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, 2020**

or

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

For the transition period from _____ to _____.

Commission File Number: **001-34822**

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.)*
5 Musick **Irvine, California** *(Address of principal executive offices)*	**92618** *(Zip Code)*

(949) 900-6833
(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, 2020, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was $42,931,687 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 18, 2021**
Common Stock, $.01 par value per share	20,672,779 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, 2020, pursuant to Regulation 14A under the Securities Exchange Act of 1934 in connection with the 2021 annual meeting of stockholders.

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Trademarks, Trade Names and Service Marks

ClearPoint Neuro®, *ClearPoint*®, *ClearTrace*®, *MRI Interventions*®, *SmartFlow*®, *SmartFrame*®, *SmartGrid*®, PURSUIT™, *Inflexion*™ and Maestro™ are 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 Americas Inc, a wholly owned subsidiary of Clinical Laserthermia Systems AB, IMRIS refers to IMRIS, Deerfield Imaging 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 Microsystems, LLC, 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, or SEC, before making an investment decision regarding our common stock.

Risks Related to Our Business and Industry

- COVID-19 could adversely impact our business.
- Our ClearPoint system may not achieve broad market acceptance or be commercially successful.
- We have relatively limited experience marketing and selling our ClearPoint system, and if we are unable to expand, manage and maintain our marketing and sales capabilities, we may be unable to generate significant growth in our product revenues.
- If coverage and reimbursement from third-party payors for procedures utilizing our ClearPoint system 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 and operating results.
- We have limited internal manufacturing resources, and if we are unable to provide an adequate supply of our ClearPoint disposable products, our growth could be limited and our business could be harmed.
- Our reliance on single-source suppliers could harm our ability to meet demand for our ClearPoint system in a timely manner or within budget.
- Our ClearTrace system remains a product candidate in development. We cannot be certain that we will be able to successfully complete development of, and obtain regulatory clearances or approvals for, our ClearTrace system in a timely fashion, or at all.
- To the extent we seek a new indication for use of, or new claims for, our ClearPoint system, 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.
- 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.
- 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.
- Our business will be subject to economic, political, regulatory and other risks associated with international operations.

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

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.
- 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.
- 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.

- 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 may be dependent upon one of our licenses from The Johns Hopkins University to develop and commercialize some components of the ClearTrace system.

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.
- Federal legislation and other payment and policy changes may have a material adverse effect on our business.
- Our products may in the future 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.
- 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.
- 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 Quality System Regulation, or 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 may be subject to privacy and data protection laws governing the transmission, use, disclosure, security and privacy of health information which may impose restrictions on technologies and subject us to penalties if we are unable to fully comply with such laws.

Risks Related to Our Facilities, Employees and Growth

- 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.
- If we do not effectively manage our growth, we may be unable to successfully market and sell our products or develop our product candidates.

Risks Related to Our Common Stock

- Our common stock may be traded infrequently and in low volumes, so stockholders may be unable to sell their shares of common stock at or near the quoted bid prices if they wish to sell their shares.

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

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.
- Damage to our reputation could harm our businesses, including our competitive position and business prospects.
- We could become subject to product liability claims that could be expensive, divert management's attention and harm our business.
- 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.

ITEM 1. BUSINESS

Overview

We are a 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 under direct, intra-procedural magnetic resonance imaging, or MRI, guidance. From our inception in 1998, we deployed significant resources to fund our efforts to develop the foundational capabilities for enabling MRI-guided interventions and to build an intellectual property portfolio. In 2003, our focus shifted to identifying and building out commercial applications for the technologies we developed in prior years.

Our ClearPoint system is in commercial use in the United States and the European Union (the "EU"). The primary applications for the ClearPoint system are to target and guide, in an MRI setting, the insertion of deep brain stimulation electrodes and laser catheters into the brain.

Our SmartFlow cannula has been used in clinical trials to inject certain fluids directly into the brain, thus bypassing the blood-brain barrier, should our pharmaceutical company customers achieve success in completion of clinical trials of their drugs and biologics.

Our ClearTrace system is a product candidate still in development, the objective of which is to perform minimally invasive surgical procedures in the heart. However, we have reduced our development expenditures related to ClearTrace, as we devote our resources to the continued development and commercialization of ClearPoint.

Our products are designed to provide a new, minimally invasive surgical approach to address large patient populations for whom we believe current surgical techniques are deficient. Our ClearPoint system is a neuro-navigation system designed for instruments or devices to treat a variety of neurological diseases and conditions and for performing biopsies. Our SmartFlow cannula is being used by several pharmaceutical companies to deliver drugs and biologics under such companies' clinical trials. We believe that our ClearPoint product platform, subject to appropriate regulatory clearances and approvals as we pursue 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, further discussed as follows:

- *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 believe that our product platforms are designed to enable physicians to see the target site, guide the surgical instrument to the site, deliver the therapy, monitor for adverse events and complications and confirm the desired results of the procedure, all under high resolution, intra-procedural MRI guidance. 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 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.

We estimate that there are 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

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 avoid vasculature and, in turn, to avoid 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 out of MR safe materials such as plastics, ceramics and liquids visible under MRI. During a 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.

ClearPoint Neuro has evolved to become a company comprised of two parts. In the past, we were viewed strictly as a medical device company providing navigation systems for neurosurgery. This part of the Company participates in an existing $500 million market, of which we have less than a 10% market share. However, we believe we are currently growing faster than the market as we continue to convert procedures from the operating room to the MRI suite. The other half of ClearPoint Neuro is focused on biologics and drug delivery companies, 25 of whom are either evaluating or using our SmartFlow cannula, depending on each such company's stage of product development, which ranges from preclinical research to late-stage regulatory trials.

Our Current Products and Product Candidates

ClearPoint Neuro Navigation System

General

Our ClearPoint system is designed to allow minimally invasive procedures in the brain to be performed in a hospital's existing MRI suite or in an inter-operative MRI. It provides guidance for the placement and operation of instruments or devices during the planning and operation of neurosurgical procedures performed within the MRI suite using MRI guidance. Our ClearPoint system is 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. It is intended 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. The CE mark is an international symbol of adherence to quality assurance standards and compliance with applicable EU medical device directives, and it allows us to market the ClearPoint system in the EU. Today, ClearPoint systems are in clinical use with MRI scanners from the three major manufacturers, Siemens, GE Healthcare and Philips Healthcare, as well as the two major interventional MR/OR platforms, which are manufactured by IMRIS and 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 drug 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, under which a special 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, essential tremor and epilepsy. The medical community has also developed another local therapy known as deep brain stimulation, or DBS. DBS uses mild electrical pulses from an implanted device to stimulate a small target region in the brain. A DBS system looks and operates 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 and essential tremor. The FDA has also approved the use of DBS for the treatment of dystonia and obsessive-compulsive disorder pursuant to humanitarian device exemptions. DBS is also being investigated as a therapy for other neurological disorders, such as epilepsy, treatment-resistant major depression and Alzheimer's disease.

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. However, 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, which target 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 55,000 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. The potential procedures include:

- *Electrode Placement* – The current standard of care for the placement of the DBS electrodes requires the patient to be awake during surgery, in order to verify proper placement. Our ClearPoint system can provide real-time visualization of the placement, which we believe will drive growth in the number of potential procedures. Both St. Jude Medical (now part of Abbott Laboratories) and Boston Scientific received FDA clearances for new DBS systems and both have received conditional FDA clearance for use of these systems in an MRI setting for the treatment of epilepsy. Abbott Laboratories began marketing the Infinity ® DBS system in 2017 and Boston Scientific launched the Vercise™ Deep Brain Stimulation System in 2018. 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 6,000 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 essential tremor, dystonia, obsessive compulsion disorder or severe depression may create additional potential procedure opportunities.
- *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, which 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, Huntington's disease and certain types of cancers, such as Glioblastoma. The potential addressable market by 2025 for these indications is estimated to be more than 300,000 patients worldwide and $1.5 billion. 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 these clinical trials and believe that the first gene therapy submissions may be reviewed by regulatory authorities throughout 2021. This said, it is early in the development cycle to estimate the potential of, and our ability to capitalize on, this market opportunity with a reasonable amount of certainty.

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 or more hours.

Our ClearPoint System Solution

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 is designed to be performed in a standard hospital-based MRI scanner or intra-operative MRI, instead of a traditional operating room.

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. Our 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. 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.

Regulatory Status

Our ClearPoint system has a general indication for use. Our 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. Similar to other conventional stereotaxy-based systems, our ClearPoint system's general neurosurgical indication for use does not reference specific neurosurgical procedures. In the EU, our CE mark approval carries the same indication for use as our 510(k) clearance in the United States.

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 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, others more on open craniotomy surgeries and others more on minimally invasive approaches, such as functional neurosurgery. We believe our ClearPoint system may be most applicable to those 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 make the reusable ClearPoint components available to hospitals pursuant to our ClearPoint Placement Program, under which we install a system at the hospital but we retain title to the system. Under that program, we may make the reusable ClearPoint components available to a hospital for use during an agreed-upon period of time while the hospital evaluates and processes the purchase opportunity. In addition, under the ClearPoint Placement Program we may permit a hospital to pay for an installed system or its use over an agreed-upon period of time. 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 18, 2021, our sales, clinical support and marketing team consisted of 27 employees. We believe that our current sales, clinical support and marketing team is sufficient for our current needs; however, we expect the size of our team to vary 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 18, 2021, our research and development team consisted of 22 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 stem 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 these 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 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 18, 2021, more than 60 hospitals in the U.S., Canada and the EU 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 35% of our functional neurosurgery navigation disposable product revenues in 2020.

At March 18, 2021, we had commercial relationships with approximately 25 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 accounted for approximately 60% of our biologics and drug delivery revenues in 2020.

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, whether wholly-owned or co-owned, or 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 18, 2021, we wholly-owned, co-owned or licensed a total of 65 United States patents and more than 30 United States patent applications, as well as foreign patents and foreign patent applications corresponding with many of our United States patents and applications. Our owned, issued patents expire at various dates beginning in 2023. Some of our patents and patent applications are co-owned by Boston Scientific, and, with respect to those patents and patent applications, we have licensing and cross-licensing arrangements in place with Boston Scientific. As a result of those arrangements, we have exclusive rights to all fields outside neuromodulation and implantable medical leads for cardiac applications, and we have licensed the fields of neuromodulation and implantable medical leads for cardiac applications to Boston Scientific.

Certain License and Collaborative Arrangements

Philips

During 2020 we entered into a worldwide license and research agreement with Philips, under which Philips has licensed the technology underlying its Philips Brain Model for use in 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.

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, with the expectation of initial product launches to occur in 2023, 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.

CLS

In October 2018, and as amended in August 2019, 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 the provides for our use of design features developed by UCSF that 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 ClearPoint software platform, version 2.0 of which received FDA clearance in November 2018, we entered into three agreements under which we receive worldwide, non-exclusive licenses to software code related to certain functional elements of the ClearPoint software, for which we are committed to pay royalties for each copy of our ClearPoint sold, or in certain cases, loaned by us to end-users.

