point in time a case is attended by our personnel.

- *Capital equipment-related services:*

    - *Equipment service:* Revenue from service of ClearPoint capital equipment and software previously sold to customers is based on agreements with terms ranging from one to three years and revenue is recognized ratably on a monthly basis over the term of the service agreement. A time-elapsed output method is used for service revenue because we transfer control evenly by providing a stand-ready service.

      We may also enter into contracts with customers who own ClearPoint capital equipment, which bundle maintenance and support services and access to software and hardware upgrades made commercially available over the term of the contract, for a single contract price, typically paid on an annual basis. We allocate the contract price among the performance obligations based on the relative

stand-alone prices for each such performance obligation and recognize the revenue ratably on a monthly basis. In line with equipment service, a time-elapsed output method is used as we are providing a stand-ready service.

- *Installation, training, and shipping:* Consistent with our recognition of revenue for capital equipment and software sales as described above, fees for installation, training, and shipping in connection with sales of capital equipment and software that have been preceded by customer evaluation periods are recognized as revenue at the point in time we are in receipt of an executed purchase order for the equipment and software. Installation, training, and shipping fees related to capital equipment and software sales not having been preceded by an evaluation period are recognized as revenue at the point in time that the related services are performed.

Inventory. Inventory is carried at the lower of cost (first-in, first-out method) or net realizable value. Items in inventory relate predominantly to our functional neurosurgical products, drug delivery and biologic products, therapy products and ClearPoint capital equipment. Software license inventory related to ClearPoint systems undergoing on-site customer evaluation is included in inventory in the accompanying consolidated balance sheets. All other software license inventory is classified as a non-current asset. We periodically review our inventory for obsolete items and provide a reserve upon identification of potentially obsolete items.

Share-Based Compensation. We account for compensation for all arrangements under which employees and others receive shares of stock or other equity instruments (including options and warrants) based on fair value. The fair value of each award is estimated as of the grant date and amortized as compensation expense over the requisite vesting period. The fair values of our share-based awards are estimated on the grant dates using the Black-Scholes valuation model. This valuation model requires the input of highly subjective assumptions, including the expected stock volatility, estimated award terms and risk-free interest rates for the expected terms. To estimate the expected terms, we utilize the simplified method for "plain vanilla" options discussed in the SEC's Staff Accounting Bulletin 107, or SAB 107. We believe that all factors listed within SAB 107 as prerequisites for utilizing the simplified method apply to us and to our share-based compensation arrangements. We intend to utilize the simplified method for the foreseeable future until more detailed information about exercise behavior becomes available. We base our estimate of expected volatility on the average of historical volatilities of publicly traded companies we deem similar to us because we lack our own relevant historical volatility data. We will consistently apply this methodology until we have sufficient historical information regarding the volatility of our own share prices to use as the input for all of our share-based fair value calculations. We utilize risk-free interest rates based on a zero-coupon U.S. treasury instrument, the term of which is consistent with the expected term of the share-based award. We have not paid, and do not anticipate paying, cash dividends on shares of our common stock; therefore, the expected dividend yield is assumed to be zero.

Results of Operations

Comparison of the Year Ended December 31, 2021 to the Year Ended December 31, 2020

	Year Ended December 31,		Percentage
(Dollars in thousands)	**2021**	**2020**	**Change**
Product revenue	$ 11,913	$ 8,832	35 %
Service and other revenue	4,386	3,997	10 %
Total revenue	16,299	12,829	27 %
Cost of revenue	5,008	3,709	35 %
Gross Profit	11,291	9,120	24 %
Research and development costs	8,985	4,686	92 %
Sales and marketing expenses	6,919	5,384	29 %
General and administrative expenses	8,761	5,270	66 %
Other income (expense):			
Other (expense) income, net	(63)	882	(107) %
Interest expense, net	(973)	(1,444)	(33) %
Net loss	$ (14,410)	$ (6,782)	112 %

Revenue. Total revenue was approximately $16.3 million and $12.8 million for the years ended December 31, 2021 and 2020, respectively.

Functional neurosurgery navigation and therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 30% to $8.1 million during the year ended December 31, 2021 from $6.2 million for the same period in 2020. This increase reflects the resumption in 2021 of elective surgery procedures, which were postponed or cancelled during 2020 due to the effects of the COVID-19 pandemic. Although elective surgeries resumed during the year ended December 31, 2021, with the emergence of new COVID-19 variants we are unable to determine the extent to which such factors as the timing, adoption or viability of such resumption will impact our revenue due to the persistence of the COVID-19 pandemic and our inability to determine the length of time that the COVID-19 pandemic will adversely affect our product revenue. There were no material increases in functional neurosurgery navigation product prices during the period between the year ended December 31, 2021 and the same period in 2020 that would be reasonably expected to affect a typical customer order.

Biologics and drug delivery revenue, which include sales of disposable products and services related to customer-sponsored clinical trials utilizing our products, increased 31% to $6.8 million for the year ended December 31, 2021, from $5.2 million for the same period in 2020. This increase was due to an increase in biologic and drug delivery product revenue of $1.8 million for the year ended December 31, 2021 due to an increase in the number of biologics and drug delivery customers and as customer-sponsored pre-clinical research and customer-sponsored clinical trials resumed from the same period in 2020. This increase notwithstanding, our biologic and drug delivery customers are reestablishing their estimated timelines for initiation or resumption of their clinical trials, however, these timelines have not been finalized, given the uncertainties of when hospitals will be able to resume such clinical trial cases. Accordingly, depending on the length and severity of the COVID-19 pandemic, future biologics and drug delivery revenue could be adversely impacted. There were no increases in biologics and drug delivery product prices during 2021 that would be reasonably expected to affect a typical customer order.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, stayed relatively consistent at $1.4 million for the years ended December 31, 2021 and 2020. While revenue from this product line historically has varied from quarter to quarter, we believe that hospitals' capital equipment acquisition activities remained at a low level, relative to the acquisition activity prior to the onset of the COVID-19 pandemic. There were no increases in capital equipment product prices during the period between the year ended December 31, 2021 and the same period in 2020 that would be reasonably expected to affect a typical customer order.

Cost of Revenue and Gross Profit. Cost of revenue was $5.0 million, resulting in gross profit of $11.3 million and gross margin of 69%, for the year ended December 31, 2021, compared to $3.7 million, resulting in gross profit of $9.1 million and gross margin of 71% for the year ended December 31, 2020. This decrease in gross margin was due primarily to an increase in overhead allocated to costs of sales in 2021 as compared to 2020. This was partially offset by an increased contribution of disposable products and service revenue during the year ended December 31, 2021 as compared to the same period in 2020, which carry a higher gross margin relative to other revenue lines, and a reduced contribution during the same comparative periods in sales of capital equipment, which carry a lower gross margin relative to other product lines.

Research and Development Costs. Research and development costs were $9.0 million for the year ended December 31, 2021, compared to $4.7 million for the same period in 2020, an increase of $4.3 million, or 92%. The increase was due primarily to increases in personnel costs of $2.3 million, due to growth in headcount, and product and software development of $2.2 million, both increases resulting from our efforts to develop new products and expand the applications of our technological platform, offset slightly by lower amortization.

Sales and Marketing Expenses. Sales and marketing expenses were $6.9 million for the year ended December 31, 2021, compared to $5.4 million for the same period in 2020, an increase of $1.5 million, or 29%. This increase was primarily due to increases in personnel costs of $1.0 million resulting from our geographical expansion and increases in headcount in our clinical and marketing teams, travel expense of $0.4 million due to increased activity, and marketing activity of $0.1 million.

General and Administrative Expenses. General and administrative expenses were $8.8 million for the year ended December 31, 2021, compared to $5.3 million for the same period in 2020, an increase of $3.5 million, or 66%. This increase was due primarily to increases in share-based compensation of $1.0 million, professional fees of $0.4 million, personnel costs of $0.4 million, insurance costs of $0.4 million, state franchise taxes of $0.4 million, occupancy costs of $0.3 million, IT costs of $0.2 million, and the allowance for doubtful accounts of $0.2 million.

Other Expense/Income. Other expense was $0.1 million for the year ended December 31, 2021, compared to other income of $0.9 million for the same period in 2020. This decrease was due primarily to the gain recognized on the forgiveness of the PPP Loan in November 2020, the proceeds of which we received in April 2020. Additional information with respect to the PPP Loan is in Note 6 to the consolidated financial statements included elsewhere in this Annual Report.

Interest Expense, net. Net interest expense for the year ended December 31, 2021 was $1.0 million, compared with $1.4 million for the same period in 2020. The decrease in interest expense is primarily due to the repayment of the 2010 Secured Notes in the first quarter of 2020, the conversion of one of the First Closing Notes in May 2021 and the conversion of the Second Closing Note in November 2021. Additional information related thereto is in Note 6 to the consolidated financial statements included elsewhere in this Annual Report.

Liquidity and Capital Resources

At December 31, 2021, we had cash and cash equivalent balances aggregating $54.1 million, resulting primarily from the 2021 public equity offering and the private note issuances pursuant to the 2020 Financing Transaction as discussed in Notes 8 and 6, respectively, to the consolidated financial statements included elsewhere in this Annual Report and as discussed further below.

We have incurred net losses since our inception which has resulted in a cumulative deficit at December 31, 2021 of approximately $134 million. In addition, our use of cash from operations amounted to $12.7 million for the year ended December 31, 2021. Since inception, we have financed our operations principally from the sale of equity securities and the issuance of notes payable.

In January 2020, we entered into the Securities Purchase Agreement (the "SPA") with the 2020 Convertible Noteholders under which we issued the First Closing Notes having an aggregate principal amount of $17.5 million, resulting in proceeds, net of financing costs and a commitment fee paid to one of the 2020 Convertible Noteholders, of approximately $16.8 million. From the net proceeds received from the issuance of the First Closing Notes, which have a five-year term, we repaid and retired the 2010 Secured Notes that otherwise would have matured in October and November 2020.

The SPA also gave us the right, but not the obligation, to request one of the 2020 Convertible Noteholders to purchase an additional $5.0 million in principal amount of the Second Closing Note. On December 29, 2020, under the terms of an Amendment to the SPA which, among other provisions, increased the principal amount of the Second Closing Note, we issued the Second Closing Note to the 2020 Convertible Noteholder in the principal amount of $7.5 million.

Additional information with respect to the 2020 Secured Notes is in Notes 6 to the consolidated financial statements included elsewhere in this Annual Report.

As discussed in Note 8 to the consolidated financial statements included elsewhere in this Annual Report, on February 23, 2021, we completed a public offering of 2,127,660 shares of our common stock. Net proceeds from the offering were approximately $46.8 million after deducting the underwriting discounts and commissions and other estimated offering expenses payable by us.

Based on the foregoing, in management's opinion, cash and cash equivalent balances at December 31, 2021, are sufficient to support the Company's operations and meet its obligations for at least the next twelve months.

Cash Flows

Cash activity for the years ended December 31, 2021 and 2020 is summarized as follows:

	Years Ended December 31,	
(in thousands)	**2021**	**2020**
Cash from operating activities	$ (12,697)	$ (7,807)
Cash from investing activities	(168)	(482)
Cash from financing activities	46,875	22,692
Net change in cash and cash equivalents	$ 34,010	$ 14,403

Net Cash Flows from Operating Activities. We used $12.7 million and $7.8 million of cash for operating activities in 2021 and 2020, respectively.

