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, 2024**

or

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

For the transition period from _____ to _____.

Commission File Number: **001-34822**

CLEARPOINT NEURO, INC.

(Exact name of Registrant as specified in its charter)

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

(888) 287-9109

(Registrant's telephone number, including area code)

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

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

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐Yes ☑ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. ☐Yes ☑ No

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☑ Yes ☐ No

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

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

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

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

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

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

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

As of June 30, 2024, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $145 million based on the closing sale price as reported on the Nasdaq Capital Market.

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

Class	Outstanding at February 18, 2025
Common Stock, $0.01 par value per share	27,632,332 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, 2024, pursuant to Regulation 14A under the Securities Exchange Act of 1934 in connection with the 2025 annual meeting of stockholders.

CLEARPOINT NEURO, INC.

TABLE OF CONTENTS

Trademarks, Trade Names and Service Marks

ClearPoint Neuro®, *ClearPoint*®, *SmartFlow*®, *SmartFrame*®, *SmartGrid*®, *Inflexion*®, *SmartTwist*™, *SmartTip*™, *ClearPoint Maestro*®, *SmartFrame Array*®, *SmartFrame OR*™, *ClearPoint Neuro Orchestra*™, *ClearPoint Prism*®, *SmartFlow Flex*™, *ClearPointer*™, *When Your Path is Unclear, We Point The Way*®, and *ClearPoint Advanced Laboratories*™ are all trademarks of ClearPoint Neuro, Inc. Any other trademarks, trade names or service marks referred to in this Annual Report are the property of their respective owners.

Company Names Used in this Annual Report

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; UCB refers to UCB Biopharma SRL and its affiliates; CLS refers to Clinical Laserthermia Systems AB and its affiliates; IMRIS refers to IMRIS, Deerfield Imaging, Inc. and its affiliates; PTC refers to PTC Therapeutics, Inc. and its affiliates; Philips refers to Koninklijke Philips N.V. and its affiliates; Abbott refers to Abbott Laboratories and its affiliates; Elekta refers to Elekta AB and its affiliates; NE Scientific refers to NE Scientific, LLC and its affiliates; NeuroPace refers to NeuroPace, Inc. and its affiliates; Medtronic refers to Medtronic plc and its affiliates; UCSF refers to the University of California, San Francisco; and Johns Hopkins refers to Johns Hopkins University.

PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains "forward-looking statements" as defined under the U.S. federal securities laws. The forward-looking statements relate to our expectations for performance, revenues and costs, and the adequacy of cash and cash equivalent balances and short-term investments to support operations and meet future obligations. 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, performance or achievements, expressed or implied by the forward-looking statements.

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.

In evaluating forward-looking statements, you should refer to (i) the section of this Annual Report entitled "Risk Factors" and (ii) Item 2 of this Annual Report, under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations - Factors Which May Influence Future Results of Operations." As a result of these risk factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We do not undertake to update any of the forward-looking statements after the date of this Annual Report, except to the extent required by applicable securities laws.

RISK FACTOR SUMMARY

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

- Our business, financial condition, and results of operations may be adversely affected by general economic and financial market conditions, and current and future social and geopolitical instability.
- Revenue can be meaningfully impacted if we cannot maintain current relationships or programs or enter into new relationships or programs with drug delivery customers.
- The size of the markets for our current and future products and services may be smaller than we estimate.
- Our ClearPoint system may not achieve broad market adoption and our future business growth is dependent upon marketing and selling our ClearPoint system, and other new products, in the operating room.
- Our long-term growth depends on our ability to compete effectively in the neurosurgery market by developing and commercializing new products and services through our research and development efforts.
- If coverage and reimbursement from third-party payors for procedures utilizing our products are inadequate, adoption of our products will be adversely affected and our revenues and prospects for profitability will suffer.
- We currently have significant customer concentration, so economic difficulties or changes in the purchasing policies or patterns of our key customers could have a significant impact on our business.
- Our internal manufacturing operations are generally conducted at a single location, which may limit our ability to provide an adequate supply of our products, and any disruption at our manufacturing facility could render us unable to produce our products, increase our expenses and decrease our revenue.
- Our reliance on single-source suppliers could harm our ability to meet demand for our products.
- To the extent we seek a new indication for use of, or new claims for, our products, the FDA may not grant 510(k) clearance or premarket approval application approval of such new use or claims.
- If we fail to obtain the necessary clearances, certifications or approvals for our new products, our ability to grow our business globally could be harmed.
- The results of our clinical trials may not support our product candidate claims or additional claims we may seek for our products and may result in the discovery of adverse side effects.
- The markets for medical devices are highly competitive, and we may not be able to compete effectively against larger, well-established as well as emerging small innovative competitors.
- We sell our products outside of the U.S., and are subject to various economic, political, regulatory and other risks relating to international operations.