Johns Hopkins

Shortly following our formation in 1998, we entered into a license agreement with Johns Hopkins pursuant to which we obtained an exclusive, worldwide license to a number of technologies owned by Johns Hopkins relating to devices, systems and methods for performing MRI-guided interventions, such as MRI-guided cardiac ablation procedures. The field of use for this exclusive license covers diagnostic or therapeutic methods, processes or devices using an intravascular, intralumen or intratissue miniature magnetic resonance coil detection probe. We are obligated to pay Johns Hopkins an annual maintenance fee, and we are also obligated to pay a royalty to Johns Hopkins based on the sale of products or provision of services covered by a licensed patent.

In December 2006, we entered into a license agreement with Johns Hopkins under which we obtained an exclusive, worldwide license to certain MRI-safety technologies owned by Johns Hopkins. Under the agreement, we are obligated to pay a royalty to Johns Hopkins based on the sale of products or provision of services covered by a licensed patent, subject to a minimum annual payment.

In June 2008, we also entered into an exclusive license agreement with Johns Hopkins with respect to certain catheter technology. Under the agreement, we are obligated to pay a royalty to Johns Hopkins based on the sale of products or provision of services incorporating the licensed technology.

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 not aware of any other company that offers a direct MRI-guided stereotactic system for neurosurgical interventions, although two companies, Monteris Medical Inc. and Medtronic plc 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, or FDCA, as implemented and enforced by the FDA. The FDA governs 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, 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, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials (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 a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute 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 have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA.

510(k) Clearance Pathway

When a 510(k) clearance is required, we will be required to submit a 510(k) application demonstrating that our proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of PMAs. By regulation, the FDA is required to clear or deny a 510(k) premarket notification within 90 days of submission of the application. As a practical matter, clearance may take longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence.

If the FDA issues an order declaring the device to be Not Substantially Equivalent, or NSE, the device is placed into a Class III or PMA category. At that time, a company can request a de novo classification of the product. A de novo classification generally applies where there is no predicate device and the FDA believes the device is sufficiently safe so that no PMA should be required. The request must be in writing and sent within 30 days from the receipt of the NSE determination. The request should include a description of the device, labeling for the device, reasons for the recommended classification and information to support the recommendation. The de novo classification process has a 60-day review period. If the FDA classifies the device into Class II, a company will then receive an approval order to market the device. This device type can then be used as a predicate device for future 510(k) submissions. However, if the FDA subsequently determines that the device will remain in the Class III category, the device cannot be marketed until we have obtained an approved PMA.

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 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 or PMA approval is obtained. If the FDA requires us to seek 510(k) clearance 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 or PMA approval is obtained and we could be subject to significant regulatory fines or penalties.

PMA Approval Pathway

A PMA must be submitted to the FDA if the device cannot be cleared through the 510(k) 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.

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. Although we believe that most components of our ClearTrace system will fall under the FDA's 510(k) regulatory process, we do believe the ablation catheter component will require the approval of a PMA. Likewise, 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 are sometimes required for 510(k) clearance. 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 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. Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an institutional review board, or IRB, for the relevant clinical trial sites and must comply with FDA regulations, including, but not limited to, those relating to good clinical practices. To conduct a clinical trial, we also are required to obtain the patient's informed consent in a form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. 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 efficacy of the device or may otherwise not be sufficient to obtain FDA clearance 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.

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 and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance of product modifications that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices;
- approval of product modifications that affect the safety or effectiveness of one of our approved devices;
- 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. 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 or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export 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 date by which the Medical Devices Regulation was to be fully implemented was originally defined as May 26, 2020. However, because of the COVID-19 pandemic, the European Commission and the European Parliament decided in April 2020 to postpone the deadline by one year to May 26, 2021. Once effective, the new regulations will among other things:

- Strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- Establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- Improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- Set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- Strengthen 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 governmental control. 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 pending legal and constitutional challenges in the United States Supreme Court. The Supreme Court heard oral arguments in California v. Texas on November 2, 2020. The Court has yet to issue its opinion, and we cannot say for certain what the decision will be or what impact, if any, it may have on our business.

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 knowingly and willfully to 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 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 18, 2021, we had 67 full time employees, of whom 22 were engaged primarily in research and development, 13 in manufacturing and quality assurance, 27 in sales, clinical support and marketing, and 5 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 2020, 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

On March 11, 2020, the World Health Organization characterized the spread of a novel strain of coronavirus ("COVID-19") as a global pandemic, and on March 13, 2020, the President of the United States proclaimed that the COVID-19 outbreak in the United States constituted a national emergency. Continued widespread infection in the United States is a possibility. Extraordinary actions have been taken by federal, state and local governmental authorities to combat the spread of COVID-19, including issuance of "stay-at-home" directives and similar mandates for many individuals to substantially restrict daily activities and for many businesses to curtail or cease normal operations. These measures, while intended to protect human life, have 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 vaccinations to combat the COVID-19 virus have commenced, 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, as hospitals postpone or reduce capital purchases and overall spending. 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 in the coming months of 2021. 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. 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 acceptance or be commercially successful.

We expect that sales of our ClearPoint system products will account for the majority of our revenues for at least the next few years. Our ClearPoint system may not gain broad market acceptance 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 physician with other devices and surgical approaches;
- 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;
- 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.

If physicians and hospitals do not perceive our ClearPoint system as an attractive alternative to other products and procedures, we will not achieve significant market penetration or be able to generate significant revenues. To the extent that our ClearPoint system is not commercially successful or is withdrawn from the market for any reason, our revenues will be adversely impacted, and our business, operating results and financial condition will be harmed.

We have relatively limited experience marketing and selling our ClearPoint system, and if we are unable to expand, manage and maintain our marketing and sales capabilities, we may be unable to generate significant growth in our product revenues.

We started selling our ClearPoint system on a limited basis in August 2010, and we did not begin to meaningfully expand our sales and clinical support capabilities until 2013. As a result, we have relatively limited experience marketing and selling our ClearPoint system. Our operating results are directly dependent upon the marketing and sales efforts of our employees. If our team fails to adequately promote, market and sell our products, our sales will suffer.

We expect to continue building our team to market, sell and support our ClearPoint system products in the United States. That effort, though, could take longer than we anticipate, in which case our commercialization efforts would be negatively impacted. Our ability to achieve significant revenue growth will depend, in large part, on our success in recruiting, training, motivating and retaining a sufficient number of qualified personnel.

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

Our ClearPoint system 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 ClearPoint system is used. Reimbursement is a significant factor considered by hospitals in determining whether to acquire and utilize medical devices such as our ClearPoint system products. Therefore, our ability to successfully commercialize our ClearPoint system depends significantly on the adequacy of coverage and reimbursement from these third-party payors.

Third-party payors, whether foreign or domestic, or 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 hospitals are reimbursed for the procedures in which our ClearPoint system 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 ClearPoint system 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 2020, one pharmaceutical customer, a related party as described in Note 3 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 28% of our total revenues. Our five largest hospital customers account for approximately 36% 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.

We have limited internal manufacturing resources, and if we are unable to provide an adequate supply of our ClearPoint disposable products, our growth could be limited and our business could be harmed.

Final assembly of many of our ClearPoint disposable components occurs at our Irvine, California facility. 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.

In connection with the continued commercialization of our ClearPoint system, we expect that we will need to increase, or "scale up," the production process of our disposable 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 ClearPoint system in a timely manner or within budget.

Many of the components and component assemblies of our ClearPoint system 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 ClearPoint system, which could harm our ability to generate revenues, lead to customer dissatisfaction and damage our reputation. Furthermore, if we are required to change the supplier of a key component or component assembly of our ClearPoint system, 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 ClearPoint system.

Our ClearTrace system remains a product candidate in development. We cannot be certain that we will be able to successfully complete development of, and obtain regulatory clearances or approvals for, our ClearTrace system in a timely fashion, or at all.

Our ClearTrace system is a product candidate in development, although in 2015 we reduced our development expenditures related to ClearTrace to enable us to focus resources on our ClearPoint system. At the time we reduced our ClearTrace development work, we had conducted only animal studies and other preclinical work with respect to that product candidate. Our ClearTrace system will require substantial additional development and testing. There can be no assurance that we will resume our ClearTrace development program, or that, if resumed, our development efforts will be successfully completed, or that the ClearTrace system will have the capabilities we expect. If we resume our work, we may encounter significant difficulties and costs during the course of our development efforts and we may encounter significant additional delays. Even if we successfully complete development of our ClearTrace system, there can be no assurance that we will obtain the regulatory clearances or approvals to market and commercialize it. If we are unable to obtain regulatory clearances or approvals for our ClearTrace system, or otherwise experience delays in obtaining such regulatory clearances or approvals, the commercialization of the ClearTrace system will be delayed or prevented. Even if cleared or approved, the ClearTrace system may not be cleared or approved for the indications that are necessary or desirable for successful commercialization. Delays in developing our ClearTrace system or obtaining regulatory clearances or approvals may also result in the loss of potential competitive advantages that might otherwise be attained by bringing products to market earlier than our competitors. Any of these contingencies could adversely affect our business. Likewise, in lieu of resuming our ClearTrace development program and undertaking the remaining development work, we may explore collaborations with one or more third parties pursuant to which the technologies underlying our ClearTrace system would be further developed and potentially commercialized. If we enter into any such collaboration with a third party, we may have to relinquish valuable rights to our ClearTrace system and its underlying technologies.

To the extent we seek a new indication for use of, or new claims for, our ClearPoint system, 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.

Clinical trials necessary to support 510(k) clearance or PMA approval for our ClearTrace system or any new indications for use for our ClearPoint system 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 ClearTrace system 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 ClearPoint system 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.

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 ClearPoint system, abandon our ClearTrace system 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 the ClearPoint system and the ClearTrace system are 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 plc, St. Jude Medical Inc. and Biosense Webster Inc., a division of Johnson & Johnson.

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;
- 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.

Our business will be subject to economic, political, regulatory and other risks associated with international operations.

At present, our commercialization activities for our ClearPoint system are focused in the United States. However, we do have CE marking approval to market our ClearPoint system in the EU. In addition, we ultimately intend to market our ClearPoint system in other foreign jurisdictions as well. There are a number of risks associated with conducting business internationally, including:

- differences in treatment protocols and methods across the markets in which we expect to market our ClearPoint system;
- requirements necessary to obtain product reimbursement;
- product reimbursement or price controls imposed by foreign governments;
- difficulties in compliance with foreign laws and regulations;
- changes in foreign regulations and customs;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or foreign governments; and
- negative consequences from changes in tax laws.

Any of these risks could adversely affect our financial results and our ability to operate outside the United States, which could harm our business.