In 2021, uses of cash in operating activities consisted primarily of: (i) our $14.4 million loss; (ii) an increase in accounts receivable of $0.7 million and inventory of $1.7 million; and (iii) a decrease in lease liabilities of $0.4 million. These uses were offset primarily by: (a) an increase in accounts payable and accrued expenses of $1.3 million; and (b) net non-cash expenses included in our net loss aggregating $3.4 million and consisting primarily of changes in the allowance for doubtful accounts, expenses related to share-based compensation, payment-in-kind interest, and net amortization of lease right of use assets.

In 2020, uses of cash in operating activities consisted primarily of: (i) our $6.8 million loss; (ii) an increase in accounts receivable of $0.8 million; and (iii) decreases in accounts payable and accrued expenses of $0.5 million, accrued interest of $1.0 million, and deferred revenue of $0.4 million. These uses were offset primarily by net non-cash expenses included in our net loss aggregating $1.6 million and consisting primarily of expenses related to depreciation and amortization, share-based compensation, amortization of debt issuance costs and original issue discounts and net amortization of lease right of use assets, which were partially offset by the gain recognized with the forgiveness of the PPP loan.

Net Cash Flows from Investing Activities. Net cash flows used in investing activities in 2021 were $0.2 million and consisted of equipment acquisitions.

Net cash flows used in investing activities in 2020 were $0.5 million and consisted primarily of an acquisition of medical device license rights.

Net Cash Flows from Financing Activities. Net cash provided by financing activities in 2021 consisted of: (a) the proceeds, net offering costs, of $46.8 million received from the public offering of our common stock; and (b) proceeds from the exercise of common stock options and warrants aggregating $0.5 million and (c) issuance of common stock under the employee stock purchase plan of $0.2 million, which were partially offset by tax payments of $0.6 million related to shares withheld in connection with vesting of restricted stock awards.

Net cash provided by financing activities in 2020 consisted of proceeds from: (a) the issuance of the 2020 Secured Notes amounting to $24.3 million net of financing cost and discount; (b) the PPP Loan, amounting to $0.9 million; and (c) the exercise of common stock warrants and options, amounting to $0.4 million, which were partially offset by repayments of notes payable amounting to $2.8 million.

Operating Capital and Capital Expenditure Requirements

To date, we have not achieved profitability. We could continue to incur net losses as we continue our efforts to expand the commercialization of our ClearPoint system products and pursue additional applications for our technology platforms. Our cash balances are typically held in a variety of demand accounts with a view to liquidity and capital preservation.

Because of the numerous risks and uncertainties associated with the development and commercialization of medical devices, we are unable to estimate the exact amounts of capital outlays and operating expenditures necessary to successfully commercialize our ClearPoint system products and pursue additional applications for our technology platforms. Our future capital requirements will depend on many factors, including, but not limited to, the following:

- the timing of broader market acceptance and adoption of our ClearPoint system products;
- the scope, rate of progress and cost of our ongoing product development activities relating to our ClearPoint system;
- the cost and timing of expanding our sales, clinical support, marketing and distribution capabilities, and other corporate infrastructure;
- the cost and timing of establishing inventories at levels sufficient to support our sales;
- the effect of competing technological and market developments;
- the cost of pursuing additional applications of our technology platforms under current collaborative arrangements, and the terms and timing of any future collaborative, licensing or other arrangements that we may establish;
- the cost and timing of any clinical trials;

- the cost and timing of regulatory filings, clearances and approvals; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The Report of Independent Registered Public Accounting Firm and Financial Statements are set forth on pages F-1 to F-25 of this Annual Report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Management's Evaluation of Disclosure Controls and Procedures

We have established disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, or the Exchange Act. Our disclosure controls and procedures are designed to ensure that material information relating to us is made known to our principal executive officer and principal financial officer by others within our organization. Under their supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2021, to ensure that the 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 periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange 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. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2021.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. 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 United States generally accepted accounting principles. Any system of internal control, no matter how well designed, has inherent limitations, including the possibility that a control can be circumvented or overridden and misstatements due to error or fraud may occur and not be detected. Also, because of changes in conditions, internal control effectiveness may vary over time. Accordingly, even an effective system of internal control will provide only reasonable assurance that the objectives of the internal control system are met.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2021, based on the criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2021.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's assessment was not subject to attestation by our independent registered public accounting firm pursuant to rules of the SEC that permit us to provide only management's assessment in this Annual Report.

Changes in Internal Control over Financial Reporting

During the year ended December 31, 2021, there were no changes in our internal control over financial reporting that materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by this item is incorporated by reference from the definitive proxy statement to be filed within 120 days after December 31, 2021, pursuant to Regulation 14A under the Exchange Act in connection with our 2022 annual meeting of stockholders.

Item 405 of Regulation S-K calls for disclosure of any known late filing or failure by an insider to file a report required by Section 16(a) of the Exchange Act. To the extent disclosure for delinquent reports is being made, it can be found under the caption "Delinquent Section 16(a) Reports" in our definitive proxy statement and, in accordance with General Instruction G to Form 10-K, is hereby incorporated herein by reference.

Our Board of Directors has adopted a Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics applies to all of our employees, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions), agents and representatives, including directors and consultants. The Code of Business Conduct and Ethics is posted on our website at www.clearpointneuro.com. We will provide a copy of this document to any person, without charge, upon request, by writing to our Investor Relations Department, 120 S. Sierra Ave. Suite 100, Solana Beach, CA 92075. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics, or waivers of such provisions, applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, persons performing similar functions or our directors on our website identified above. The inclusion of our website address in this Annual Report does not include or incorporate by reference the information on our website into this Annual Report.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the definitive proxy statement to be filed within 120 days after December 31, 2021, pursuant to Regulation 14A under the Exchange Act in connection with our 2022 annual meeting of stockholders.

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 definitive proxy statement to be filed within 120 days after December 31, 2021, pursuant to Regulation 14A under the Exchange Act in connection with our 2022 annual meeting of stockholders.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required by this item is incorporated by reference from the definitive proxy statement to be filed within 120 days after December 31, 2021, pursuant to Regulation 14A under the Exchange Act in connection with our 2022 annual meeting of stockholders.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required by this item is incorporated by reference from the definitive proxy statement to be filed within 120 days after December 31, 2021 pursuant to Regulation 14A under the Exchange Act in connection with our 2022 annual meeting of stockholders.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)(1) The following documents are filed under "Item 8. Financial Statements and Supplementary Data," pages F-2 through F-8, and are included as part of this Annual Report:

(a)(2) Financial statement schedules are omitted as they are not applicable.

(a)(3) See Item 15(b) below.

(b) Exhibits

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation	10-Q	000-54575	3.1	May 11, 2012
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of MRI Interventions, Inc.	8-K	000-54575	3.1	June 8, 2015
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of MRI Interventions, Inc.	S-1	333-211647	3.3	August 2, 2016
3.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of ClearPoint Neuro, Inc.	8-K	001-34822	3.1	February 12, 2020
3.5	Amended and Restated Bylaws	10-Q	000-54575	3.2	May 11, 2012
3.6	Second Amended and Restated Bylaws of ClearPoint Neuro, Inc.	8-K	001-34822	3.2	February 12, 2020
3.7	Third Amended and Restated Bylaws of ClearPoint Neuro, Inc.	8-K	001-34822	3.1	December 17, 2021
4.1	Reference is made to Exhibits 3.1 through 3.7				
4.2	Specimen of Common Stock Certificate of ClearPoint Neuro, Inc.	8-K	001-34822	4.1	February 12, 2020
4.3	Form of Junior Secured Promissory Note Due 2020, as amended by that certain Omnibus Amendment dated as of April 5, 2011, as further amended by that certain Second Omnibus Amendment dated as of October 14, 2011	10	000-54575	4.4	December 28, 2011
4.4	Form of Warrant to Purchase Common Stock issued in 2017 private offering	8-K	001-34822	4.1	May 25, 2017

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
4.5	Form of Senior Secured Convertible Note (First Closing)	8-K	001-34822	4.1	January 13, 2020
4.6	Form of Senior Secured Convertible Note (Second Closing)	8-K	001-34822	4.1	December 29, 2020
4.7	Form of Senior Secured Convertible Note (Third Closing)	8-K	001-34822	4.3	January 13, 2020
4.8	Fourth Omnibus Amendment to the Junior Secured Promissory Notes Due 2020, dated January 27, 2020	8-K	001-34822	4.4	January 29, 2020
4.17	Description of Securities	10-K	001-34822	4.23	March 27, 2020
10.1†	License Agreement by and between SurgiVision, Inc. and The Johns Hopkins University entered into on or around June 20, 1998, as amended by that certain Amendment to License Agreement dated as of January 15, 2000, and as further amended by that certain Addendum to License Agreement entered into on or around December 7, 2004	10	000-54575	10.9	December 28, 2011
10.2†	License Agreement by and between SurgiVision, Inc. and The Johns Hopkins University entered into on or around December 7, 2006	10	000-54575	10.10	December 28, 2011
10.3†	License Agreement by and between SurgiVision, Inc. and The Johns Hopkins University entered into on or around June 30, 2008	10	000-54575	10.21	December 28, 2011
10.4†	Technology License Agreement dated as of December 30, 2005 by and between SurgiVision, Inc. and Boston Scientific Neuromodulation Corporation (formerly known as Advanced Bionics Corporation), as amended by that certain Omnibus Amendment dated June 30, 2007, as further amended by that certain Omnibus Amendment #2 dated March 19, 2008	10	000-54575	10.11	March 15, 2012
10.5†	System and Lead Development and Transfer Agreement dated as of December 30, 2005 by and between SurgiVision, Inc. and Boston Scientific Neuromodulation Corporation (formerly known as Advanced Bionics Corporation), as amended by that certain Amendment No. 1 dated May 31, 2006, as further amended by that certain Omnibus Amendment dated June 30, 2007, as further amended by that certain Omnibus Amendment #2 dated March 19, 2008	10	000-54575	10.12	March 15, 2012