•Disruptions of critical information systems or material breaches in the security of our systems could harm us.
•We may acquire other businesses, form joint ventures, or make investments in other companies or technologies that may not result in commercial success and could lead to significant losses.
•We need to hire and retain additional qualified personnel to grow and manage our business.
•We have incurred losses since our inception, and we may continue to do so. We may never achieve or sustain profitability.
•We may need additional funding for our business, and we may not be able to raise capital when needed or on terms that are acceptable to us, and raising additional funds may cause dilution, restrict our operations or require us to relinquish proprietary rights.
•Our cash, cash equivalents, and short-term marketable securities are subject to economic risk.
•We hold assets at financial institutions that may exceed the insurance coverage offered by the Federal Deposit Insurance Corporation ("FDIC"), which could negatively affect our operations or liquidity.
•If we, or the third parties from whom we license intellectual property, are unable to secure and maintain patent or other intellectual property protection for the intellectual property covering our marketed products or our product candidates, our ability to compete will be harmed.
•If we are subject to third-party claims of intellectual property infringement, we may become engaged in costly disputes.
•If our intellectual property is inadequately protected, our ability to successfully commercialize our marketed products and product candidates will be harmed.
•Patent terms may be inadequate to protect our competitive position for an adequate amount of time and we may not be able to protect our intellectual property rights throughout the world.
•If we lose access to third-party software that is integrated into our products, our costs could increase and new installations of our products could be delayed.
•Our rights to develop and commercialize our products are subject, in part, to the terms and conditions of licenses granted to us by others.
•We operate in a highly regulated industry and any failure to comply with the extensive government regulations may subject us to fines, injunctions and other penalties.
•Federal legislation and other payment and policy changes may have a material adverse effect on our business.
•Our products may be subject to product recalls that could harm our reputation, business operating results and financial condition.
•If our products cause or contribute to a death or a serious injury, or malfunction, we will be subject to Medical Device Reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.
•We may incur significant liability if it is determined that we are promoting off-label uses of our products in violation of federal and state regulations in the U.S. or elsewhere.
•If we or our third-party suppliers fail to comply with the FDA's Quality Management System Regulation ("QMSR") or any applicable state equivalent, our manufacturing operations could be interrupted, and our potential product sales and operating results could suffer.
•We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.
•We are subject to various laws protecting the confidentiality and security of certain personal information, and our failure to comply could result in penalties and reputational damage.
•Our Fourth Amended and Restated Bylaws include exclusive forum provisions for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.
•The market price of our common stock may be volatile, and stockholders may not be able to resell shares at or above the purchase price.
•Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.
•We have not paid dividends in the past and do not expect to pay dividends in the future.
•Anti-takeover provisions in our certificate of incorporation, bylaws and Delaware law could prevent or delay a change in control.
•We may fail to meet our publicly announced guidance or other expectations about our business and future operating results, which could cause a decline in our stock price.
•Securities analysts may not continue coverage for our common stock or may issue negative reports.
•We are subject to certain general risks, including, but not limited to, risks related to damage to our reputation, natural disasters, product and professional liability claims or other lawsuits, and the requirements of being a public company.

ITEM 1. BUSINESS

Overview

We are a commercial-stage medical device company, incorporated in 1998 as a Delaware corporation, that develops and commercializes innovative platforms for performing minimally invasive surgical procedures in the brain. From our inception in 1998, we have deployed significant resources to fund our efforts to develop the foundational capabilities for enabling magnetic resonance imaging ("MRI") guided interventions, building an intellectual property portfolio, and identifying and building out commercial applications for the technologies we develop. In 2021, our efforts expanded beyond the MRI suite to encompass development and commercialization of neurosurgical device products for the operating room setting, as well as consulting services for pharmaceutical companies. Our products have been installed or used at over 90 centers globally.