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. 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, 2020 was approximately $120 million. Net cash used in operations was $7.8 million for the year ended December 31, 2020, and at December 31, 2020, we had cash and cash equivalent balances aggregating $20.1 million. Since our inception, we have financed our operations principally from the sale of equity securities, the issuance of notes payable and license arrangements. Recent such financing activities consist of: (i) private placements in January and December 2020 of secured convertible notes due in 2025, which resulted in net proceeds of $24.3 million (the "2020 Financing Transaction"); and (ii) a May 2019 private placement of equity, which resulted in net proceeds of $7.4 million (the "2019 PIPE"); and (iii) a February 2021 public offering of equity, which resulted in net proceeds of $46.8 million. In addition, at any time up to January 11, 2022, we have the right, but not the obligation, to request one of the noteholders in the 2020 Financing Transaction to purchase up to an additional $10.0 million of secured convertible notes (the "Additional Convertible Notes"), provided that such noteholder has the right, but not the obligation, to purchase the Additional Convertible Notes.

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, from sales of clinical services. 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 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, 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, including MRI-guided intervention systems and the components and methods and processes related to these systems. 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. The source code licensees are perpetual, except in the event we breach our agreement with any of the third parties, in which case such a third party may terminate the license for cause. 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.

We may be dependent upon one of our licenses from The Johns Hopkins University to develop and commercialize some components of the ClearTrace system.

We have entered into exclusive license agreements with The Johns Hopkins University, or Johns Hopkins, with respect to a number of technologies owned by Johns Hopkins. Under one of those agreements, which we entered into in 1998, we licensed a number of technologies relating to devices, systems and methods for performing MRI-guided interventions, particularly MRI-guided cardiac ablation procedures. Therefore, that license is important to the development of the ClearTrace system. Without that license, we may not be able to commercialize some of the components of the ClearTrace system, when and if developed, subject to regulatory clearance or approval. Johns Hopkins has the right to terminate the license under specified circumstances, including a breach by us and failure to cure such breach. We are obligated to use commercially reasonable efforts to develop and commercialize products based on the licensed patents and patent applications. This obligation could require us to take actions related to the development of the ClearTrace system that we would otherwise not take.

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 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 FDA requirements, including: required submissions of safety and other post-market information; manufacturing facility registration and device listing requirements; compliance with the FDA's medical device current Good Manufacturing Practice regulations, as codified in the Quality System Regulation, or QSR; requirements regarding field corrections and removals of our marketed products; reporting of adverse events and certain product malfunctions to the FDA; 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 510(k) clearances or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals 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 results of the 2020 election may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities, such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these requirements will be implemented and whether or how they will be rescinded or replaced under the Biden administration. The policies and priorities of a new 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 remains subject to pending legal and constitutional challenges in the United States Supreme Court. The Supreme Court heard oral arguments in California v. Texas on November 2, 2020. The Court has yet to issue its opinion, and we cannot say for certain what the decision will be or what impact, if any, it may have on our business.

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. A two-year moratorium applied to this tax through December 2019. 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 in the future 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 in order 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 our ClearPoint system also could become subject to a recall. Our ClearPoint system is 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 system, 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, such as biopsies and catheter and electrode insertions, 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. 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 in order 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 a physician or teaching hospital 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 may be subject to privacy and data protection laws governing the transmission, use, disclosure, security and privacy of health information which may impose restrictions on technologies and subject us to penalties if we are unable to fully comply with such laws.

Numerous federal, state and international laws and regulations govern the collection, use, disclosure, storage and transmission of patient-identifiable health information. These laws include:

- HIPAA and the Privacy and Security Rules promulgated thereunder apply to covered entities, which include most healthcare facilities that purchase and use our products. The HIPAA Privacy and Security Rules set forth minimum standards for safeguarding individually identifiable health information, impose certain requirements relating to the privacy, security and transmission of individually identifiable health information and provide certain rights to individuals with respect to that information. HIPAA also requires covered entities to contractually bind third parties, known as business associates, in the event that they perform an activity or service for or on behalf of the covered entity that involves access to patient identifiable health information.
- The federal Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, which strengthens and expands the HIPAA Privacy and Security Rules and its restrictions on use and disclosure of patient identifiable health information, including imposing liability on business associates of covered entities.
- Both HITECH and state data breach laws that necessitate the notification in certain situations of a breach that compromises the privacy or security of personal information.
- Other federal and state laws restricting the use and protecting the privacy and security of patient information may apply, many of which are not preempted by HIPAA. Federal and state consumer protection laws are being applied increasingly by the United States Federal Trade Commission 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 website content.
- Other countries also have, or are developing, laws governing the collection, use and transmission of personal or patient information.
- Federal and state laws regulating the conduct of research with human subjects.

We are required to comply with federal and state laws governing the transmission, security and privacy of patient identifiable health information that we may obtain or have access to in connection with manufacture and sale of our products. We do not believe that we are a HIPAA-covered entity because we do not submit electronic claims to third-party payors, but there may be limited circumstances in which we may operate as a business associate to covered entities if we receive patient identifiable data through activities on behalf of a healthcare provider. We may be required to make costly system modifications to comply with the HIPAA privacy and security requirements that will be imposed on us contractually through business associate agreements by covered entities and directly under HITECH or HIPAA regulations. Our failure to comply may result in criminal and civil liability because the potential for enforcement action against business associates is now greater. Enforcement actions can be costly and interrupt regular operations which may adversely affect our business.

In addition, numerous other federal and state laws protect the confidentiality of patient information as well as employee personal information, including state medical privacy laws, state social security number protection laws, state data breach laws and federal and state consumer protection laws. These various laws in many cases are not preempted by the HIPAA rules and may be subject to varying interpretations by the courts and government agencies, creating complex compliance issues for us and our customers and potentially exposing us to additional expense, adverse publicity and liability. In connection with any clinical trials we conduct, we will be subject to state and federal privacy and human subject protection regulations. The HIPAA requirements and other human-subject research laws could create liability for us or increase our cost of doing business because we must depend on our research collaborators to comply with the applicable laws. We may adopt policies and procedures that facilitate our collaborators' compliance, and contractually require compliance, but we cannot ensure that non-employee collaborators or investigators will comply with applicable laws. As a result, unauthorized uses and disclosures of research subject information in violation of the law may occur. Any such violations could lead to sanctions that could adversely affect our business.

Risks Related to Our Employees and Growth

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.

If we do not effectively manage our growth, we may be unable to successfully market and sell our products or develop our product candidates.

Our future revenue and operating results will depend on our ability to manage the anticipated growth of our business. In order 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.

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 Securities and Exchange Commission, or 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 develop successfully 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 18, 2021, 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 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 pursuant to this prospectus, Rule 144 or otherwise 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. 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.

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, supplier, 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 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 incorporates 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 ClearPoint system is 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.

The medical device industry has historically been subject to extensive litigation over product liability claims. A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs. Although we maintain product 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 product liability claims. Additionally, we may be unable to maintain our existing product liability insurance in the future at satisfactory rates or in adequate amounts. A product 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 substantially all our activities, including executive management, 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 recent outbreak of the novel coronavirus COVID-19, 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

Not applicable.

ITEM 2. PROPERTIES.

We lease approximately 7,400 square feet of space in Irvine, California under a lease that expires in September 2023. Our principal executive office and our principal operations are based at this facility. We believe that this facility is sufficient to meet our needs for the foreseeable future.

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 18, 2021, we had 20,672,779 shares of common stock outstanding and no shares of preferred stock outstanding. As of March 18, 2021, we had 210 stockholders of record. In addition, as of March 18, 2021, options and warrants to purchase 3,321,532 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 (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by stockholders[(1)]	1,290,717	$ 5.89	1,023,811
Equity compensation plans not approved by stockholders[(1)(2)(3)(4)(5)(6)(7)]	515,375	$ 10.82	—
Total	1,806,092	$ 7.12	1,023,811

(1) The information presented in this table is as of December 31, 2020.
(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, 2020, awards with respect to 10,375 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.

Not applicable.

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 medical device company that develops and commercializes innovative platforms for performing minimally invasive surgical procedures in the brain under direct, intra-procedural MRI guidance. Our principal product platform is our ClearPoint system, which is in commercial use and is used to perform minimally invasive surgical procedures in the brain. The ClearPoint system utilizes intra-procedural MRI to guide the procedures and are designed to work in a hospital's existing MRI suite. We believe that this product platform delivers better patient outcomes, enhances revenue potential for both physicians and hospitals, and reduces costs to the healthcare system.

In 2010, we received regulatory clearance from the FDA to market our ClearPoint system in the U.S. for general neurosurgery procedures. In 2011, we also obtained CE marking approval for our ClearPoint system, which enables us to sell our ClearPoint system in the EU. Substantially all our product revenues for the years ended December 31, 2020 and 2019 relate to sales of our ClearPoint system products and related services. We have financed our operations and internal growth primarily through the sale of equity securities, the issuance of convertible and other secured notes, and license arrangements. We have incurred significant losses since our inception in 1998 as we have devoted substantial efforts to research and development. As of December 31, 2020, we had accumulated losses of approximately $120 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

On March 11, 2020, the World Health Organization characterized the spread of a novel strain of coronavirus ("COVID-19") as a global pandemic, and on March 13, 2020, the President of the United States proclaimed that the COVID-19 outbreak in the United States constituted a national emergency. Continued widespread infection in the United States is an ongoing possibility. Although vaccinations to combat the COVID-19 virus have commenced, we are unable to determine the timing and extent to which the vaccination process will affect the progression of the virus. Extraordinary actions have been taken by federal, state and local governmental authorities to combat the spread of COVID-19, including issuance of "stay-at-home" directives and similar mandates for many individuals to substantially restrict daily activities and for many businesses to curtail or cease normal operations. These measures, while intended to protect human life, have 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.

Furthermore, the recessionary conditions on the global economy caused by the COVID-19 pandemic could have a material adverse effect on our business, as hospitals postpone or reduce capital purchases and overall spending. 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 in the coming months of 2021. 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. 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 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 hospital and by type of procedure to gain information that informs targeted sales and marketing activities. During the year ended December 31, 2020, the ClearPoint system was used in 682 cases, respectively, as compared to 801 cases during 2019, representing a decrease of 15%. Consistent with the discussion in the section "Results of Operations – Revenues," we attribute this decrease to the COVID-19 pandemic.
    - Number of "Active Surgical Centers" – For purposes of analyzing this performance indicator, an Active Surgical Center is a hospital that has purchased products from us or has performed procedures utilizing our ClearPoint system within a rolling 24-month period, and includes hospital 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 neurosurgical product is sold to such hospitals for their use in cases. In addition to signifying growth, the number of Active Surgical 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, 2020 and 2019, the ClearPoint system was used in more than 60 Active Surgical Centers. Consistent with the discussion in the section "Results of Operations –Revenues," we attribute the minimal growth in this performance indicator to the COVID-19 pandemic.