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.6†	Omnibus Amendment No. 3 to Technology License Agreement and System and Lead Development and Transfer Agreement effective February 2, 2012, between MRI Interventions, Inc. and Boston Scientific Neuromodulation Corporation	10	000-54575	10.38	March 15, 2012
10.7†	Omnibus Amendment No. 4 to Technology License Agreement and System and Lead Development and Transfer Agreement , between MRI Interventions, Inc. and Boston Scientific Neuromodulation Corporation, effective March 19, 2014	10-Q/A	000-54575	10.5	August 29, 2014
10.8†	Technology License Agreement dated as of March 19, 2008 by and between SurgiVision, Inc. and Cardiac Pacemakers, Inc.	10	000-54575	10.13	December 28, 2011
10.9†	Omnibus Amendment No. 1 to Technology License Agreement and Development Agreement between MRI Interventions, Inc. and Cardiac Pacemakers, Inc., dated March 19, 2014	10-Q/A	000-54575	10.4	August 29, 2014
10.10†	Development Agreement dated as of March 19, 2008 by and between SurgiVision, Inc. and Cardiac Pacemakers, Inc.	10	000-54575	10.14	December 28, 2011
10.11†	Asset Purchase Agreement dated March 19, 2014 between MRI Interventions, Inc. and Boston Scientific Neuromodulation Corporation	10-Q/A	000-54575	10.2	August 29, 2014
10.12†	Exclusive License Agreement dated March 19, 2014 between MRI Interventions, Inc. and Boston Scientific Neuromodulation Corporation	10-Q/A	000-54575	10.3	August 29, 2014
10.13†	Development Agreement between MRI Interventions, Inc. and Siemens Medical Solutions USA, Inc.	10-Q/A	000-54575	10.1	August 29, 2014
10.14†	Co-Development and Distribution Agreement dated as of April 5, 2011 by and between SurgiVision, Inc. and Brainlab AG, as amended by that certain First Amendment dated as of July 18, 2011	10	000-54575	10.17	March 15, 2012
10.15†	Second Amendment to Co-Development and Distribution Agreement, dated March 6, 2013, between MRI Interventions, Inc. and Brainlab AG	8-K	000-54575	10.1	March 7, 2013
10.16†	Master Services and Licensing Agreement dated as of July 20, 2007 by and between SurgiVision, Inc. and Cedara Software Corp., as amended by that certain First Amendment dated January 18, 2011	10	000-54575	10.20	March 15, 2012

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.17†	Second Amendment to the Master Services and Licensing Agreement, dated as of June 22, 2012, by and between Merge Healthcare Canada Corp. and MRI Interventions, Inc.	8-K	000-54575	10.1	June 26, 2012
10.18†	Third Amendment to the Master Services and Licensing Agreement, dated as of July 28, 2013, by and between Merge Healthcare Canada Corp. and MRI Interventions, Inc.	10-Q	000-54575	10.56	August 14, 2013
10.19	License and Collaboration Agreement, dated April 25, 2017, by and between MRI Interventions, Inc. and Acoustic Medsystems, Inc.	10-Q	001-34822	10.1	May 9, 2017
10.20†	License and Collaboration Agreement, dated as of October 16, 2018, by and between MRI Interventions, Inc. and Clinical Laserthermia Systems AB	10-Q	001-34822	10.2	November 13, 2018
10.21†	Distribution Agreement, dated as of October 16, 2018, by and between MRI Interventions, Inc. and Clinical Laserthermia Systems AB	10-Q	001-34822	10.3	November 13, 2018
10.22	Lease Agreement, dated as of April 21, 2008, by and between Shaw Investment Company, LLC and Surgi-Vision, Inc., as amended by that certain Amendment to Lease dated January 20, 2011, as further amended by that certain Amendment to Lease dated March 26, 2012	10-Q	000-54575	10.27	May 11, 2012
10.23	Second Amendment to Lease Agreement dated as of February 24, 2015, by and between Shaw Investment Company, LLC and MRI Interventions, Inc.	10-K	000-54575	10.24	March 17, 2015
10.24	Third Amendment to Lease Agreement, dated as of April 18, 2018, by and between Shaw Investment Company, LLC and MRI Interventions, Inc.	10-Q	001-34822	10.1	August 14, 2018
10.25+	2010 Incentive Compensation Plan	10	000-54575	10.4	December 28, 2011
10.26+	2010 Non-Qualified Stock Option Plan	10	000-54575	10.5	December 28, 2011
10.27+	MRI Interventions, Inc. 2012 Incentive Compensation Plan	10	000-54575	10.34	February 9, 2012
10.28+	MRI Interventions, Inc. Amended and Restated 2013 Incentive Compensation Plan	Schedule 14A	000-54575	B	April 17, 2015
10.29+	Second Amended and Restated 2013 Incentive Compensation Plan	Schedule 14A	001-34822	A	September 5, 2017
10.30+	MRI Interventions, Inc. 2013 Incentive Compensation Plan Form of Incentive Stock Option Agreement	10-Q	000-54575	10.53	August 14, 2013

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.31+	MRI Interventions, Inc. 2013 Incentive Compensation Plan Form of Non-Qualified Stock Option Agreement	10-Q	000-54575	10.54	August 14, 2013
10.32+	MRI Interventions, Inc. 2013 Incentive Compensation Plan Form of Non-Qualified Stock Option Agreement for Non-Employee Directors	10-Q	000-54575	10.55	August 14, 2013
10.33+	MRI Interventions, Inc. 2013 Incentive Compensation Plan Form of Restricted Share Award Agreement	10-Q	001-34822	10.2	August 12, 2019
10.34+	MRI Interventions, Inc. 2013 Non-Employee Director Equity Incentive Plan Form of Non-Qualified Stock Option Agreement	10-K	000-54575	10.41	March 28, 2014
10.35+	Employment Agreement, dated as of June 19, 2012, by and between Peter G. Piferi and MRI Interventions, Inc.	8-K	000-54575	10.2	June 21, 2012
10.36+	Non-Competition Agreement between Harold A. Hurwitz and MRI Interventions, Inc.	10-Q	000-54575	10.2	May 7, 2015
10.37+	Non-Disclosure and Proprietary Rights Agreement between Harold A. Hurwitz and MRI Interventions, Inc.	10-Q	000-54575	10.3	May 7, 2015
10.38+	Second Amended and Restated Key Personnel Incentive Program	10-Q	000-54575	10.3	August 14, 2013
10.39+	Second Amended and Restated Key Personnel Incentive Award Agreement, dated June 13, 2013, by and between MRI Interventions, Inc. and Paul A. Bottomley	10-Q	000-54575	10.31	August 14, 2013
10.40+	Amended and Restated Key Personnel Incentive Award Agreement, dated June 13, 2013, by and between MRI Interventions, Inc. and Paul A. Bottomley	10-Q	000-54575	10.32	August 14, 2013
10.41+	Second Amended and Restated Key Personnel Incentive Award Agreement, dated June 13, 2013, by and between MRI Interventions, Inc. and Parag V. Karmarkar	10-Q	000-54575	10.33	August 14, 2013
10.42+	SurgiVision, Inc. Cardiac EP Business Participation Plan	10	000-54575	10.29	December 28, 2011
10.43+	Cardiac EP Business Participation Plan Award Agreement, dated June 3, 2010, by and between SurgiVision, Inc. and Nassir F. Marrouche	10	000-54575	10.30	December 28, 2011
10.44+	Non-Qualified Stock Option Agreement, effective as of December 5, 2013, granted by MRI Interventions, Inc. to Parag Karmarkar	10-K	000-54575	10.56	March 28, 2014
10.45+	Non-Qualified Stock Option Agreement, effective as of October 6, 2014, granted by MRI Interventions, Inc. to Francis P. Grillo	S-1	333-201471	10.63	January 13, 2015

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.46+	Non-Qualified Stock Option Agreement, effective as of December 1, 2014, granted by MRI Interventions, Inc. to Wendelin C. Maners	S-1	333-201471	10.65	January 13, 2015
10.47+	Non-Qualified Stock Option Agreement, effective as of March 30, 2015 granted by MRI Interventions, Inc. to Harold A. Hurwitz	10-Q	000-54575	10.1	August 10, 2015
10.48+	Employment Agreement, dated as of October 6, 2017, by and between MRI Interventions, Inc. and Joseph Michael Burnett	8-K	001-34822	10.2	October 10, 2017
10.49	Securities Purchase Agreement, dated January 11, 2020, by and among MRI Interventions, Inc., each investor identified on the signature pages thereto, and Petrichor Opportunities Fund I LP, as collateral agent.	8-K	001-34822	10.1	January 13, 2020
10.50	First OmnibusAmendment to Securities Purchase Agreement and Senior Secured Promissory Notes, dated January 29, 2020, by and among MRI Interventions, Inc., PTC Therapeutics, Inc., and Petrichor Opportunities Fund I LP	8-K	001-34822	10.2	January 29, 2020
10.51	Security Agreement, dated January 29, 2020, by and between MRI Interventions, Inc. and Petrichor Opportunities Fund I LP, in its capacity as collateral agent	8-K	001-34822	10.3	January 29, 2020
10.52	Third Amended and Restated 2013 Incentive Compensation Plan	DEF14A	001-34822	Appendix A	April 20, 2020
10.53	Transition Agreement, dated as of September 14, 2020, by and between the Company and Harold A. Hurwitz	8-K	001-34822	10.1	September 14, 2020
10.54+	Employment Agreement, dated as of September 14, 2020, by and between the Company and Danilo D'Alessandro	8-K	001-34822	10.2	September 14, 2020
10.55	Second Omnibus Amendment to the Securities Purchase Agreement and Senior Secured Convertible Notes, dated December 29, 2020, by and among ClearPoint Neuro, Inc., each investor identified on the signature pages thereto, and Petrichor Opportunities Fund I LP, as collateral agent.	8-K	001-34822	10.1	December 29, 2020
10.56+	Form of Indemnification Agreement	8-K	001-34822	10.2	June 28, 2021
10.57+	2021 Employee Stock Purchase Plan	DEF14A	001-34822	Appendix A	April 20, 2021

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.58+	ClearPoint Neuro, Inc. Non-Employee Director Compensation Plan, as amended and restated by the Board of Directors on June 25, 2021	8-K	001-34822	10.1	June 28, 2021
21*	Subsidiaries of ClearPoint Neuro, Inc.				
23.1*	Consent of Cherry Bekaert LLP				
24.1*	Power of Attorney (included on the signature pages hereto)				
31.1*	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934				
31.2*	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) Under the Securities Exchange Act of 1934				
32++	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Rule 13a-14(b) Under the Securities Exchange Act of 1934 and Section 1350 of Chapter 60 of Title 18 of the United States Code				
101.INS*	XBRL Instance				
101.SCH*	XBRL Taxonomy Extension Schema				
101.CAL*	XBRL Taxonomy Extension Calculation				
101.DEF*	XBRL Taxonomy Extension Definition				
101.LAB*	XBRL Taxonomy Extension Labels				

* Filed herewith.

† Confidential treatment granted under Rule 24b-2 under the Securities Exchange Act of 1934. The confidential portions of this exhibit have been omitted and are marked accordingly. The confidential portions have been filed separately with the Securities and Exchange Commission pursuant to the request for confidential treatment.

\+ Indicates management contract or compensatory plan.

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

SIGNATURES

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

CLEARPOINT NEURO, INC.