Since 2020, we have evolved to become a company comprised of two components: (i) a business providing medical devices for neurosurgical applications, and (ii) a business focused on partnerships in the biologics and drug delivery space.

Medical Devices for Neurosurgical Application

The first foundational component of our business is focused on providing medical devices for neurosurgical applications.

Our primary medical device product, the ClearPoint system, is an integrated system comprised of hardware components, disposable components, and intuitive, menu-driven software. The primary applications for the ClearPoint system are to target and guide: (a) the insertion of deep brain stimulation electrodes, biopsy needles, and laser catheters; and (b) the infusion of pharmaceuticals into the brain. The ClearPoint system was originally designed for use in an MRI setting. In 2021, we launched the SmartFrame Array Neuro Navigation System and Software, which allows for operating room placement of the ClearPoint system and completion of the procedure in the MRI suite. In 2024, we introduced the SmartFrame OR Stereotactic System to the market, which allows for complete procedures to be performed in the operating room.

In 2022, we commenced commercialization of the ClearPoint Prism Neuro Laser Therapy System, a laser ablation system. The ClearPoint Prism Neuro Laser Therapy System was developed and is manufactured for us by CLS. We have exclusive global rights to commercialize the system for neuro applications.

Biologics and Drug Delivery

The second component of our business is focused on partnerships in the biologics and drug delivery space, supporting our customers from the earliest stages of their research through their clinical study and commercialization process. Since 2021, a growing and significant part of the revenue from our business is derived from preclinical development services, which include protocol consultation and solutions for preclinical study design and execution. Our consulting services include a core competency of in vivo biology services in large and small research models to assist our customers with establishing drug safety prior to and in support of their human clinical trials.

Currently, we have more than 60 pharma/biotech, academic, and contract research organization partners who are evaluating or using our products and services in trials to inject gene and cell therapies directly into the brain. These partnerships involve drug development programs that are at various stages of development ranging from preclinical research to late-stage regulatory trials for multiple distinct disease states. This part of our business potentially represents the largest opportunity for growth, which we estimate could have an approximately $7 billion market potential; however, our ability to grow in this market is dependent on our ability to maintain and establish new relationships with pharmaceutical company customers, such customers' continuation of research and product development plans, and such customers achieving success in completion of clinical trials and subsequent regulatory approvals of their drugs and biologics. In 2024, the U.S. Food and Drug Administration (the "FDA") granted marketing authorization for our SmartFlow cannula to be used to deliver a gene therapy for the treatment of aromatic L-amino acid decarboxylase ("AADC") deficiency directly to regions of interest within the brain.

Our Products and Services

The ClearPoint System

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

ClearPoint Hardware. Our hardware components consist primarily of a head fixation frame, computer workstation and in-room monitor. The head fixation frame immobilizes the patient's head during the procedure, and it is designed to optimize the placement of an imaging head coil in proximity to the patient's head. When performed in the MRI suite, the ClearPoint system software is installed

on a computer workstation networked with an MRI scanner, for which we use a commercially available laptop computer. The in-room monitor allows the physician to view the display of our ClearPoint system workstation from the scanner room while performing the procedure.

ClearPoint Disposables. The disposable components of our ClearPoint system consist primarily of our SmartFrame trajectory device, a hand controller and related accessories, and our SmartFlow cannula. Our SmartFrame device is an adjustable trajectory guide that attaches to the patient's skull and holds the targeting cannula. The hand controller attaches to our SmartFrame device, and it is used by the physician to adjust the roll, pitch, and X and Y orientation of the targeting cannula while the patient is in the MRI scanner. The accessories include all other components necessary to facilitate the MRI-guided neurosurgical procedure, such as our SmartGrid patch, which is an MRI-visible marking grid that enables rapid localization of the entry position into the brain, and our customized surgical draping, which creates a sterile field within the MRI scanner. The SmartFrame OR Stereotactic System is a single use disposable that does not require MRI guidance. 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. In 2022, we received FDA approval for the ClearPoint Maestro Brain Model, a software tool which we designed to automate the process of identifying, labelling, and quantifying the volume and shape of brain structures visible in MRI images.

ClearPoint Therapeutic Solutions

Our ClearPoint Prism Neuro Laser Therapy System is indicated for use to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy for neuro applications under 3.0T MRI guidance. The laser system can be used in conjunction with the ClearPoint navigation platform to refine the desired trajectory for the laser therapy catheter and to confirm accurate laser catheter placement. The laser system consists of a mobile laser unit, Thermoguide software to monitor changes in tissue temperature during therapy, and disposable laser applicator and magnetic resonance ("MR") introducer components.