- 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 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 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 the use of our products and services in delivering our Partners' therapies. At December 31, 2020, we had commercial relationships with approximately 25 Partners, as compared with approximately 20 Partners at December 31, 2019.

- Therapy products – We do not expect meaningful revenue from therapy products in 2021 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 Surgical 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. Future revenues from sales of our ClearPoint platform products and services are 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 revenues from the sale of products is an important part of our business model for our ClearPoint system. We anticipate that, over time, recurring revenues will constitute an increasing percentage of our total revenues as we leverage installations of our ClearPoint system to generate recurring sales of our functional neurosurgical products. Our product revenues were approximately $8.8 million and $9.8 million for the years ended December 31, 2020 and 2019, respectively, and were almost entirely related to our ClearPoint system.

In addition, we expect that, over time, service revenues will constitute an increasing portion of our total revenues based on: (a) leveraging current and future installations of ClearPoint systems, as discussed above, so as to result in an increase in functional neurosurgical service revenues; and (b) increasing biologics and drug delivery service revenues should our customers in this space be successful in expansion of their clinical trials, and should we be successful in continuing to establish relationships with new biologic and drug delivery partners. Our service revenues were approximately $4.0 million and $1.4 million for the years ended December 31, 2020 and 2019, respectively.

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

Cost of Revenues

Cost of revenues includes the direct costs associated with the assembly and purchase of components for functional neurosurgical products, drug delivery and biologic products, non-neurosurgical 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 revenues 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. With the anticipated increases in the contribution to total revenues of sales of recurring products and services, as discussed above, we expect gross margin, as a percentage of total revenue, to increase over time.

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. 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, 2020, we have incurred approximately $61 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 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 Policies and Significant Judgments and 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, or 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 revenues are comprised primarily of: (1) product revenues resulting from the sale of functional neurosurgery, navigation, therapy, and biologics and drug delivery disposable products; (2) product revenues resulting from the sale of ClearPoint capital equipment and software; (3) revenues resulting from the service, installation, training and shipping related to ClearPoint capital equipment and software; and (4) clinical case support revenues in connection with customer-sponsored clinical trials. We recognize revenue when control of our products and services is transferred to our customers in an amount that reflects the consideration we expect to receive from our customers in exchange for those products and services. This process 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 we have 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 non-neurosurgery therapy product sales*: Revenues 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) are 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 of generally 90 days. 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.

- *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*

    - *Outsourced technical clinical support of cases performed pursuant to customer-sponsored clinical trials:*

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

- *Services related to sales of capital equipment and software:* Revenues from services related to sales of capital equipment and software are recognized over the period of time such services are rendered.
- *Capital equipment and software-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 revenues because we transfer control evenly by 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, non-neurosurgical 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.

Research and Development Costs. Costs related to research, design and development of products are charged to research and development expense as incurred. These costs include direct salary and employee benefit-related costs for research and development personnel, costs incurred under the terms of collaborative agreements, costs for materials used in research and development activities, and costs for outside services.

Results of Operations

Comparison of the Year Ended December 31, 2020 to the Year Ended December 31, 2019

	Year Ended December 31,		Percentage
(Dollars in thousands)	**2020**	**2019**	**Change**
Product revenues	$ 8,789	$ 9,796	(10)%
Service and other revenues	4,040	1,421	184%
Total revenues	12,829	11,217	14%
Cost of revenues	3,709	3,942	(6)%
Research and development costs	4,686	2,810	67%
Sales and marketing expenses	5,384	4,756	13%
General and administrative expenses	5,270	4,303	22%
Other income (expense):			
Other income, net	882	9	NM%
Interest expense, net	(1,444)	(955)	51%

Net loss	$ (6,782)	$ (5,540)	22%

NM – The percentage change is not meaningful.

Revenue. Total revenues were approximately $12.8 million and $11.2 million for the years ended December 31, 2020 and 2019, respectively.

Functional neurosurgery navigation and therapy product and service revenues, which consists of disposable product commercial sales related to cases utilizing the ClearPoint system and related services, decreased 12% to $6.3 million during the year ended December 31, 2020 from $7.1 million for the same period in 2019. This decrease was due primarily to the effects of the COVID-19 pandemic, in which elective surgical procedures, historically representing approximately 80% of our ClearPoint system case volume, were postponed or cancelled for a substantial portion of 2020. Although vaccinations to combat the COVID-19 virus have commenced, we are unable to determine the timing and extent to which the vaccination process will affect virus progression; 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. There were no increases in functional neurosurgery navigation product prices during the period between the year ended December 31, 2020 and the same period in 2019 that would be reasonably expected to affect a typical customer order.

Biologics and drug delivery revenues, which include sales of services related to customer-sponsored clinical trials utilizing the ClearPoint system and of related disposable products, increased 109% to $5.0 million for the year ended December 31, 2020, from $2.4 million for the same period in 2019. This increase was due primarily to an increase from 2019 to 2020 of approximately $2.7 million, or 302%, in biologics and drug delivery services, due primarily to an increase in service revenue from a customer who is a related party, as described in Note 3 to the consolidated financial statements included elsewhere in this Annual Report. There were no increases in biologics and drug delivery product prices during 2020 that would be reasonably expected to affect a typical customer order.

Capital equipment revenue, consisting of sales of ClearPoint reusable hardware and software, and of related services, decreased 10% to $1.5 million for the year ended December 31, 2020, as compared with $1.7 million for the same period in 2019. While revenues from this product line historically have varied from quarter to quarter, we believe that many hospitals have postponed capital equipment acquisition activities due to the COVID-19 pandemic. There were no increases in capital equipment product prices during the period between the year ended December 31, 2020 and the same period in 2019 that would be reasonably expected to affect a typical customer order.

Cost of Revenues. Cost of revenues was approximately $3.7 million for the year ended December 31, 2020, compared to $3.9 million for the year ended December 31, 2019, representing gross margin of 71% and 65%, respectively. This increase in gross margin was due primarily to a shift in the mix of revenues by line of business that resulted in service revenues, which bear higher gross margins in comparison to other product lines, representing a greater contribution to total sales for the year ended December 31, 2020, relative to the same period in 2019. While we believe that this factor may prevail during the period that precautionary measures are in effect due to the COVID-19 pandemic, we also believe it is likely that gross margin will erode from its current level if the mix of revenues and overhead allocations return to historical norms.

Research and Development Costs. Research and development costs were $4.7 million for the year ended December 31, 2020, compared to $2.8 million for the same period in 2019, an increase of $1.9 million, or 67%. The increase was due primarily to increases in: (a) compensation costs, due primarily to increases in headcount, of $0.6 million; (b) research costs of $0.5 million incurred in connection with collaborative agreements entered into during the year ended December 31, 2020; (c) product and software development costs of $0.2 million; (d) intellectual property costs, including amortization of acquired license rights, of $0.4 million; and (e) professional fees of $0.3 million.

Sales and Marketing Expenses. Sales and marketing expenses were $5.4 million for the year ended December 31, 2020, compared to $4.8 million for the same period in 2019, an increase of $0.6 million, or 13%. This increase was primarily due to a $1.1 million increase in base compensation costs, attributable primarily to headcount increases in our clinical and marketing teams, that were partially offset by decreases in travel of $0.4 million and incentive-based compensation of $0.3 million.

General and Administrative Expenses. General and administrative expenses were $5.3 million for the year ended December 31, 2020, compared to $4.3 million for the same period in 2019, an increase of $1.0 million, or 22%. This increase was due primarily to increases in: (a) compensation, consisting primarily of stock-based compensation and officer transition costs, of $0.6 million; (b) occupancy costs of $0.1 million; and (c) corporate legal fees of $0.2 million related primarily to new and potential biologic and drug delivery relationships.

Other Income. Other income was $0.9 million for the year ended December 31, 2020, compared to $9,000 for the same period in 2019. This increase was due primarily to the gain recognized on the forgiveness of the PPP Loan in November 2020, the proceeds of which the Company 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, 2020 was $1.4 million, compared with $1.0 million for the same period in 2019. This increase was primarily due to: (a) an increase of $0.2 million in amortization of discount associated with notes payable, due to the acceleration of such amortization in 2020 of the 2010 Secured Notes, which were repaid and retired in 2020, and the amortization of the discount and financing costs incurred in January 2020 in connection with the 2020 Secured Notes; and (b) a $0.4 million increase in cash-based interest expense associated with notes payable, due to the issuance of the 2020 Secured Notes, as compared to the interest expense incurred in 2019 associated with the 2010 Secured Notes and the secured notes issued in 2014 and repaid in June 2019. Additional information with respect to the 2010 Secured Notes and the 2020 Secured Notes is in Note 6 to the consolidated financial statements included elsewhere in this Annual Report.

Liquidity and Capital Resources

At December 31, 2020, we had cash and cash equivalent balances aggregating $20.1 million, resulting primarily from completion of the 2019 PIPE and the 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, 2020 of approximately $120 million. In addition, our use of cash from operations amounted to $7.8 million for the year ended December 31, 2020. Since inception, we have financed our operations principally from the sale of equity securities, the issuance of notes payable and license arrangements.

As discussed in Note 8 to the consolidated financial statements included elsewhere in this Annual Report, in May 2019, we completed the 2019 PIPE with certain accredited investors under which such investors purchased 2,426,455 shares of our common stock at $3.10 per share, resulting in proceeds of approximately $7.5 million, before deducting offering expenses aggregating approximately $0.1 million.

In January 2020, we entered into the 2020 Financing Transaction with two investors (the “2020 Convertible Noteholders”) under which we issued an aggregate principal amount of $17.5 million of floating rate secured convertible notes (the “First Closing Notes”), resulting in proceeds, net of financing costs paid and payable, 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 Junior Secured Notes Payable that otherwise would have matured in October and November 2020.

The terms of the Securities Purchase Agreement (the "SPA") underlying the 2020 Financing Transaction 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 a note (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.

In April 2020, we received $896,000 in proceeds through a loan funded under the Payroll Protection Program as part of the CARES Act (the "PPP Loan"). In November 2020, we were notified by the U.S. Small Business Administration that the loan had been forgiven under the provision of the CARES Act.

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

As discussed in Note 11 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, 2020, 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, 2020 and 2019 is summarized as follows:

	Years Ended December 31,	
(in thousands)	**2020**	**2019**
Cash from operating activities	$ (7,808)	$ (2,850)
Cash from investing activities	(482)	(160)
Cash from financing activities	22,693	5,605
Net change in cash and cash equivalents	$ 14,403	$ 2,595

Net Cash Flows from Operating Activities. We used $7.8 million and $2.8 million of cash for operating activities in 2020 and 2019, respectively.

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; lease liabilities of $0.1 million, and deferred revenue of $0.4 million. These uses were offset by: (a) a decrease in prepaid expenses and other current assets of $0.1 million; and (b) net non-cash expenses included in our net loss aggregating $1.6 million and consisting of expenses related to depreciation and amortization, share-based compensation, paid-in-kind interest, amortization of debt issuance costs and original issue discounts and amortization of lease right of use assets, and net of accretion in lease liabilities, which were partially offset by the gain recognized with the forgiveness of the PPP loan.