Date: March 8, 2022

/s/ Joseph M. Burnett
Joseph M. Burnett
Chief Executive Officer and President
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENT, that each person whose signature appears below constitutes and appoints Joseph M. Burnett and Danilo D'Alessandro, and each of them, acting individually, as his attorney-in-fact, each with full power of substitution and resubstitution, for him and in his 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 Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Joseph M. Burnett **Joseph M. Burnett**	*President, Chief Executive Officer, and Director (Principal Executive Officer)*	March 8, 2022
/s/ Danilo D'Alessandro **Danilo D'Alessandro**	*Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)*	March 8, 2022
/s/ R. John Fletcher **R. John Fletcher**	*Chairman and Director*	March 8, 2022
/s/ Lynnette C. Fallon **Lynnette C. Fallon**	*Director*	March 8, 2022
/s/ Pascal E.R. Girin **Pascal E.R. Girin**	*Director*	March 8, 2022
/s/ B. Kristine Johnson **B. Kristine Johnson**	*Director*	March 8, 2022
/s/ Matthew B. Klein **Matthew B. Klein**	*Director*	March 8, 2022
/s/ Linda M. Liau **Linda M. Liau**	*Director*	March 8, 2022
/s/ Timothy T. Richards **Timothy T. Richards**	*Director*	March 8, 2022

Table of Contents

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
ClearPoint Neuro, Inc.
Solana Beach, California

Opinion on the Financial Statements
We have audited the accompanying consolidated balance sheets of ClearPoint Neuro, Inc. (the "Company") as of December 31, 2021 and 2020, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

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

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

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

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

Critical Audit Matter Description

The Company had $16,299,000 in revenue for the year ended December 31, 2021. Revenue is derived from (1) product revenue resulting from the sale of functional neurosurgery, navigation, therapy, and biologics and drug delivery disposable products; 2) product revenue resulting from the sale of ClearPoint capital equipment and software; 3) revenue resulting from the service, installation, training and shipping related to ClearPoint capital equipment and software; and 4) consultation revenue and clinical case support revenue in connection with customer-sponsored clinical trials. As disclosed in Note 2 to the financial statements, the Company recognizes revenue when control of the Company's products and services is transferred to its customers in an amount that reflects the consideration the Company expects to receive from its customers in exchange for those products and services in a process that involves identifying the contract with the customer, determining the performance obligation in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied.

Due to the nature of the Company's customer agreements, management exercises judgment in the following areas in determining appropriate revenue recognition:

a. The pattern and timing of delivery for each distinct performance obligation; and
b. The identification and treatment of contract terms that may impact the timing and amount of revenue recognized.

As a result, a degree of auditor judgment was required in performing audit procedures to evaluate the reasonableness of management's judgments. Changes in these judgments can have a material effect on the amount of revenue recognized.

How the Critical Audit Matter Was Addressed In the Audit

Based on our knowledge of the Company, we determined the nature and extent of procedures to be performed over service and other revenue as discussed above, including the determination of the revenue streams over which those procedures were performed. Our audit procedures included the following for service and other revenue:

a. Obtained an understanding of the internal controls and processes in place over the Company's revenue recognition processes.
a. Assessed the recorded revenue by selecting a sample of transactions and compared the amounts recognized to underlying documentation, including evidence of contracts with customers.

We have served as the Company's auditors since 2008.

/s/ Cherry Bekaert LLP

Tampa, Florida
March 8, 2022

CLEARPOINT NEURO, INC.

Consolidated Balance Sheets

(Dollars in thousands, except for per share data)

	December 31,	
	2021	**2020**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 54,109	$ 20,099
Accounts receivable, net	2,337	1,881
Inventory, net	4,938	3,238
Prepaid expenses and other current assets	508	244
Total current assets	61,892	25,462
Property and equipment, net	539	319
Operating lease rights of use	2,241	2,736
Software license inventory	519	589
Licensing rights	265	353
Other assets	125	59
Total assets	$ 65,581	$ 29,518
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 427	$ 300
Accrued compensation	2,604	1,595
Other accrued liabilities	537	349
Operating lease liabilities, current portion	507	394
Deferred product and service revenue, current portion	678	562
Total current liabilities	4,753	3,200
Operating lease liabilities, net of current portion	1,939	2,446
Deferred product and service revenue, net of current portion	264	215
2020 senior secured convertible notes payable, net	9,838	21,280
Total liabilities	16,794	27,141
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized at December 31, 2021 and 2020; none issued and outstanding at December 31, 2021 and 2020	—	—
Common stock, $0.01 par value; 200,000,000 shares authorized at December 31, 2021 and 2020; 23,665,991 and 17,047,584 shares issued and outstanding at December 31, 2021 and 2020, respectively	237	170
Additional paid-in capital	182,482	121,729
Accumulated deficit	(133,932)	(119,522)
Total stockholders' equity	48,787	2,377
Total liabilities and stockholders' equity	$ 65,581	$ 29,518

See notes to Consolidated Financial Statements.

CLEARPOINT NEURO, INC.

Consolidated Statements of Operations
(Dollars in thousands, except for per share data)

	Years Ended December 31,	
	2021	**2020**
Revenue:		
Product revenue	$ 11,913	$ 8,832
Service and other revenue	4,386	3,997
Total revenue	16,299	12,829
Cost of revenue	5,008	3,709
Gross profit	11,291	9,120
Research and development costs	8,985	4,686
Sales and marketing expenses	6,919	5,384
General and administrative expenses	8,761	5,270
Operating loss	(13,374)	(6,220)
Other income (expense):		
Other (expense) income, net	(63)	882
Interest expense, net	(973)	(1,444)
Net loss	$ (14,410)	$ (6,782)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.69)	$ (0.43)
Weighted average shares outstanding:		
Basic and diluted	20,734,236	15,849,667

See notes to consolidated financial statements.

CLEARPOINT NEURO, INC.

Consolidated Statements of Stockholders' Equity
Years Ended December 31, 2021 and 2020
(Dollars in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balances, January 1, 2020	15,235,308	$ 152	$ 117,174	$ (112,740)	$ 4,586
2020 senior secured convertible note beneficial conversion feature	—	—	3,107	—	3,107
Issuances of common stock:					
Share-based compensation	267,608	3	1,087	—	1,090
Warrant and option exercises	1,544,668	15	361	—	376
Net loss for the year	—	—	—	(6,782)	(6,782)
Balances, December 31, 2020	17,047,584	$ 170	$ 121,729	$ (119,522)	$ 2,377
Adoption of ASU 2020-06	—	—	(3,107)	—	(3,107)
Conversion of 2020 senior secured convertible notes	2,029,589	21	14,953	—	14,974
Issuances of common stock:					
Public offering of common stock	2,127,660	21	46,764	—	46,785
Share-based compensation	185,051	2	2,076	—	2,078
Warrant and option exercises (cash and cashless)	2,285,490	23	442	—	465
Issuance of common stock under employee stock purchase plan	22,918	—	224	—	224
Payments for taxes related to net share settlement of equity awards	(32,301)	—	(599)	—	(599)
Net loss for the year	—	—	—	(14,410)	(14,410)
Balances, December 31, 2021	23,665,991	$ 237	$ 182,482	$ (133,932)	$ 48,787

See notes to consolidated financial statements.

CLEARPOINT NEURO, INC.
Consolidated Statements of Cash Flows
(Dollars in thousands)

	Years Ended December 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (14,410)	$ (6,782)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for doubtful accounts	202	27
Depreciation and amortization	159	334
Share-based compensation	2,078	1,090
Payment-in-kind interest	325	3
Forgiveness of Paycheck Protection Program loan	—	(896)
Amortization of debt issuance costs and original issue discounts	100	890
Amortization of lease right of use assets, net of accretion in lease liabilities	533	216
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(658)	(818)
Inventory	(1,714)	(25)
Prepaid expenses and other current assets	(264)	113
Other assets	(66)	25
Accounts payable and accrued expenses	1,285	(459)
Accrued interest	—	(960)
Lease liability	(432)	(128)
Deferred revenue	165	(437)
Net cash flows from operating activities	(12,697)	(7,807)
Cash flows from investing activities:		
Purchases of property and equipment	(168)	(41)
Acquisition of licensing rights	—	(441)
Net cash flows from investing activities	(168)	(482)
Cash flows from financing activities:		
Proceeds from issuance of 2020 senior secured convertible notes, net of financing costs and discount	—	24,258
Proceeds from issuance of Paycheck Protection Program loan	—	896
Proceeds from public offering of common stock, net of offering costs	46,785	—
Proceeds from stock option and warrant exercises	465	376
Proceeds from issuance of common stock under employee stock purchase plan	224	—
Payments for taxes related to net share settlement of equity awards	(599)	—
Repayment of notes payable	—	(2,838)
Net cash flows from financing activities	46,875	22,692
Net change in cash and cash equivalents	34,010	14,403
Cash and cash equivalents, beginning of year	20,099	5,696
Cash and cash equivalents, end of year	$ 54,109	$ 20,099
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ —	$ —
Interest	$ 597	$ 1,578

CLEARPOINT NEURO, INC.
Consolidated Statements of Cash Flows

NON-CASH INVESTING AND FINANCING TRANSACTIONS:

- The Company had $0.04 million in capital expenditures accrued but not yet paid at December 31, 2021.
- During each of the years ended December 31, 2021 and 2020, the Company recorded net transfers of ClearPoint reusable components having an aggregate net book value of $0.1 million between loaned systems, which are included in property and equipment in the accompanying consolidated balance sheets, and inventory.
- As discussed in Note 2, on January 1, 2021, the Company adopted the provisions of Topic 470-20 within the Accounting Standards Codification, which resulted in the elimination of a previously recorded discount in connection with the issuance of the 2020 Secured Notes and a corresponding reduction of additional paid-in capital, each in the amount of $3.1 million.
- As discussed in Note 6, in May 2021, one of the 2020 Convertible Noteholders converted the entire $7.5 million principal amount of its First Closing Note, and related accrued interest amounting to approximately $0.04 million, into 1,256,143 shares of the Company's common stock. As a result, the discount on such First Closing Note, amounting to $0.2 million at the conversion date and representing an access fee paid to the noteholder at origination of such First Closing Note, was eliminated and a corresponding amount was charged to additional paid-in capital upon conversion. Additionally, in November 2021, the same 2020 Convertible Noteholder also converted the entire Second Closing Note principal balance of $7.5 million, along with related accrued and payment in-kind interest aggregating $0.3 million, into 773,446 shares of the Company's common stock.
- As discussed in Note 7, in December 2020, the Company entered into a lease for additional office space. In connection with the new lease, the Company recorded increases to operating lease rights of use and operating lease liabilities, each in the amount of approximately $2.6 million.

See notes to consolidated financial statements.

CLEARPOINT NEURO, INC.
Notes to Consolidated Financial Statements

1. Description of the Business and Financial Condition

ClearPoint Neuro, Inc. (the "Company") is a medical device company focused on the development and commercialization of technology for performing minimally invasive surgical procedures in the brain. The Company was incorporated in the state of Delaware in March 1998, and has headquarters located in Solana Beach, California. The Company established ClearPoint Neuro (Canada) Inc., a wholly owned subsidiary incorporated in Canada, in August 2013, primarily for the purpose of performing software development, and established ClearPoint Neuro U.K. Ltd, a wholly owned subsidiary incorporated in the United Kingdom, in October 2020, primarily for the purpose of employing the Company's clinical services representatives serving the Company's customers in the United Kingdom and the EU. The activities of both subsidiaries are reflected in these consolidated financial statements.

The Company's initial product offering, the ClearPoint system, is an integrated system comprised of capital equipment and disposable products, designed to allow minimally invasive procedures in the brain to be performed in an MRI suite. The ClearPoint Array Neuro Navigation System, introduced in 2021, also can be used in an MRI suite, and the principal disposable component of the Array system can be deployed in an operating room setting. Both systems provide guidance for the placement and operation of instruments or devices during the planning and operation of neurosurgical procedures. The Company received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") in 2010 to market the ClearPoint system in the United States for general neurosurgical interventional procedures; in February 2011, the Company also obtained CE marking approval for its ClearPoint system.