In 2019, uses of cash in operating activities consisted of: (i) our $5.5 million loss; (ii) increases in inventory of $1.0 million and prepaid expenses and other current assets of $0.1 million; and (iii) a decrease in the lease liability of $0.1 million. These uses were offset by: (a) a decrease in accounts receivable of $0.1 million; (b) increases in accounts payable and accrued expenses of $1.2 million and in deferred revenue of $0.9 million; and (c) non-cash expenses included in our net loss aggregating $1.8 million and consisting of depreciation and amortization, share-based compensation, amortization of debt issuance costs and original issue discounts and amortization of lease right of use assets, net of accretion in lease liabilities.

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

Net cash flows used in investing activities in 2019 were $0.2 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 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.

Net cash provided by financing activities in 2019 consisted of proceeds from the 2019 PIPE of $7.4 million and the exercise of warrants of $0.4 million. These proceeds were partially offset by (i) the prepayment in 2019 of financing costs in connection with the 2020 Secured Notes; and (ii) principal repayments of the 2014 and 2010 Secured Notes of $2.1 million.

Off-balance Sheet Arrangements

We are not a party to any off-balance sheet arrangements that have, or are reasonably likely to have, a material current or future effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

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-26 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, 2020, 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, 2020.

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, 2020, 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, 2020.

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 Securities and Exchange Commission 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, 2020, 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.

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, 2020, pursuant to Regulation 14A under the Exchange Act in connection with our 2021 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, 5 Musick, Irvine, CA 92618. 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, 2020, pursuant to Regulation 14A under the Exchange Act in connection with our 2021 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, 2020, pursuant to Regulation 14A under the Exchange Act in connection with our 2021 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, 2020, pursuant to Regulation 14A under the Exchange Act in connection with our 2021 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, 2020 pursuant to Regulation 14A under the Exchange Act in connection with our 2021 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
4.1	Reference is made to Exhibits 3.1 through 3.5				
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 Series A Warrant to Purchase Common Stock issued in 2015 private offering	8-K	000-54575	4.1	December 15, 2015

4.5	Form of Series B Warrant to Purchase Common Stock issued in 2015 private offering	8-K	000-54575	4.2	December 15, 2015

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
4.6	Form of Series A Warrant to Purchase Common Stock issued to Brainlab AG	8-K	000-54575	4.1	March 22, 2016
4.7	Form of Series B Warrant to Purchase Common Stock issued to Brainlab AG	8-K	000-54575	4.2	March 22, 2016
4.8	Form of Omnibus Amendment dated June 30, 2016 by and among MRI Interventions, Inc., and certain holders of MRI Interventions, Inc.'s 12% Second-Priority Secured Non-Convertible Promissory Notes Due 2019	8-K	000-54575	10.1	July 1, 2016
4.9	Form of Omnibus Amendment dated June 30, 2016 to Second Amended and Restated Secured Note Due 2018	8-K	000-54575	10.2	July 1, 2016
4.10	Form of Warrant to Purchase Common Stock issued in connection with August 2016 note conversion	8-K	001-34822	4.1	September 1, 2016
4.11	Form of Second Omnibus Amendment dated August 31, 2016 by and among MRI Interventions, Inc., and certain holders of the Company's 12% Second-Priority Secured Non-Convertible Promissory Notes Due 2019	8-K	001-34822	10.3	September 1, 2016
4.12	Form of Third Omnibus Amendment Dated September 25, 2018 by and among MRI Interventions, Inc., and the holders of the Company's 12% Second-Priority Secured Non-Convertible Promissory Notes Due 2019	8-K	001-34822	10.1	September 25, 2018
4.13	Form of Warrant to Purchase Common Stock issued in 2017 private offering	8-K	001-34822	4.1	May 25, 2017
4.14	Form of Senior Secured Convertible Note (First Closing)	8-K	001-34822	4.1	January 13, 2020
4.15	Form of Senior Secured Convertible Note (Third Closing)	8-K	001-34822	4.3	January 13, 2020
4.16	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
4.18	Form of Senior Secured Convertible Note (Second Closing)	8-K	001-34822	4.1	December 29, 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

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
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

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

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
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
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

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.24	Amendment to Standard Industrial/Commercial Single-Tenant Lease-Net, dated as of May 11, 2018, by and between MRI Interventions, Inc. and Shaw Investment Company, LLC	10-Q	001-34822	10.1	August 14, 2018

10.25	Form of Registration Rights Agreement by and between the Company and the investors party thereto with respect to the May 2017 private offering	8-K	001-34822	10.2	May 25, 2017
10.26+	2010 Incentive Compensation Plan	10	000-54575	10.4	December 28, 2011
10.27+	2010 Non-Qualified Stock Option Plan	10	000-54575	10.5	December 28, 2011
10.28+	MRI Interventions, Inc. 2012 Incentive Compensation Plan	10	000-54575	10.34	February 9, 2012
10.29+	MRI Interventions, Inc. Amended and Restated 2013 Incentive Compensation Plan	Schedule 14A	000-54575	B	April 17, 2015
10.30+	Second Amended and Restated 2013 Incentive Compensation Plan	Schedule 14A	001-34822	A	September 5, 2017
10.31+	MRI Interventions, Inc. 2013 Incentive Compensation Plan Form of Incentive Stock Option Agreement	10-Q	000-54575	10.53	August 14, 2013
10.32+	MRI Interventions, Inc. 2013 Incentive Compensation Plan Form of Non-Qualified Stock Option Agreement	10-Q	000-54575	10.54	August 14, 2013
10.33+	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
10.34+	MRI Interventions, Inc. 2013 Incentive Compensation Plan Form of Restricted Share Award Agreement	10-Q	001-34822	10.2	August 12, 2019
10.35+	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
10.36+	MRI Interventions, Inc. Non-Employee Director Compensation Plan, as amended and restated by the Board of Directors of MRI Interventions, Inc. on December 12, 2017	8-K	001-34822	10.1	December 14, 2017
10.37+	Form of Indemnification Agreement	10	000-54575	10.8	December 28, 2011
10.38+	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
10.39+	Employment Offer Letter between MRI Interventions, Inc. and Harold A. Hurwitz	10-Q	000-54575	10.1	May 7, 2015

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.40+	Non-Competition Agreement between Harold A. Hurwitz and MRI Interventions, Inc.	10-Q	000-54575	10.2	May 7, 2015
10.41+	Non-Disclosure and Proprietary Rights Agreement between Harold A. Hurwitz and MRI Interventions, Inc.	10-Q	000-54575	10.3	May 7, 2015
10.42+	Second Amended and Restated Key Personnel Incentive Program	10-Q	000-54575	10.3	August 14, 2013
10.43+	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
10.44+	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
10.45+	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
10.46+	SurgiVision, Inc. Cardiac EP Business Participation Plan	10	000-54575	10.29	December 28, 2011
10.47+	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
10.48+	Non-Qualified Stock Option Agreement, effective as of November 10, 2012, granted by MRI Interventions, Inc. to Robert C. Korn	S-8	333-191908	99.3	October 25, 2013
10.49+	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
10.50+	Non-Qualified Stock Option Agreement, effective as of December 5, 2013, granted by MRI Interventions, Inc. to Paul A. Bottomley	10-K	000-54575	10.57	March 28, 2014

10.51+	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
10.52+	Non-Qualified Stock Option Agreement, effective as of November 10, 2014, granted by MRI Interventions, Inc. to Robert C. Korn	S-1	333-201471	10.64	January 13, 2015
10.53+	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

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.54+	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
10.55+	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
10.56	Form of Securities Purchase Agreement, dated as of May 9, 2019, by and among MRI Interventions, Inc. and each purchaser identified on the signature pages thereto	8-K	001-34822	10.1	May 9, 2019
10.57	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
10.58	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
10.59	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
10.60	Board Observer Agreement, dated January 29, 2020, by and between MRI Interventions, Inc. and Petrichor Opportunities Fund I LP	8-K	001-34822	10.4	January 29, 2020
10.61	Third Amended and Restated 2013 Incentive Compensation Plan	DEF14A	001-34822	Appendix A	April 20, 2020
10.62	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
10.63+	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
10.64	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
21*	Subsidiaries of MRI Interventions, Inc.				
23.1*	Consent of Cherry Bekaert LLP				

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
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.
\+ 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 22, 2021

/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 22, 2021
/s/ Danilo D'Alessandro **Danilo D'Alessandro**	*Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)*	March 22, 2021
/s/ R. John Fletcher **R. John Fletcher**	*Chairman and Director*	March 22, 2021
/s/ Pascal E.R. Girin **Pascal E.R. Girin**	*Director*	March 22, 2021
/s/ B. Kristine Johnson **B. Kristine Johnson**	*Director*	March 22, 2021
/s/ Matthew B. Klein **Matthew B. Klein**	*Director*	March 22, 2021
/s/ Timothy T. Richards **Timothy T. Richards**	*Director*	March 22, 2021
/s/ John N. Spencer, Jr. **John N. Spencer, Jr.**	*Director*	March 22, 2021

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Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements
We have audited the accompanying consolidated balance sheets of ClearPoint Neuro, Inc. (formerly, MRI Interventions, Inc.) (the "Company") as of December 31, 2020 and 2019, 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, 2020 and 2019, 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 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 that 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) relates 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 matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which they relate.

Critical Audit Matter Description

The Company had $4,039,516 in service and other revenues for the year ended December 31, 2020. Service and other revenues relate to revenue derived from: 1) service, installation, training, and shipping related to ClearPoint capital equipment and software; and 2) clinical case support revenues 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 contracts including multiple performance obligations, management exercises significant judgment in the following areas in determining appropriate revenue recognition:

- Determination of which products and services are considered distinct performance obligations that should be accounted for separately or combined;
- Determination of stand-alone selling prices for each performance obligation;
- Estimation of contract transaction price and allocation of the transaction price to the performance obligations; and
- The pattern of delivery for each distinct performance obligation.

As a result, a high 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 on these contracts.

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:

- Obtained an understanding of the internal controls and processes in place over the Company's revenue recognition processes.
- Analyzed the significant assumptions and estimates made by management as discussed above.
- Assessed the recorded revenue by selecting a sample of transactions, analyzing the related contract, testing management's identification of distinct performance obligations, and comparing the amounts recognized for consistency with underlying documentation.

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

/s/ Cherry Bekaert LLP
Tampa, Florida
March 22, 2021

CLEARPOINT NEURO, INC.
(formerly MRI Interventions, Inc.)

Consolidated Balance Sheets
(Dollars in thousands, except for per share data)

	December 31,	
	2020	**2019**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,099	$ 5,696
Accounts receivable, net	1,881	1,090
Inventory, net	3,238	3,240
Prepaid expenses and other current assets	244	358
Total current assets	25,462	10,384
Property and equipment, net	319	447
Operating lease rights of use	2,736	374
Software license inventory	589	504
Licensing rights	353	—
Other assets	59	218
Total assets	$ 29,518	$ 11,927
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 300	$ 966
Accrued compensation	1,595	1,408
Other accrued liabilities	349	328
Operating lease liabilities, current portion	394	114
Deferred product and service revenues	562	1,017
Total current liabilities	3,200	3,833
Accrued interest	—	960
Operating lease liabilities, net of current portion	2,446	277
Deferred product and service revenues, net of current portion	215	198
2020 senior secured convertible notes payable, net	21,280	—
2010 secured notes payable, net	—	2,073
Total liabilities	27,141	7,341
Commitments and contingencies (Notes 7 and 10)		
Stockholders' equity:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized at December 31, 2020 and 2019; none issued and outstanding at December 31, 2020 and 2019	—	—
Common stock, $0.01 par value; 200,000,000 shares authorized at December 31, 2020 and 2019; 17,047,584 and 15,235,308 shares issued and outstanding at December 31, 2020 and 2019, respectively	170	152
Additional paid-in capital	121,729	117,174
Accumulated deficit	(119,522)	(112,740)
Total stockholders' equity	2,377	4,586
Total liabilities and stockholders' equity	$ 29,518	$ 11,927

See notes to Consolidated Financial Statements.

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

	Years Ended December 31,	
	2020	2019
Revenues:		
Product revenues	$ 8,789	$ 9,796
Service and other revenues	4,040	1,421
Total revenues	12,829	11,217
Cost of revenues	3,709	3,942
Research and development costs	4,686	2,810
Sales and marketing expenses	5,384	4,756
General and administrative expenses	5,270	4,303
Operating loss	(6,220)	(4,594)
Other income (expense):		
Other income, net	882	9
Interest expense, net	(1,444)	(955)
Net loss	$ (6,782)	$ (5,540)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.43)	$ (0.42)
Weighted average shares outstanding:		
Basic and diluted	15,849,667	13,155,163

See notes to consolidated financial statements.

CLEARPOINT NEURO, INC.
(formerly MRI Interventions, Inc.)

Consolidated Statements of Stockholders' Equity
Years Ended December 31, 2020 and 2019
(Dollars in thousands)

	Common Stock		Additional Paid-in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balances, January 1, 2019	11,018,364	$ 110	$ 108,600	$ (107,200)	$ 1,510
Cumulative adjustment for adoption of new accounting standard	—	—	—	—	—
Issuances of common stock:					
Share-based compensation	194,694	2	797	—	799
Warrant and option exercises	1,595,795	16	373	—	389
May 2019 private placement, net of offering costs of $94,162	2,426,455	24	7,404	—	7,428
Net loss for the year	—	—	—	(5,540)	(5,540)
Balances, December 31, 2019	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

See notes to consolidated financial statements.

CLEARPOINT NEURO, INC.
(formerly MRI Interventions, Inc.)

Consolidated Statements of Cash Flows
(Dollars in thousands)

	Years Ended December 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (6,782)	$ (5,540)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation and amortization	334	144

Share-based compensation	1,090	799
Payment-in-kind interest	3	—
Forgiveness of PPP loan	(896)	—
Amortization of debt issuance costs and original issue discounts	890	729
Amortization of lease right of use assets, net of accretion in lease liabilities	216	107
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(791)	144
Inventory	(25)	(1,025)
Prepaid expenses and other current assets	113	(144)
Other assets	25	15
Accounts payable and accrued expenses	(459)	1,166
Accrued interest	(960)	—
Lease liability	(128)	(109
Deferred revenue	(437)	864
Net cash flows from operating activities	(7,807)	(2,850)
Cash flows from investing activities:		
Purchases of property and equipment	(41)	(10)
Acquisition of licensing rights	(441)	(150)
Net cash flows from investing activities	(482)	(160)
Cash flows from financing activities:		
Proceeds from issuance of 2020 senior secured convertible notes, net of financing costs and discount	24,258	—
Prepayment of offering costs in connection with issuance of 2020 senior secured convertible notes	—	(75)
Proceeds from private offering, net of offering costs	—	7,428
Proceeds from issuance of Paycheck Protection Program loan	896	—
Proceeds from stock option and warrant exercises	376	389
Repayment of notes payable	(2,838)	(2,137)
Net cash flows from financing activities	22,692	5,605
Net change in cash and cash equivalents	14,403	2,595
Cash and cash equivalents, beginning of year	5,696	3,101
Cash and cash equivalents, end of year	$ 20,099	$ 5,696
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ —	$ —
Interest	$ 1,578	$ 317

CLEARPOINT NEURO, INC.
(formerly MRI Interventions, Inc.)

Consolidated Statements of Cash Flows

NON-CASH INVESTING AND FINANCING TRANSACTIONS:

- As discussed in Note 6, upon issuance of a senior secured convertible note payable in December 2020, the Company recorded a discount on the note and a corresponding amount to additional paid-in capital, each in the amount of approximately $3.1 million, representing the value of the deemed beneficial conversion feature embedded in the note.
- 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.
- During the year ended December 31, 2020, the Company recorded net transfers of ClearPoint reusable components having an aggregate net book value of $0.1 million from loaned systems, which are included in property and equipment in the accompanying consolidated balance sheets, to inventory. During the year ended December 31, 2019, the Company recorded net transfers of ClearPoint reusable components having an aggregate net book value of $0.2 million from inventory to loaned systems.
- On January 1, 2019, the Company adopted the provisions of Topic 842 within the Accounting Standards Codification, which resulted in the establishment of operating lease right-of-use assets and operating lease liabilities, each in the aggregate amount of $0.5 million.

See notes to consolidated financial statements.

CLEARPOINT NEURO, INC.
(formerly MRI Interventions, 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 that enables physicians to see inside the brain using direct, intra-procedural magnetic resonance imaging ("MRI") guidance while performing minimally invasive surgical procedures. The Company was

incorporated in the state of Delaware in March 1998. The Company's principal executive office and principal operations are located in Irvine, 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 EU. The activities of both subsidiaries are reflected in these consolidated financial statements.

The Company's ClearPoint system, an integrated system comprised of capital equipment and disposable products, is designed to allow minimally invasive procedures in the brain to be performed in an MRI suite. 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.

On February 12, 2020, the Company changed its corporate name from MRI Interventions, Inc. to ClearPoint Neuro, Inc., pursuant to a Certificate of Amendment to the Company's Amended and Restated Certificate of Incorporation filed with the Secretary of State of the State of Delaware. In addition, effective as of February 12, 2020, the Company's Board of Directors adopted the Second and Amended Restated Bylaws, to reflect the name change of the Company. No other changes were made to the Company's certificate of incorporation or bylaws. In connection with the Company's name change, effective as of the opening of trading on February 12, 2020, the Company's shares of common stock commenced trading on the Nasdaq Capital Market under the symbol "CLPT."

COVID-19

On March 11, 2020, the World Health Organization characterized the spread of a novel strain of coronavirus ("COVID-19") as a global pandemic, and on March 13, 2020, the President of the United States proclaimed that the COVID-19 outbreak in the United States constituted a national emergency. Continued widespread infection in the United States is a possibility. Extraordinary actions have been taken by federal, state and local governmental authorities to combat the spread of COVID-19, including issuance of "stay-at-home" directives and similar mandates for many individuals to substantially restrict daily activities and for many businesses to curtail or cease normal operations. These measures, while intended to protect human life, have 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. 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, as hospitals postpone or reduce capital purchases and overall spending. 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 in 2021. 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. 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, 2020 of approximately $120 million. In addition, the Company's use of cash from operations amounted to $7.8 million for the year ended December 31, 2020. Since inception, the Company has financed its operations principally from the sale of equity securities, the issuance of notes payable and license arrangements.

As discussed in Note 8, in May 2019, the Company entered into a Securities Purchase Agreement with certain accredited investors under which such investors purchased 2,426,455 shares of the Company's common stock at $3.10 per share (the "2019 PIPE"), resulting in proceeds of approximately $7.5 million, before deducting offering expenses aggregating approximately $0.1 million.

In January 2020, the Company entered into a Securities Purchase Agreement (the "SPA") with two investors (the "2020 Convertible Noteholders") under which the Company issued an aggregate principal amount of $17.5 million of floating rate secured convertible notes (the "First Closing Notes"), resulting in proceeds, net of financing costs paid and payable, 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, the Company repaid and retired 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 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 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 amount of $7.5 million.

In April 2020, the Company received $0.9 million in proceeds through a loan funded under the Payroll Protection Program as part of the CARES Act (the "PPP Loan"). In November 2020, the Company was notified by the U.S. Small Business Administration that the loan had been forgiven under the provision of the CARES Act.

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

As discussed in Note 11, 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, 2020, 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

In 2020 and 2019, the Company entered into certain license agreements that provide rights to the Company for the development and commercialization of products in the functional neurosurgery field. Under the terms of those certain 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.

Property and Equipment

Property and equipment are recorded at cost and are depreciated on a straight-line basis over their estimated useful lives, principally five 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 revenues are comprised primarily of: (1) product revenues resulting from the sale of functional neurosurgery, navigation, therapy, and biologics and drug delivery disposable products; (2) product revenues resulting from the sale of ClearPoint capital equipment and software; (3) revenues resulting from the service, installation, training and shipping related to ClearPoint capital equipment and software; and (4) clinical case support revenues 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*: Revenues 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) are 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 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 of generally 90 days. 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 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 has been delivered to the customer.

For both types of capital equipment and software sales described above, the Company's 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.

- *Therapy services:* The Company recognizes revenue from such services at the point in time the service obligation has been satisfied.
- *Biologics and drug delivery services*
  - *Outsourced technical clinical support of cases performed pursuant to customer-sponsored clinical trials:*
    - *Service Access Fees*: For contracts in which the Company receives a periodic fixed fee, irrespective of the number of cases attended by Company 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.
    - *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 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 revenues because the Company transfers control evenly by 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 provides a one-year warranty on its functional neurosurgery navigation products, biologics and drug delivery products, and capital equipment and software products that are not otherwise covered by a third-party manufacturer's warranty. The Company's contracts with customers do not provide for a right of return other than for product defects.

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, 2020 and 2019, 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 dilution of the 2020 Secured Notes and the Second Closing Note as described in Note 6, would be anti-dilutive.

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 Securities and Exchange Commission (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 is 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 (see Note 1), the Company's common stock was traded on the Nasdaq Capital Market under the symbol "MRIC." For the period from July 3, 2019 through December 8, 2019, the Company's common stock was traded on the NYSE American LLC, and prior to July 3, 2019, the Company's common stock was traded in the over-the-counter market and was quoted on the OTCQB Marketplace and the OTC Bulletin Board 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, 2020, the Company had approximately $14.8 million in bank balances that were in excess of the insured limits.