COVID-19

In March 2020, the World Health Organization characterized the spread of a novel strain of coronavirus ("COVID-19") as a global pandemic, and the President of the United States later proclaimed that the COVID-19 outbreak in the United States constituted a national emergency. Extraordinary actions were taken by federal, state and local governmental authorities to combat the spread of COVID-19, including issuances of "stay-at-home" directives and similar mandates that substantially restricted daily activities and for many businesses curtailed or ceased normal operations. These measures led to reduced economic activity, including the postponement or cancellation of elective surgical procedures, which historically have represented approximately 80% of the number of surgical procedures using the Company's ClearPoint system. Although economic activity is returning to normalized levels, new variants of COVID-19, such as Delta and Omicron, continue to spread in the United States and across the globe. The ultimate impact of the COVID-19 pandemic cannot be predicted at this time, and could depend on numerous factors, including vaccination rates among the population, the effectiveness of vaccines against different variants and the response by governmental bodies and regulators. Management is unable to determine the timing and extent to which the vaccination process will affect the progression of the virus; the timing, adoption or viability of periodic resumption, if any, of elective procedures; and the resulting length of time that the COVID-19 pandemic will adversely affect our product revenues.

Furthermore, the recessionary conditions on the global economy caused by the COVID-19 pandemic could have a material adverse effect on the Company's business. Although most segments of the United States economy have reopened, the effects of the COVID-19 pandemic remain intense in many areas of the country, and many public health experts continue to anticipate future surges of COVID-19 due to new variants. Accordingly, reinstatement of directives and mandates requiring businesses to again curtail or cease normal operations, including the postponement or cancellation of elective surgeries, remains a possibility. Additionally, global economic and supply chain disruptions, labor shortages, which may affect the Company's ability to retain and attract new talent, and inflationary conditions caused by the COVID-19 pandemic could have a material adverse effect on the Company's business. The rapid development and fluidity of the situation precludes any prediction as to the ultimate impact COVID-19 will have on the Company's business, financial condition, results of operation and cash flows, which will depend largely on future developments directly or indirectly relating to the duration and scope of the COVID-19 outbreak in the United States.

Liquidity

The Company has incurred net losses since its inception which has resulted in a cumulative deficit at December 31, 2021 of approximately $134 million. In addition, the Company's use of cash from operations amounted to $12.7 million for the year ended December 31, 2021. Since inception, the Company has financed its operations principally from the sale of equity securities and the issuance of notes payable.

In January 2020, the Company entered into a Securities Purchase Agreement (the "SPA") with two investors (each, a "2020 Convertible Noteholder," and together, the "2020 Convertible Noteholders") under which the Company issued an aggregate principal amount of $17.5 million of floating rate secured convertible notes with a five year term (the "First Closing Notes"), resulting in proceeds, net of financing costs, and a commitment fee paid to one of the 2020 Convertible Noteholders, of approximately $16.8 million. In the first quarter of 2020, the Company used $3.7 million from the net proceeds received from the issuance of the First Closing Notes to repay and retire the 2010 Junior Secured Notes Payable (the "2010 Secured Notes") that otherwise would have matured in October and November 2020.

The SPA also gave the Company the right, but not the obligation, to request one of the 2020 Convertible Noteholders to purchase an additional $5.0 million in principal amount of a note (the "Second Closing Note", and, together with the First Closing Note, the "2020 Secured Notes"). On December 29, 2020, under the terms of an amendment to the SPA (the "Amendment") which, among other provisions, increased the principal amount of the Second Closing Note, the Company issued the Second Closing Note to the 2020 Convertible Noteholder in the principal amounts of $7.5 million.

Additional information with respect to the 2020 Secured Notes is found in Note 6.

As discussed in Note 8, on February 23, 2021, the Company completed a public offering of 2,127,660 shares of its common stock. Net proceeds from the offering were approximately $46.8 million after deducting the underwriting discounts and commissions and other estimated offering expenses payable by the Company.

Based on the foregoing, in management's opinion, cash and cash equivalent balances at December 31, 2021, are sufficient to support the Company's operations and meet its obligations for at least the next twelve months.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant inter-company accounts and transactions have been eliminated.

Basis of Presentation and Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents include all highly liquid investments with an original maturity of three months or less.

Inventory

Inventory is carried at the lower of cost (first-in, first-out method) or net realizable value. Items in inventory relate predominantly to the Company's ClearPoint system. Software license inventory related to ClearPoint systems undergoing on-site customer evaluation is included in inventory in the accompanying consolidated balance sheets. All other software license inventory is classified as a non-current asset. The Company periodically reviews its inventory for obsolete items and provides a reserve upon identification of potential obsolete items.

Intangible Assets

The Company is a party to certain license agreements that provide rights to the Company for the development and commercialization of products. Under the terms of those license agreements, the Company paid an aggregate $0.6 million to the licensors upon execution of the license agreements for access to the underlying technologies and will make future payments based on the achievement of regulatory and commercialization milestones as defined in the license agreements. In the fourth quarter of 2020, the Company determined that the technology underlying the licensing rights acquired in 2019 was unlikely to be of future benefit. As a result, the Company recorded an impairment charge of $0.1 million, representing the unamortized balance of its investment in the licensing rights, which is included in amortization and depreciation in the accompanying 2020 consolidated statement of operations.

In conformity with Accounting Standards Codification Section 350, "Intangibles – Goodwill and Other," the Company amortizes its investment in the license rights described above over an expected useful life of five years. In addition, the Company periodically evaluates the recoverability of its investment in the license rights and records an impairment charge in the event such evaluation indicates that the Company's investment is not likely to be recovered.

Property and Equipment

Property and equipment are recorded at cost and are depreciated on a straight-line basis over their estimated useful lives, principallyfive to seven years. Leasehold improvements are depreciated on a straight-line basis over the lesser of their estimated useful lives or the term of the related lease.

Impairment of Long-Lived Assets

The Company periodically evaluates the recoverability of its long-lived assets (finite-lived intangible assets and property and equipment). Whenever events or changes in circumstances indicate that the carrying amount of such assets may not be fully recoverable, the expected undiscounted future cash flows are compared to the net book value of the related assets. If the net book value of the related assets were to exceed the undiscounted expected future cash flows of the assets, the carrying amount would be reduced to the present value of the expected future cash flows and an impairment loss would be recognized.

Revenue Recognition

The Company's revenue is comprised primarily of: (1) product revenue resulting from the sale of functional neurosurgery, navigation, therapy, and biologics and drug delivery disposable products; (2) product revenue resulting from the sale of ClearPoint capital equipment and software; (3) revenue resulting from the service, installation, training, and shipping related to ClearPoint capital equipment and software; and (4) consultation revenue and clinical case support revenue in connection with customer-sponsored clinical trials. The Company recognizes revenue when control of the Company's products and services is transferred to its customers in an amount that reflects the consideration the Company expects to receive from its customers in exchange for those products and services, in a process that involves identifying the contract with a customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. When a contract calls for the satisfaction of multiple performance obligations for a single contract price, the Company allocates the contract price among the performance obligations based on the relative stand-alone prices for each such performance obligation customarily charged by the Company. The Company considers a performance obligation satisfied once it has transferred control of a good or service to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service. The Company recognizes revenue for satisfied performance obligations only when it determines there are no uncertainties regarding payment terms or transfer of control.

Lines of Business; Timing of Revenue Recognition

- *Functional neurosurgery navigation product, biologics and drug delivery systems product, and therapy product sales:* Revenue from the sale of functional neurosurgery navigation products (consisting of disposable products sold commercially and related to cases utilizing the Company's ClearPoint system), biologics and drug delivery systems (consisting primarily of disposable products related to customer-

sponsored clinical trials utilizing the ClearPoint system), and therapy products (consisting primarily of disposable laser-related products used in non-neurosurgical procedures) is generally based on customer purchase orders, the predominance of which require delivery within one week of the order having been placed, and are recognized at the point in time of delivery to the customer, which is the point at which legal title, and risks and rewards of ownership, along with physical possession, transfer to the customer.

- *Capital equipment and software sales:*
    - *Capital equipment and software sales preceded by evaluation periods:* The predominance of capital equipment and software sales (consisting of integrated computer hardware and software that are integral components of the Company's ClearPoint system) are preceded by customer evaluation periods. During these evaluation periods, installation of, and training of customer personnel on, the systems have been completed and the systems have been in operation. Accordingly, revenue from capital equipment and software sales following such evaluation periods is recognized at the point in time that the Company is in receipt of an executed purchase agreement or purchase order.
    - *Capital equipment and software sales not preceded by evaluation periods:* Revenue from sales of capital equipment and software not having been preceded by an evaluation period is recognized at the point in time that the equipment and software has been delivered to the customer.

  For both types of capital equipment and software sales described above, the determination of the point in time at which to recognize revenue represents that point at which the customer has legal title, physical possession, and the risks and rewards of ownership, and the Company has a present right to payment.

- *Functional neurosurgery navigation and therapy services:* The Company recognizes revenue for such services at the point in time that the performance obligation has been satisfied.

- *Biologics and drug delivery services:*
    - *Consultation Services:* The Company recognizes consultation revenue at the point in time such services are performed.
    - *Clinical Service Access Fees:* For contracts in which the Company receives a periodic fixed fee, irrespective of the number of cases attended by the Company's personnel during such periods, revenue is recognized ratably over the period covered by such fees. A time-elapsed output method is used for such fees because the Company transfers control evenly by providing a stand-ready service.
    - *Clinical Service Procedure-Based Fees:* The Company recognizes revenue at the point in time a case is attended by Company personnel.

- *Capital equipment-related services:*
    - *Equipment service:* Revenue from service of ClearPoint capital equipment and software previously sold to customers is based on agreements with terms ranging from one to three years and revenue is recognized ratably on a monthly basis over the term of the service agreement. A time-elapsed output method is used for service revenue because the Company transfers control evenly by providing a stand-ready service.

      The Company may also enter into contracts with customers who own ClearPoint capital equipment, which bundle maintenance and support services and access to software and hardware upgrades made commercially available over the term of the contract, for a single contract price, typically paid on an annual basis. The Company allocates the contract price among the performance obligations based on the relative stand-alone prices for each such performance obligation and recognizes the revenue ratably on a monthly basis. In line with equipment service, a time-elapsed output method is used as the Company is providing a stand-ready service.
    - *Installation, training, and shipping:* Consistent with the Company's recognition of revenue for capital equipment and software sales as described above, fees for installation, training, and shipping

in connection with sales of capital equipment and software that have been preceded by customer evaluation periods are recognized as revenue at the point in time the Company is in receipt of an executed purchase order for the equipment and software. Installation, training, and shipping fees related to capital equipment and software sales not having been preceded by an evaluation period are recognized as revenue at the point in time that the related services are performed.

The Company operates in one industry segment, and substantially all its sales are to U.S.-based customers.

Payment terms under contracts with customers generally are in a range of 30-60 days after the customers' receipt of the Company's invoices.

The Company's terms and conditions do not provide for a right of return unless for: (a) product defects; or (b) other conditions subject to the Company's approval.

See Note 3 for additional information regarding revenue recognition.

Research and Development Costs

Costs related to research, design and development of products are charged to research and development expense as incurred.

Income Taxes

Deferred income tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective income tax bases. Such assets and liabilities are measured using enacted tax rates expected to apply to taxable income or loss in the years in which those temporary differences are expected to be recovered or settled. The effect of a change in tax rates is recognized in the period that includes the enactment date. The Company provides a valuation allowance against net deferred income tax assets unless, based upon available evidence, it is more likely than not the deferred income tax assets will be realized. The Company recognizes interest and penalties related to unrecognized tax benefits as a component of income tax expense. As of December 31, 2021 and 2020, the Company had no accrued interest or penalties related to uncertain tax positions.

Net Loss Per Share

The Company computes net loss per share using the weighted-average number of common shares outstanding during the period. Basic and diluted net loss per share are the same because the conversion, exercise or issuance of all potential common stock equivalents, which comprise the entire amount of the Company's outstanding common stock options and warrants as described in Note 8, and the potential conversion of the First Closing Notes, as described in Note 6, would be anti-dilutive, due to the reporting of a net loss for each of the periods in the accompanying consolidated statements of operations.

Share-Based Compensation

The Company accounts for compensation for all arrangements under which employees, directors and others receive shares of stock or other equity instruments (including options and warrants) based on fair value. The fair value of each award is estimated as of the grant date and amortized as compensation expense over the requisite vesting period. The fair values of the Company's share-based awards are estimated on the grant dates using the Black-Scholes valuation model. This valuation model requires the input of highly subjective assumptions, including the expected stock volatility, estimated award terms and risk-free interest rates for the expected terms. To estimate the expected terms, the Company utilizes the simplified method for "plain vanilla" options discussed in the Staff Accounting Bulletin 107 ("SAB 107") issued by the SEC. The Company believes that all factors listed within SAB 107 as pre-requisites for utilizing the simplified method apply to the Company and its share-based compensation arrangements. The Company intends to utilize the simplified method for the foreseeable future until more detailed information about exercise behavior becomes available. The Company based its estimate of expected volatility on the average of: (i) historical volatilities of publicly traded companies it deemed similar to the Company; and (ii) the Company's historical volatility, which is limited, and will consistently apply this methodology until its own sufficient relevant historical data exists. The Company utilizes risk-free interest rates based on zero-coupon U.S. treasury instruments, the terms of

which are consistent with the expected terms of the equity awards. The Company has not paid and does not anticipate paying cash dividends on its shares of common stock; therefore, the expected dividend yield is assumed to be zero.

Fair Value Determination of Share-Based Transactions

The Company's common stock is traded on the Nasdaq Capital Market under the symbol "CLPT." Quoted closing stock prices are used as a key input in determining the fair value for share-based transactions. For the period from December 9, 2019 until the Company's corporate name change and stock trading symbol change on February 12, 2020, the Company's common stock was traded on the Nasdaq Capital Market under the symbol "MRIC."

Concentration Risks and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivable. The Company holds substantially all its cash and cash equivalents on deposit with financial institutions in the U.S. insured by the Federal Deposit Insurance Corporation. At December 31, 2021, the Company had approximately $48.4 million in bank balances that were in excess of the insured limits.

At December 31, 2021, one customer accounted for 15% of accounts receivable, and at December 31, 2020, one customer accounted for 11% of accounts receivable.

During the year ended December 31, 2021, one customer, who is a stockholder and a noteholder (see Note 6), and whose executive officer is a member of the Company's Board of Directors, accounted for 18% of total revenue, and of 28% total revenue for the year ended December 31, 2020. Under the terms of the agreement with this customer, the Company bills and recognizes as revenue quarterly service fees of $0.7 million.

Prior to granting credit, the Company performs credit evaluations of its customers' financial condition, and generally does not require collateral from its customers. The Company will provide an allowance for doubtful accounts when collections become doubtful. The allowance for doubtful accounts at December 31, 2021 and 2020 was $0.3 million and $0.1 million, respectively.

The Company is subject to risks common to emerging companies in the medical device industry, including, but not limited to: new technological innovations; acceptance and competitiveness of its products; dependence on key personnel; dependence on key suppliers; dependence on third-party collaboration, license and joint development partners; changes in general economic conditions and interest rates; protection of proprietary technology; compliance with changing government regulations; uncertainty of widespread market acceptance of products; access to credit for capital purchases by customers; and product liability claims. Certain components used in manufacturing have relatively few alternative sources of supply and establishing additional or replacement suppliers for such components cannot be accomplished quickly. The inability of any of these suppliers to fulfill the Company's supply requirements may negatively impact future operating results.

Recent Accounting Standards

Effective January 1, 2021, the Company adopted, on a modified retrospective method of transition, the provisions of Accounting Standards Update No. 2020-06, "Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40) – Accounting for Convertible Instruments and Contracts in an Entity's Own Equity" (the "ASU"). The ASU is effective for public companies, other than smaller reporting companies as defined by the SEC, for fiscal years beginning after December 15, 2021, and for smaller reporting companies, which is the Company's current classification, for fiscal years beginning after December 31, 2023. However, the ASU permits early adoption, no earlier than for fiscal years beginning after December 31, 2020, and the Company elected such early adoption. The ASU amends prior authoritative literature to reduce the number of accounting models for, among others, convertible debt instruments for which the embedded conversion features of such instruments had previously been required to be separated from the host contract. The Company determined that the conversion feature embedded in the Second Closing Note (see Note 6) was within the scope of the ASU. Accordingly, the discount originally recorded in connection with the issuance of the Second Closing Note and a corresponding amount recorded in additional paid-in capital, each in the amount of approximately $3.1 million at the date of issuance of the Second Closing Note, were reversed as of the date of adoption of the ASU.

Reclassifications

The accompanying consolidated statement of operations for the year ended December 31, 2021 contains certain items formerly classified as service revenue that have been reclassified to product revenue. The accompanying consolidated statement of operations for the year ended December 31, 2020 has been conformed to the 2021 presentation.

3. Revenue Recognition

Revenue by Service Line

(in thousands)	Years Ended December 31, 2021	2020
Functional neurosurgery navigation and therapy		
Disposable products	$ 7,696	$ 6,211
Services	375	—
Subtotal – Functional neurosurgery navigation and therapy	8,071	6,211
Biologics and drug delivery		
Disposable products	3,353	1,528
Services	3,442	3,672
Subtotal – Biologics and drug delivery revenue	6,795	5,200
Capital equipment and software		
Systems and software products	864	1,093
Services	569	325
Subtotal – Capital equipment and software revenue	1,433	1,418
Total revenue	$ 16,299	$ 12,829

Contract Balances

- *Contract assets* – Substantially all the Company's contracts with customers are based on customer-issued purchase orders for distinct products or services. Customers are billed upon delivery of such products or services, and the related contract assets comprise the accounts receivable balances included in the accompanying consolidated balance sheets.

- *Contract liabilities* – The Company generally bills and collects capital equipment and software-related service fees at the inception of the service agreements, which have terms ranging from one to three years. The Company may also enter into agreements with customers that bundle the capital equipment and software-related service fees with software and hardware upgrades that are made commercially available over the term of the contract. The unearned portion of such fees are classified as deferred revenue.

During the years ended December 31, 2021 and 2020, the Company recognized capital equipment and software-related service revenue of approximately $0.3 million and $0.5 million, respectively, which was previously included in deferred revenue in the accompanying consolidated balance sheets at December 31, 2020 and 2019.

The Company offers an upgraded version of its software at no additional charge to customers purchasing a three-year systems service agreement. The transaction prices of the software and the service agreement were determined through an allocation of the service agreement price based on the standalone prices of the software and the service agreements customarily charged by the Company. The transaction price of the software was recognized as revenue upon its installation and comprised approximately $0.04 million and $0.1 million of unbilled accounts receivable at December 31, 2021 and 2020, respectively.

Revenue with respect to remaining performance obligations related to capital equipment and software-related service agreements and the upfront payments discussed under the heading "Contract Balances" above amounted to approximately $0.8 million at December 31, 2021. The Company expects to recognize approximately 67% of this revenue over the next twelve months and the remainder thereafter.

4. Inventory

Inventory consists of the following as of December 31:

(in thousands)	2021	2020
Raw materials and work in process	$ 2,718	$ 1,485
Software licenses	210	193
Finished goods	2,010	1,560
Inventory included in current assets	4,938	3,238
Software licenses – non-current	519	589
	$ 5,457	$ 3,827

5. Property and Equipment

Property and equipment consist of the following as of December 31:

(in thousands)	2021	2020
Equipment	$ 1,440	$ 1,173
Furniture and fixtures	112	112
Leasehold improvements	201	201
Computer equipment and software	150	150
Loaned systems	525	503
	2,428	2,139
Less accumulated depreciation and amortization	(1,889)	(1,820)
Total property and equipment, net	$ 539	$ 319

Depreciation and amortization expense related to property and equipment for each of the years ended December 31, 2021 and 2020 was $0.1 million. Loaned systems are ClearPoint systems that are in operation at customer sites on an evaluation basis.

6. Notes Payable

2020 Secured Notes

As a result of the transactions described below, an aggregate principal amount of $10 million of the 2020 Secured Convertible Notes was outstanding at December 31, 2021. At the option of the holder, who is a customer and has a representative on the Company's Board of Directors, at any time prior to maturity, the principal amount may be convertible to the Company's common stock at a conversion price of $6.00, subject to adjustments as set forth in the SPA and note agreement.

On January 29, 2020 (the “Closing Date”), the Company completed a financing transaction (the “2020 Financing Transaction”) with the 2020 Convertible Noteholders, whereby the Company issued an aggregate principal amount of $17.5 million of the First Closing Notes pursuant to the SPA dated January 11, 2020, which, unless earlier converted or redeemed, mature on the fifth anniversary of the Closing Date, and bear interest at a rate equal to the sum of (i) the greater of (a) the three (3)-month London Interbank Offered Rate (“LIBOR”) and (b) two percent (2)%, plus (ii) a margin of 2% on the outstanding balance of the First Closing Notes, payable quarterly on the first business day of each calendar quarter. The First Closing Notes may be converted at a price of $6.00 per share, subject to certain adjustments set forth in the SPA, and may not be pre-paid without the consent of the noteholder, provided that the Company must offer to pre-pay such other noteholder on the same terms and conditions.

In May 2021, one of the 2020 Convertible Noteholders (the "Converting Noteholder") converted the entire $7.5 million principal amount of such Converting Noteholder's First Closing Note, and related accrued interest, amounting to approximately $0.04 million, into 1,256,143 shares of the Company's common stock.

At the Closing Date, the SPA gave the Company the right, but not the obligation, to request, at any time on or prior to January 11, 2022, that one of the 2020 Convertible Noteholders purchase an additional $5 million in aggregate principal amount of the Second Closing Note and an additional $10 million in aggregate principal amount of the Third Closing Note (as defined in the SPA; together, with the Second Closing Note, the "Additional Closing Notes"), provided that such 2020 Convertible Noteholder has the right, but not the obligation, to purchase such notes. The Additional Closing Notes would also mature on the fifth anniversary of the Closing Date.