At December 31, 2020, one customer accounted for 11% of accounts receivable, and at December 31, 2019, one customer accounted for 12% of accounts receivable.

During the year ended December 31, 2020, one customer, a related party as described in Note 3, accounted for 28% of total revenue.

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 as of each of December 31, 2020 and 2019 was less than $0.1 million.

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; 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

In August 2020, the Financial Accounting Standards Board issued 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 amends prior authoritative literature to reduce the number of accounting models for convertible debt instruments and convertible preferred stock. For convertible instruments with conversion features that are not required to be accounted for as derivatives under Topic 815, "Derivatives and Hedging", or that do not result in substantial premiums accounted for as paid-in-capital, the embedded conversion features no longer are separated from the host contract. The Company has determined that the conversion feature embedded in the Second Closing Note (see Note 6) is within the scope of the ASU. Accordingly, upon adoption of the ASU, the discount recorded in association with the Second Closing Note, the corresponding amount recorded in additional paid-in capital amounting to approximately $3.1 million at the date of issuance of the Second Closing Note, and the accumulated amortization of the discount which will have been charged to interest expense during the period between the date of issuance of the Second Closing Note and the date of adoption of the ASU, will be reversed.

The ASU is effective for public business entities, other than smaller reporting companies, as defined by the Securities and Exchange Commission, for fiscal years beginning after December 15, 2021. For all other entities, the ASU is effective for fiscal years beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. Adoption is allowed under either the modified or fully retrospective method of transition. The Company, which is a smaller reporting company as of December 31, 2020, is evaluating both the timing and the method in which to adopt the ASU.

Reclassifications

The accompanying consolidated statement of operations for the year ended December 31, 2020 contains certain items formerly classified as service revenue that that have been reclassified to product revenue, and certain items formerly classified as general and administrative expenses, research and development expenses, and sales and marketing expenses that have been reclassified to cost of revenues. The accompanying consolidated statement of operations for the year ended December 31, 2019 has been conformed to the 2020 presentation.

3. Revenue Recognition

Revenue by Service Line

	Years Ended December 31,	
(in thousands)	**2020**	**2019**
Functional neurosurgery navigation and therapy		
Disposable products	$ 6,271	$ 6,918
Services	25	225
Subtotal – Functional neurosurgery navigation and therapy	6,296	7,143
Biologics and drug delivery		
Disposable products	1,468	1,522
Services	3,575	890
Subtotal – biologics and drug delivery revenue	5,043	2,412
Capital equipment and software		
Systems and software products	1,050	1,356

Services	440	306
Subtotal – capital equipment and software revenue	1,490	1,662
Total revenue	$ 12,829	$ 11,217

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 unearned portion of such service fees are classified as deferred revenue.

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

In September 2019, the Company entered into a Development Services Agreement with a customer under which the Company was entitled to bill the customer for an upfront payment of $0.13 million, of which approximately $0.05 million and $0.10 million are included in deferred revenue in the accompanying December 31, 2020 and 2019 consolidated balance sheets, respectively.

Also, in September 2019, the Company entered into a Letter of Intent, followed by a related Statement of Work (together with the Letter of Intent, the "Project Documents") in November 2019, with a customer which is a stockholder (and, commencing in 2020, a noteholder, as described in Note 6) and whose then Chief Operating Officer was a member of the Company's Board of Directors (and was subsequently replaced with the customer's Chief Development Officer), to commence a product development project. Under the terms of the Project Documents, the Company was entitled to bill the customer for: (a) an upfront, nonrefundable payment of $0.5 million; and (b) quarterly service fees of $0.5 million commencing in the fourth quarter of 2019. In February 2020, the Company entered into a Supply Agreement and a Statement of Work (the "European SOW") with a European affiliate of the customer. Under the terms of the European SOW, the Company was entitled to bill the customer on a quarterly basis, commencing in the first quarter of 2020, for service fees of $0.25 million. During 2020, the clinical trials contemplated by the Project Documents and the European SOW were delayed as a result of the COVID-19 pandemic. As a result, the Company agreed to reduce such quarterly service fees by an aggregate of $0.25 million through September 30, 2020. In November 2020, the Company entered into an addendum to the Project Documents and the European SOW that, among other provisions, set the customer's aggregate at $0.7 million per quarter, effective October 1, 2020. The Company recognizes as revenue each of the upfront payments described in this paragraph in proportional relationship to the transaction prices of the performance obligations contained in the related agreements and recognizes as revenue the quarterly service fees described in this paragraph as stand-by services beginning in the quarter such services commenced. Based on the foregoing: (a) the Company recognized revenue of approximately $3.5 million and $0.5 million for the years ended December 31, 2020 and 2019, respectively; (b) accounts receivable from the customer amounted to approximately $0.1 million at each of December 31, 2020 and 2019; and (c) approximately $0.1 million and $0.6 million of the aggregate amount of all the payments described in this paragraph were included in deferred revenue in the accompanying consolidated balance sheets as of December 31, 2020 and 2019, respectively.

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 $0.1 million and $0.2 million of unbilled accounts receivable at December 31, 2020 and 2019, respectively.

Remaining Performance Obligations

The Company's contracts with customers, other than capital equipment and software-related service agreements discussed below, are predominantly for terms of less than one year. Accordingly, the transaction price of remaining performance obligations related to such contracts at December 31, 2020 are not material.

Revenue with respect to remaining performance obligations related to capital equipment and software-related service agreements with original terms in excess of one year and the upfront payments discussed under the heading "Contract Balances" above amounted to approximately $0.5 million at December 31, 2020. The Company expects to recognize this revenue within the next three years.

4. Inventory

Inventory consists of the following as of December 31:

(in thousands)	**2020**	**2019**
Raw materials and work in process	$ 1,485	$ 1,495
Software licenses	193	332
Finished goods	1,560	1,413
Inventory included in current assets	3,238	3,240
Software licenses – non-current	589	504
	$ 3,827	$ 3,744

5. Property and Equipment

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

(in thousands)	2020	2019
Equipment	$ 1,173	$ 1,195
Furniture and fixtures	112	112
Leasehold improvements	201	201
Computer equipment and software	150	148
Loaned systems	503	585
	2,139	2,241
Less accumulated depreciation and amortization	(1,820)	(1,794)
Total property and equipment, net	$ 319	$ 447

Depreciation and amortization expense related to property and equipment for each of the years ended December 31, 2020 and 2019 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

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 $17,500,000 of the First Closing Notes pursuant to the SPA dated January 11, 2020. Unless earlier converted or redeemed, the First Closing Notes will 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 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.

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 $5,000,000 in aggregate principal amount of the Second Closing Note and an additional $10,000,000 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 notes issued under the terms of the SPA, as amended, to $10.14, such conversion subject to certain adjustments set forth in the SPA. Upon execution of the Amendment, the Company issued the Second Closing Note.

The aggregate carrying amount of the First Closing Notes in the accompanying December 31, 2020 consolidated balance sheet is presented net of: (a) financing costs, comprised of commissions and legal expenses, having an unamortized balance of approximately $0.4 million; and (b) a discount, comprised of a commitment fee paid to one of the 2020 Convertible Noteholders, having an unamortized balance amounting to approximately $0.2 million at that date. The unamortized balance of the financing costs and the discount are charged to interest expense over the term 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. Under GAAP, such 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. In such instances, the resulting discount is calculated as the product of (i) the number of shares into which the Second Closing Note can 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. The unamortized balance of the discount is charged to interest expense over the term of the Second Closing Note under the effective interest method.

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, 2020, 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, and, 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 an individual to attend and observe 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.

2014 Junior Secured Notes Payable

On June 6, 2019, the Company repaid in full all the outstanding principal, which, together with accrued and unpaid interest, totaled approximately $2.0 million, of its 12% Second-Priority Secured Non-Convertible Promissory Notes due 2019, as amended (the "2014 Secured Notes"). The 2014 Secured Notes had a maturity date of September 30, 2020, and interest was payable semi-annually in arrears. In connection with the repayment, the security agreement under which the 2014 Secured Note had been collateralized by all the assets of the Company was terminated.

2010 Junior Secured Notes Payable

As discussed above, the Company repaid in full the aggregate principal amount outstanding of the 2010 Secured Notes which, together with the Company's payment of the related accrued interest, resulted in the retirement of the 2010 Secured Notes.

The Company's then-chairman of the board of directors and one of the Company's officers held 2010 Secured Notes, which they purchased at the date of original issuance having an aggregate principal balance of $0.2 million.

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, 2020 with respect to notes payable are summarized as follows:

Years ending December 31,	*(in thousands)*
2025	$ 25,003
Total scheduled principal payments	25,003
Less unamortized discounts and financing costs	(3,723)
	$ 21,280

7. Leases

The Company leases office space in Irvine, California that houses its headquarters and 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 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 office leases are classified as operating leases in conformity with the provisions of Topic 842.

The lease cost, included in general and administrative expense, was $0.2 million and $0.1 million for the years ended December 31, 2020 and 2019, respectively.

The assumptions used in determining the Solana Beach lease component of the operating lease right of use asset and operating lease liability included in the accompanying December 31, 2020 consolidated balance sheet are as follows:

- Lease term – Topic 842 provides that the lease term consists of: (a) the non-cancelable period of the lease; and (b) the period covered by the Company option to extend the lease for which the Company is reasonably certain to do so. Based on the foregoing, management determined the lease term to extend to December 2026 for the Solana Beach office lease.

- Discount rate – Topic 842 provides that the discount rate is the rate implicit in the lease unless that rate cannot be determined, in which case the lessee's incremental borrowing rate shall be used. Because neither the rate implicit in the lease nor the Company's incremental borrowing rate were determinable, discount rates were obtained with reference to published U.S. High Yield CCC corporate bond rates at the inception dates of the Solana Beach lease, which was 8.8%.

As of December 31, 2020, future minimum lease payments are as follows:

Years ending December 31,	*(in thousands)*
2021	$ 432
2022	541
2023	542
2024	472
2025	486
Thereafter	500
Total minimum payments	2,973
Less: Discount to present value of lease payments	(133)
Discounted present value of lease payments	$ 2,840

8. Stockholders' Equity

2019 PIPE

On May 9, 2019, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain accredited investors (collectively, the "Investors") for the private placement of 2,426,455 shares of the Company's common stock at $3.10 per share. The Company received aggregate gross proceeds of approximately $7.5 million, before deducting offering expenses aggregating approximately $0.1 million.

The Purchase Agreement also contains representations and warranties by the Company and the Investors and covenants of the Company and the Investors (including indemnification from the Company in the event of breaches of its representations and warranties), certain information rights and other rights, obligations and restrictions, which the Company believes are customary for transactions of this type.