On December 29, 2020, the Company and the 2020 Convertible Noteholders entered into an amendment to the SPA (the "Amendment"), the terms of which, among other provisions, provided for: (a) an increase in the principal amount of the Second Closing Note to $7.5 million; (b) a revision of the interest rate to be borne by the Second Closing Note to consist of: (i) cash interest of 2% per annum, payable quarterly; and (ii) payment-in-kind interest of 5% per annum, accruable quarterly as an addition to the unpaid principal balance of the Second Closing Note; and (c) an increase in the conversion price of the Second Closing Notes to $10.14 per share, subject to certain adjustments set forth in the SPA. Upon execution of the Amendment, the Company issued the Second Closing Note.

On November 3, 2021, the holder of the Second Closing Note converted the entire $7.5 million principal amount of such note, along with related accrued and payment in-kind interest aggregating $0.3 million, into 773,446 shares of the Company's common stock.

The aggregate carrying amount of the First Closing Notes in the accompanying December 31, 2021 and December 31, 2020 consolidated balance sheets are presented net of financing costs, comprised of commissions and legal expenses, having an unamortized balance of $0.2 million and $0.4 million at those respective dates. In addition, the aggregate carrying amount of the First Closing Note in the accompanying December 31, 2020 consolidated balance sheets is presented net of a discount, comprised of a commitment fee paid to the Converting Noteholder, amounting to an unamortized balance of $0.2 million. Upon conversion of the related note, the discount, amounting to $0.2 million at the date of conversion, was reversed, with a corresponding amount being recorded as a reduction of additional paid-in capital. The unamortized balances of the financing costs and the discount, during the period prior to the conversion of the related First Closing Note, are charged to interest expense over the respective terms of the First Closing Notes under the effective interest method.

The carrying amount of the Second Closing Note in the accompanying December 31, 2020 consolidated balance sheet is presented net of a discount, amounting to approximately $3.1 million at December 31, 2020, and representing the value of the deemed beneficial conversion feature embedded in the Second Closing Note. A beneficial conversion feature is deemed to be beneficial when the conversion price, discussed above, is lower than the closing price per share of the Company's common stock, which was $14.34 on the date of issuance of the Second Closing Note. Under GAAP in existence at the date of issuance of the Second Closing Note, the resulting discount was calculated as the product of (i) the number of shares into which the Second Closing Note could be converted, multiplied by (ii) the difference between the closing price per share and the conversion price. Upon recordation of the discount, a corresponding amount was added to additional paid-in capital. As discussed in Note 2, effective January 1, 2021, the Company adopted the provisions of the ASU that no longer required such beneficial conversion features to be separately accounted for as previously described in this paragraph. As a result, the accompanying December 31, 2021 condensed consolidated balance sheet reflects the elimination of both the discount and the corresponding increase to additional paid-in capital previously described in this paragraph.

Under the terms of the SPA, as amended, the Company retains the right, but not the obligation, to request the 2020 Convertible Noteholder to purchase the Third Closing Note, and the 2020 Convertible Noteholder has the right, but not the obligation, to purchase such note. As of December 31, 2021, the Company had not made such a request.

The 2020 Secured Notes are secured by all the assets of the Company.

An executive officer of one of the 2020 Convertible Noteholders is a member of the Company's Board of Directors. Pursuant to the terms of the SPA and a Board Observer Agreement entered into by the other 2020 Convertible Noteholder and the Company, the other 2020 Convertible Noteholder appointed a representative to attend and observe meetings of the Company's Board of Directors. On February 25, 2021, such 2020 Convertible Noteholder terminated the Board Observer Agreement, thus precluding its representative from attending future meetings of the Company's Board of Directors.

On January 27, 2020, as a condition to completion of the 2020 Financing Transaction, the Company entered into the Fourth Omnibus Amendment to the 2010 Secured Notes, whereby the 2010 Secured Notes were subordinated to the Company's obligations under the terms of the 2020 Secured Notes and the Additional Convertible Notes, as applicable. During its first fiscal quarter of 2020, the Company repaid in full the aggregate outstanding principal amount of the 2010 Secured Notes, amounting to approximately $2.8 million, which, along with the Company's payment of accrued interest amounting to approximately $0.9 million, resulted in the full retirement of the 2010 Secured Notes.

PPP Loan Payable

In April 2020, the Company received $0.9 million in proceeds through an unsecured loan funded under the Payroll Protection Program as part of the CARES Act, which was enacted by the U.S. Congress in response to the COVID-19 pandemic. In November 2020, prior to the otherwise scheduled payments under the terms of the loan, the Company was notified by the U.S. Small Business Administration that the loan had been forgiven under the provisions of the CARES Act. The gain realized from such forgiveness is included in other income in the accompanying consolidated statement of operations for the year ended December 31, 2020.

Scheduled Notes Payable Maturities

Scheduled principal payments as of December 31, 2021 with respect to notes payable are summarized as follows:

Years ending December 31,	*(in thousands)*
2025	$ 10,000
Total scheduled principal payments	10,000
Less unamortized discounts and financing costs	(162)
	$ 9,838

7. Commitments

Operating Leases

The Company leases office space in Irvine, California that houses office space and a manufacturing facility under a non-cancellable operating lease. The lease term commenced on October 1, 2018 and expires in September 2023. The Company has the option to renew the lease for two additional periods of five years each. The Company also leases office space in Solana Beach, California that serves as its corporate headquarters and houses certain management and research and development personnel. The lease term commenced on December 15, 2020, is set to expire on December 31, 2026, and is renewable for an additional five-year period, at the Company's option, provided that the Company's landlord has entered into an extension of its lease for the office space that encompasses the Company's office space for at least five years. Both optional periods are not considered in the determination of the right-of-use asset or the lease liability as the Company does not consider it reasonably certain that it would exercise such options.

Operating lease liabilities are based on the net present value of the remaining lease payments over the remaining lease term. In determining the present value of lease payments, the Company used the published U.S. High Yield CCC corporate bond rates at the lease commencement date. As of December 31, 2021, the weighted average remaining lease term of the Company's operating leases is approximately 4.75 years and the weighted average discount rate used to determine the operating lease liability was 8.6%.

The lease cost, included in general and administrative expense, was $0.5 million and $0.2 million for the years ended December 31, 2021 and 2020, respectively.

As of December 31, 2021, future minimum lease payments are as follows:

Years ending December 31,	*(in thousands)*
2022	$ 544
2023	544
2024	472
2025	486
2026	500
Total minimum payments	2,546
Less: Discount to present value of lease payments	(100)
Discounted present value of lease payments	$ 2,446

Minimum Purchase Commitments

The Company is party to a license and collaboration agreement, and related distribution agreements, with a third-party under which the parties will collaborate on developing a system that integrates their current stand-alone systems. The agreements subject the Company to minimum purchase commitments for the systems and related disposable products for a minimum of five years following the date the integrated system and related disposable products are commercially available, which has not yet occurred.

8. Stockholders' Equity

2021 Public Offering

On February 23, 2021, the Company completed a public offering of 2,127,660 shares of its common stock, composed of 1,850,140 shares of common stock initially offered at a public offering price of $23.50 per share and an additional 277,520 shares of common stock sold pursuant to the exercise of the underwriters' option to purchase additional shares at the price of $22.09 per share.

Net proceeds from the offering totaled approximately $46.8 million after deducting underwriting discounts and commissions, and other offering expenses paid by the Company.

The underwriting agreement contains representations, warranties, agreements and indemnification obligations by the Company that are customary for this type of transaction.

Issuance of Common Stock in Lieu of Cash Payments

Under the terms of the Amended and Restated Non-Employee Director Compensation Plan, each compensated non-employee member of the Company's Board of Directors may elect to receive all or part of his or her director fees in shares of the Company's common stock. Effective from June 25, 2021, director fees, whether paid in cash or in shares of common stock, are payable quarterly on the first business day following the end of the quarter. The number of shares of common stock issued to directors is determined by dividing the product of: (i) (a) the fees otherwise payable to each director in cash, times (b) the percentage of fees the director elected to receive in shares of common stock, by (ii) the volume weighted average price per share of common stock over the last five trading days of the quarter. During the years ended December 31, 2021 and 2020, 6,386 shares and 28,039 shares, respectively, were issued to directors as payment for director fees, amounting to $0.1 million in each of 2021 and 2020 in lieu of cash.

Equity Compensation Plans

The Company has various share-based compensation plans and share-based compensatory contracts (collectively, the "Plans") under which it has granted share-based awards, such as stock grants, and incentive and non-qualified stock options, to employees, directors, consultants, and advisors. Awards may be subject to a vesting schedule as set forth in individual award agreements.

From October 2017 until June 2020, the Company granted share-based awards under the Company's Second Amended and Restated 2013 Incentive Compensation Plan (the "Second Amended Plan"). On June 2, 2020, the Company's stockholders approved the Company's Third Amended and Restated 2013 Incentive Compensation Plan

(the "Third Amended Plan" and, together with the Second Amended Plan, the "2013 Plan"), under which 1.0 million shares of the Company's common stock were made available for future issuances under the 2013 Plan, resulting in a total of 2,956,250 shares of the Company's common stock being reserved for issuance under the 2013 Plan. Of this amount, 1,180,932 shares were outstanding as of December 31, 2021 and 718,384 shares remained available for grants under the 2013 Plan as of that date.

Stock Option Activity

Stock option activity under all of the Company's Plans as of and for the year ended December 31, 2021 is summarized below:

	Stock Options	Weighted-average Exercise price per share	Weighted-average Remaining Contractual Life (in years)	Intrinsic Value *(in thousands)*
Outstanding at December 31, 2020	1,806,092	$ 7.12		
Granted	128,399	$ 18.09		
Exercised	(563,476)	$ 2.68		
Forfeited or expired	(20,542)	$ 19.01		
Outstanding at December 31, 2021	1,350,473	$ 10.10	6.43	$ 8,350
Exercisable at December 31, 2021	1,059,253	$ 10.05	5.76	$ 7,201
Vested and expected to vest at December 31, 2021	1,350,473	$ 10.10	6.43	$ 8,350

A summary of the status of the Company's non-vested stock options for the year ended December 31, 2021 is presented below:

	Non-vested Stock Options	Weighted - Average Grant Date Fair Value
Nonvested, December 31, 2020	294,154	$ 2.09
Granted	128,399	$ 9.48
Vested	(129,291)	$ 2.01
Forfeited or expired	(2,042)	$ 5.85
Nonvested, December 31, 2021	291,220	$ 5.38

The weighted-average grant-date fair value of stock options granted during the years ended December 31, 2021 and 2020 was $9.48 and $2.22, respectively.

The total intrinsic value of stock options exercised during the years ended December 31, 2021 and 2020 was $1.4 million and $0.3 million, respectively, and represents the difference between the exercise price of the option and the fair value of the common stock on the dates exercised. The total grant-date fair value of stock options vested during the years ended December 31, 2021 and 2020 was $0.3 million and $0.4 million, respectively.

Restricted Stock Award Activity

Restricted Stock Award ("RSA") activity as of and for the year ended December 31, 2021 is summarized below:

	Restricted Stock Award		Weighted - Average Grant Date Fair Value
Outstanding, December 31, 2020	347,106	$	3.66
Granted	185,932	$	18.12
Vested	(143,983)	$	4.40
Forfeited or expired	(8,950)	$	5.36
Outstanding, December 31, 2021	380,105	$	10.41

The RSAs vest in annual installments over a two to three-year period, contingent on the holder's continued employment with the Company. Annual grants of RSAs to the Board of Directors typically vest in one year.

The estimated fair value of the RSAs is based on the closing market value of the Company's common stock on the date of grant. The total fair value of RSAs vested during the years ended December 31, 2021 and 2020 was $0.6 million and $0.5 million, respectively.

There was no common stock held in treasury as of December 31, 2021 and 2020.

Employee Stock Purchase Plan Activity

On June 3, 2021, the Company's stockholders adopted and approved the ClearPoint Neuro, Inc. Employee Stock Purchase Plan (the "Purchase Plan"). A total of 400,000 shares of the Company's common stock are available for issuance pursuant to the terms of the Purchase Plan. The Purchase Plan provides eligible employees the opportunity to purchase shares of common stock at the lower of 85% of the fair market value on either the first day or the last day of the applicable offering period, by having withheld from their salary an amount up to 15% of their compensation. No employee may purchase more than $25,000 worth of common stock (calculated at the time the purchase right is granted) in any calendar year, nor may any employee purchase more than 3,500 shares in any six-month purchase period.

The Purchase Plan is deemed to be compensatory, and therefore, Purchase Plan expense has been included in share-based compensation expenses in the consolidated statement of operations for the year ended December 31, 2021.

The initial six-month purchase period commenced in July 2021. During the year ended December 31, 2021 22,918 shares were purchased at an average per share price of $9.78. On December 31, 2021, 377,082 shares of common stock were available for issuance under the Purchase Plan.

Warrants

Warrants to purchase shares of the Company's common stock were issued in connection with financing transactions in 2015, 2016, and 2017, and are generally for terms of five years. These warrants contain net exercise provisions giving the holder the option of acquiring a number of shares having a value equal to the difference between the exercise price

and the current stock price, in lieu of paying the exercise price to acquire the full number of stated shares. All of the warrants outstanding at December 31, 2021 will terminate in 2022 or 2023.

Common stock warrant activity for the year ended December 31, 2021 is as follows:

	Shares	Weighted - Average Exercise Price
Outstanding at January 1, 2020	5,532,267	$ 4.00
Exercised	(2,163,042)	2.36
Terminated	(286,238)	18.31
Outstanding at December 31, 2020	3,082,987	3.82
Exercised	(2,023,190)	3.31
Terminated	(390,890)	7.78
Outstanding at December 31, 2021	668,907	$ 2.97

Information regarding outstanding warrants at December 31, 2021 is as follows (contractual life expressed in years):

Exercise Price	Number Outstanding	Weighted-Average Remaining Contractual Life	Intrinsic Value *(in thousands)*[1]
$2.20	632,353	0.41	$ 5,704
$16.23	36,554	1.46	—
	668,907	0.47	$ 5,704

(1) Intrinsic value is calculated as the estimated fair value of the Company's stock at December 31, 2021 less the warrant exercise price of in-the-money warrants.

Fair Value Assumptions

The fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model utilizing the following weighted average assumptions for options granted during the year ended December 31, 2021 and the following ranges for 2020:

	Years Ended December 31,	
	2021	2020
Risk-free interest rate	0.95%	0.34% - 0.49%
Expected life (in years)	5.86	5.5 to 6.0
Estimated volatility	57.20%	56.05% - 57.00%
Expected dividends	None	None
Weighted-average grant date fair value	$9.48	$2.22

The risk-free interest rate for periods within the contractual life of the stock option is based on the implied yield available on U.S. Treasury constant maturity securities with the same or substantially equivalent remaining terms at the time of grant.

The expected option terms are calculated based on the simplified method for "plain vanilla" options due to the Company's limited exercise information. The simplified method calculates the expected term as the average of the vesting term and the original contractual term of the options.

The estimated volatility was calculated using the average of the historical volatility of the Company's common stock and comparable companies using daily closing prices over a period generally commensurate with the expected term of the options. No periods were excluded due to discrete historical events. The historical volatility of similar companies was utilized due to the limited trading history of the Company's common stock.

A zero value of the expected dividend value factor is utilized since the Company has not declared any dividends in the past and does not anticipate declaring dividends in the foreseeable future.

The first offering period under the Purchase Plan commenced in July 2021. The fair value of the first purchase option under the Purchase Plan is estimated at the beginning of the purchase period using the Black-Scholes model utilizing the following assumptions:

	2021
Risk-free interest rate	0.05%
Expected life (in years)	0.5
Estimated volatility	57.82%
Expected dividends	None
Fair value of purchase right	$5.78

The computation of the expected volatility assumption used in the Black-Scholes model for purchase rights is based on the trading history of the Company's common stock and comparable companies. The expected life assumption is based on the six-month term of each offering period. The risk-free interest rate is based on the U.S. Treasury constant maturity securities with the same or substantially equivalent remaining term in effect at the beginning of the offering period. A zero value for the expected dividend value factor is utilized since the Company has not declared dividends in the past and does not anticipate declaring dividends in the foreseeable future.

Share-Based Compensation Expense

The Company records share-based compensation expense on a straight-line basis over the related vesting period and recognizes forfeitures as they occur. The following table sets forth share-based compensation expense included in selling, general and administrative expense in the consolidated statements of operations:

Years Ended December 31,

(in thousands)

2021	2020
$2,078	$1,090

In the year ended December 31, 2021, the Company recognized $0.1 million of share-based compensation related to the Purchase Plan.

As of December 31, 2021, there was $1.2 million and $3.1 million of total unrecognized compensation expense related to stock options and RSAs, respectively, which is expected to be recognized over a weighted-average period of 1.9 years and 2.2 years, respectively.

9. Income Taxes

The Company had no income tax expense for the years ended December 31, 2021 and 2020. Due to uncertainties surrounding the realization of its deferred income tax assets in future periods, the Company has recorded a 100% valuation allowance against its net deferred income tax assets. If it is determined in the future that it is more likely than

not that any deferred income tax assets are realizable, the valuation allowance will be reduced by the estimated net realizable amounts. For the years ended December 31, 2021 and 2020, the valuation allowance increased by $4.8 million and $0.7 million, respectively, based on changes in deferred tax assets and liabilities.

	Years Ended December 31,	
(in thousands)	**2021**	**2020**
Income tax benefit at federal statutory rate	$ (3,060)	$ (1,420)
Adjustments for tax effects of:		
State income tax, net of federal benefit	(1,560)	(388)
Permanent adjustments	114	68
Other	(9)	4
Share based compensation	(1,999)	(42)
Net operating loss write-off	1,649	1,252
Paycheck Protection Program loan forgiveness	—	(188)
Change in valuation allowance	4,865	714
Income tax expense	$ —	$ —

The tax effect of temporary differences and net operating losses that give rise to components of deferred income tax assets and liabilities consist of the following:

	Years Ended December 31,	
(in thousands)	**2021**	**2020**
Deferred income tax assets:		
Net operating loss carryforwards	$ 26,379	$ 21,547
Share based compensation	2,083	2,118
Accrued expenses	860	841
Other	69	58
	29,391	24,564
Less valuation allowance	(29,324)	(24,459)
Total deferred income tax assets	67	105
Deferred tax liability - depreciation	(67)	(105)
Net deferred tax assets	$ —	$ —

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. Generally, the ultimate realization of deferred tax assets is dependent on the generation of future taxable income during the periods in which those temporary differences become deductible. Based on all relevant factors, a valuation allowance of $29.3 million has been established against deferred tax assets as of December 31, 2021 as management determined that it is more likely than not that sufficient taxable income will not be generated to realize those temporary differences.

At December 31, 2021, the Company had cumulative federal and state net operating losses of approximately $106 million and $57 million, respectively, available to reduce future taxable income, if any. The federal net operating loss carryforward begins expiring in 2021, and the state net operating loss carryforward begins expiring in 2028. It is possible that the Company will not generate taxable income in time to use these net operating loss carryforwards before their expiration. In addition, under Section 382 of the Internal Revenue Code of 1986 (the "Code"), as amended, if a corporation undergoes an "ownership change" (as defined in the Code), the corporation's ability to use its pre-change tax attributes to offset its post-change income may be limited. In general, an "ownership change" occurs if there is a cumulative change in a "loss corporation's" (as defined in the Code) ownership by 5% shareholders that exceeds 50 percentage points over a rolling three-year period. The Company has not determined whether such an ownership change has occurred. However, given the equity transactions in which the Company has engaged, the Company believes that the use of the net operating losses shown as deferred tax assets will be significantly limited.

Management has evaluated the effect of guidance provided by GAAP regarding accounting for uncertainty in income taxes and determined the Company has no uncertain tax positions that could have a significant impact on its

consolidated financial statements. The Company's federal income tax return for 2018 and subsequent years remain open for examination.

EXHIBIT 21

List of Subsidiaries

Name of Subsidiary	Jurisdiction of Formation
ClearPoint Neuro (Canada) Inc.	Canada (New Brunswick)
ClearPoint Neuro UK Ltd	United Kingdom

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the inclusion or incorporation by reference of our report, dated March 8, 2022, with respect to the consolidated balance sheets of ClearPoint Neuro, Inc. (formerly, MRI Interventions, Inc.) and subsidiaries (the "Company") as of December 31, 2021 and 2020 and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended, in (i) the Company's Registration Statement on Form S-8 (No. 333-183382), (ii) the Company's Registration Statement on Form S-8 (No. 333-191908), (iii) the Company's Registration Statement on Form S-8 (No. 333-206432), (iv) the Company's Registration Statement on Form S-8 (No. 333-220783), (v) the Company's Registration Statement on Form S-8 (No. 333-238907), (vi) the Company's Registration Statement on Form S-3 No. (333-252346); and (vii) the Company's Registration Statement on Form S-8 No. (333-256789).

/s/ Cherry Bekaert LLP

Tampa, Florida
March 8, 2022

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(a) UNDER
THE SECURITIES EXCHANGE ACT OF 1934

I, Joseph M. Burnett, certify that:

1. I have reviewed this annual report on Form 10-K for the fiscal year ended December 31, 2021, of ClearPoint Neuro, Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: March 8, 2022

/s/ Joseph M. Burnett
Joseph M. Burnett
Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(a) UNDER
THE SECURITIES EXCHANGE ACT OF 1934

I, Danilo D'Alessandro, certify that:

1. I have reviewed this annual report on Form 10-K for the fiscal year ended December 31, 2021, of ClearPoint Neuro, Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: March 8, 2022

/s/ Danilo D'Alessandro
Danilo D'Alessandro
Chief Financial Officer

EXHIBIT 32

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO RULE 13a-14(b) UNDER THE SECURITIES EXCHANGE ACT OF 1934 AND SECTION 1350 OF CHAPTER 63 OF TITLE 18 OF THE UNITED STATES CODE

Each of the undersigned, Joseph M. Burnett and Danilo D'Alessandro, certifies pursuant to Rule 13a-14(b) under the Securities Exchange Act of 1934 and Section 1350 of Chapter 63 of Title 18 of the United States Code, that (1) this annual report on Form 10-K for the fiscal year ended December 31, 2021, of ClearPoint Neuro, Inc. (the "Company") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934, and (2) the information contained in this report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 8, 2022

/s/ Joseph M. Burnett
Joseph M. Burnett
Chief Executive Officer

/s/ Danilo D'Alessandro
Danilo D'Alessandro
Chief Financial Officer