Issuance of Common Stock in Lieu of Cash Payments

Under the terms of the Amended and Restated Non-Employee Director Compensation Plan, each 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. Director fees, whether paid in cash or in shares of common stock, are payable quarterly on the last day of each fiscal 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, 2020 and 2019, 28,039 shares and 29,861 shares, respectively, were issued to directors as payment for director fees, amounting to $0.1 million in each of 2020 and 2019 in lieu of cash.

Stock Incentive 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. Certain of the Plans also have provided for cash-based performance bonus awards.

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, stock grants of 662,492 shares have been awarded and option grants, net of options terminated, expired or forfeited, of 1,269,947 shares were outstanding as of December 31, 2020. Accordingly, 1,023,811 shares remained available for grants under the 2013 Plan as of that date.

Stock option activity under all of the Company's Plans during the years ended December 31, 2019 and 2020 is summarized below:

	Options Outstanding	Options Exercisable	Range of Exercise Prices		Weighted-average Exercise price per share	Intrinsic Value[1] *(in thousands)*
Outstanding at January 1, 2019	1,386,396		$ 1.40	$ 385.60	$ 11.09	$ 11
Exercisable at January 1, 2019		973,498				—
Activity during the year ended December 31, 2019						
Granted	256,601		1.65	4.11	3.44	349
Exercised	(3,025)		1.74	2.60	1.89	
Cancelled or forfeited	(805)		2.60	385.60	95.37	
Outstanding at December 31, 2019	1,639,167		1.40	83.60	9.87	2,892
Exercisable at December 31, 2019		1,293,121				2,245
Activity during the year ended December 31, 2020						
Granted	264,268		3.24	5.85	4.34	3,052
Exercised	(30,958)		1.40	5.00	2.47	
Cancelled or forfeited	(66,385)		72.00	72.00	72.00	
Outstanding at December 31, 2020	1,806,092		$ 1.40	$ 83.40	$ 7.12	$ 20,760
Exercisable at December 31, 2020		1,511,938				$ 17,287

(1) Intrinsic value is calculated as the estimated fair value of the Company's stock at the end of the related period less the option exercise price of in-the-money options.

The per share weighted average grant date fair value of options granted during the years ended December 31, 2020 and 2019 was $2.22 and $1.72, respectively.

A summary of the status of the Company's nonvested stock options during the years ended December 31, 2020 and 2019 is presented below:

Nonvested Stock Options	Shares	Weighted - Average Per Share Grant Date Fair Value
Nonvested, January 1, 2019	380,283	$ 1.21
Activity during the year ended December 31, 2019		
Granted	256,601	1.72
Exercised	(2,725)	0.93
Forfeited	(580)	42.66
Vested	(287,533)	1.35
Nonvested, December 31, 2019	346,046	1.46
Activity during the year ended December 31, 2020		
Granted	264,268	2.22
Exercised	(30,958)	1.23
Forfeited	(60,830)	33.20
Vested	(224,372)	1.50
Nonvested, December 31, 2020	294,154	$ 2.09

The Company records share-based compensation expense on a straight-line basis over the related vesting period. For the years ended December 31, 2020 and 2019, share-based compensation expense was:

Years Ended December 31, (in thousands)	
2020	2019
$ 1,090	$ 799

As of December 31, 2020, there was unrecognized compensation expense of approximately $1.6 million related to outstanding stock options and shares of restricted stock, which is expected to be recognized over a weighted-average period of 2.1 years.

The assumptions used in calculating the fair value under the Black-Scholes option-pricing model are as follows:

	Years Ended December 31,	
	2020	2019
Dividend yield	0%	0%
Expected Volatility	56.05% - 57.00	52.17% to 52.90%
Risk free Interest rates	0.34% - 0.49%	1.39% to 1.72%
Expected lives (in years)	5.5 to 6.0	5.5 to 6.0

Warrants

Warrants have generally been issued in connection with financing transactions and for terms of up to five years. Common stock warrant activity for the years ended December 31, 2020 and 2019 is as follows:

	Shares	Weighted - Average Exercise Price
Outstanding at January 1, 2019	8,676,481	$ 4.17
Activity during the year ended December 31, 2019		
Exercised	(2,928,681)	2.20
Terminated	(215,533)	35.32
Outstanding at December 31, 2019	5,532,267	4.00
Activity during the year ended December 31, 2020		
Exercised	(2,163,042)	2.36
Terminated	(286,238)	18.31
Outstanding at December 31, 2020	3,082,987	$ 3.82

Information regarding outstanding warrants at December 31, 2020 is as follows (contractual life expressed in years):

Exercise Price	Number Outstanding	Weighted-Average Remaining Contractual Life	Intrinsic Value *(in thousands)*[1]
$ 2.20	1,967,750	1.42	$ 26,938
5.50	1,004,955	0.67	10,441
16.23	80,490	2.37	—
$ 21.10	29,792	0.25	—
	3,082,987	1.19	$ 37,379

(1) Intrinsic value is calculated as the estimated fair value of the Company's stock at December 31, 2020 less the warrant exercise price of in-the-money warrants.

9. Income Taxes

The Company had no income tax expense for the years ended December 31, 2020 and 2019. 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, 2020 and 2019, the valuation allowance increased by $0.7 million and $1.3 million, respectively, based on changes in deferred tax assets and liabilities.

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:

	As of December 31,	
(in thousands)	2020	2019
Deferred income tax assets:		
Net operating loss carryforwards	$ 21,547	$ 21,063
Share based compensation	2,118	1,985
Accrued expenses	841	779
Other	58	3
	24,564	23,830

Less valuation allowance	(24,459)	(23,745)
Total deferred income tax assets	105	85
Deferred tax liability - depreciation	(105)	(85)
Net deferred tax assets	$ —	$ —

At December 31, 2020, the Company had cumulative federal and state net operating losses of approximately $90 million and $35 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 2017 and subsequent years remain open for examination.

10. Commitments

Licenses

Certain license arrangements require minimum royalty payments. As of December 31, 2020, future minimum payments under these arrangements are as follows:

Years ending December 31,	*(in thousands)*
2021	$ 60
2022	60
2023	50
2024	50
2025	50
Thereafter	210
Total minimum payments	$ 480

Royalty payment amounts may be greater than the minimum required payment amounts based on the negotiated royalty rates. If the Company sublicenses the intellectual property that is licensed from the licensor and the Company receives any royalty payment under, or with respect to, such sublicense, the Company is obligated to pay the licensor an agreed upon percentage of any such payments. Under the terms of these license agreements, the Company is required to reimburse the licensor for costs incurred by the licensor associated with patent filing, prosecution and maintenance. The Company may terminate these license agreements for any reason, upon giving the licensor either 60 or 90 days' written notice, depending on the agreement.

Under the license agreements described above, the Company incurred royalty expense of less than $0.01 million for each of the years ended December 31, 2020 and 2019.

Technical Service and Training Agreements

The Company is a party to agreements with a university under which the Company may receive technical and training services. Pursuant to the terms of the amended agreements, the Company incurred expense of approximately less than $0.01 million for technical research services during the years ended December 31, 2020 and 2019, respectively.

Software License Agreements

The Company is a party to a Master Services and Licensing Agreement (as amended, the "Master Software Agreement") with Merge Healthcare Canada Corp. f/k/a Cedara Software Corp. ("Merge") under which the Company may internally perform development, maintenance and support of its ClearPoint system software that was originally developed for the Company by Merge, utilizing certain of its own pre-existing software code. Under the Master Software Agreement, the Company received a non-exclusive, worldwide license to Merge's software code, in exchange for which the Company agreed to pay Merge a license fee for each copy of the ClearPoint system software that the Company sells in which the Merge code is embedded, subject to a minimum license purchase commitment (the "Minimum License Purchase") that the Company satisfied in 2013. The per license cost is charged to costs of sales based on the Company's sales of the ClearPoint system software in which the Merge code is embedded. The Company will have an obligation to pay Merge a license fee for each copy of the ClearPoint system software in which the Merge code is embedded that the Company sells in excess of the licenses it purchased under the Minimum License Purchase.

In connection with the development of the Company's most recent software platform ("ClearPoint version 2.0"), the Company entered into two additional agreements under which it received worldwide, non-exclusive licenses to software code related to certain functional elements of ClearPoint version 2.0, for which the Company is committed to pay royalties for each copy of its ClearPoint version 2.0 system sold, or in certain cases, loaned by to end-users.

Royalties incurred by the Company under the software license agreements described above during each of the years ended December 31, 2020 and 2019 amounted to $0.01 million.

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.

Cardiac EP Business Participation Plan

The Company is party to agreements under which it may provide a key product development advisor and consultant with financial rewards in the event that the Company sells its business operations relating to catheter-based MRI-guided cardiac ablation to treat cardiac arrhythmias ("Cardiac EP Operations"). In the event the Company sells its Cardiac EP Operations, whether on a stand-alone basis or as part of the sale of the Company, the participant will receive a payment under the plan equal to: (i) the transaction value paid for or allocated to the Cardiac EP Operations in the sale, multiplied by (ii) the participant's "participation interest" at the time of the sale. The participant was initially awarded a participation interest of 6.6%. However, pursuant to the terms of the plan, the participation interest is equitably reduced from time to time to take into account equity financing transactions in which the Company issues shares of its common stock, or securities convertible into shares of its common stock, in exchange for cash proceeds. At December 31, 2020, the participation interest was 0.29%. The plan will terminate in June 2025.

Employment Agreements

The Company has employment agreements with its executive officers that, among other provisions customary for agreements of this nature, provide for severance payments in the event the Company terminates an officer's employment without cause. The agreements also provide for certain payments in connection with a change of control transaction and a termination of employment following a change of control transaction.

Key Personnel Incentive Program

Under the terms of the Company's Key Personnel Incentive Program (as amended, "KPIP"), two participants, one a consultant to the Company and a former non-employee director of the Company, and the other a former employee of the Company, will each be entitled to receive a $1.0 million payment in the event of a sale of the Company. In addition, one of the participants will be entitled to receive a payment equal to $0.7 million in the event the net proceeds from a sale of the Company exceed $50.0 million. If a sale of the Company has not occurred by December 31, 2025, the KPIP will terminate.

11. Subsequent Event

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 estimated offering expenses payable by the Company.

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

EXHIBIT 21

List of Subsidiaries

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

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the inclusion or incorporation by reference of our report, dated March 22, 2021, with respect to the consolidated balance sheets of ClearPoint Neuro, Inc. (formerly, MRI Interventions, Inc.) and subsidiary (the "Company") as of December 31, 2020 and 2019 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) and (vi) the Company's Registration Statement on Form S-3 No. (333-252346).

/s/ Cherry Bekaert LLP

Tampa, Florida
March 22, 2021

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, 2020, 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 22, 2021

/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, 2020, 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 22, 2021

/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, 2020, 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 22, 2021

/s/ Joseph M. Burnett

Joseph M. Burnett

Chief Executive Officer

/s/ Danilo D'Alessandro

Danilo D'Alessandro

Chief Financial Officer