ClearPoint Services

We provide consulting services to our pharmaceutical and other medical technology partners for improving outcome predictability and optimizing preclinical and clinical workflows. Our expertise is concentrated in benchtop testing, preclinical studies, clinical trial support, regulatory consultation, and over-arching translation from the preclinical to the clinical setting to enhance accuracy and precision of drug delivery. In 2021, we expanded our expertise to include in vivo biology services in large and small research models to assist our customers with establishing drug safety prior to and in support of human clinical trials.

Regulatory Status

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

In the United States, our SmartFlow cannula has received 510(k) clearance for injection of Cytarabine or for removal of cerebrospinal fluid ("CSF") from the ventricles and De Novo marketing authorization for intraputaminal administration of eladocagene exuparvovec-tneq for the treatment of adult and pediatric patients with AADC deficiency. 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.

Our development partner CLS received 510(k) clearance for its laser system to necrotize or coagulate soft tissue through interstitial irradiation or thermal therapy in neuro applications under 3.0T MRI guidance. In the U.S., the laser system is commercialized by us as the ClearPoint Prism Neuro Laser Therapy System.

Our SmartFrame OR Stereotactic System received 510(k) clearance in 2024. SmartFrame OR is intended to provide stereotactic guidance for the placement and operation of instruments or devices during planning and operation of neurological procedures performed in conjunction with the use of a compatible optical stereotaxic navigation system using preoperative MRI and/or Computed Tomography ("CT") imaging. These procedures include biopsies, catheter placement and electrode introduction, including the placement of deep brain stimulation ("DBS") leads. SmartFrame OR is a disposable device intended for single patient use only.

Market Discussion

Medical Devices for Neurosurgical Application

We believe there are more than 140,000 potential neurosurgical procedures per year in the U.S. in which our ClearPoint products could be used as a navigational platform for functional stereotactic neurosurgery in indications currently approved by the FDA or as a therapy device for performance of laser interstitial thermal therapy ("LITT"):

- *Electrode Placement* – The current standard of care for the placement of the DBS or responsive neurostimulation ("RNS") electrodes in the operating room requires the patient to be awake during surgery in order to verify proper placement. When DBS or RNS is performed in the MRI suite, our ClearPoint system can provide intra-procedural navigation and visualization of the electrode placement and the patient may be placed under general anesthesia for the procedure. Three manufacturers have received FDA clearances for DBS systems: Medtronic, Boston Scientific and Abbott Laboratories. All three have products that are indicated for Parkinson's disease, essential tremor, and drug resistant epilepsy. DBS is used to treat the symptoms of Parkinson's Disease, a degenerative condition that affects more than one million people in the U.S. and 10 million people worldwide. DBS works by stimulating a targeted region of the brain through implanted leads that are powered by a device called an implantable pulse generator. We estimate 120,000 Parkinson's disease and essential tremor patients per year are potential candidates for the implantation of deep brain stimulation electrodes utilizing our ClearPoint system. In addition, patients suffering from drug resistant epilepsy, refractory essential tremor, dystonia, severe obsessive compulsion disorder, severe major depressive disorder, paralysis, Huntington's disease, auditory nerve implantation, Alzheimer's disease and stroke rehabilitation may create additional potential procedure opportunities in the future. The only commercially available RNS system on the market is manufactured by NeuroPace. Their brain-responsive neuromodulation system is currently approved for use in patients with drug resistant epilepsy and refractory idiopathic generalized epilepsy.
- *LITT* – LITT is a minimally-invasive MRI-guided technique to treat primary and metastatic brain tumors, as well as patients with drug-resistant epilepsy. The treatment uses heat to treat and ablate the tumor or regions where seizures begin. In the U.S. approximately 35,000 patients have brain tumors that could benefit from LITT and up to one million suffer from drug-resistant epilepsy. Historically two manufacturers have FDA cleared laser therapy systems in North America – Medtronic's Visualase system and Monteris Medical's NeuroBlate system. In September 2022, our development partner CLS received 510(k) clearance for its MRI guided laser interstitial thermal therapy system for neuro applications, and we commenced commercialization of this laser system, marketed as the ClearPoint Prism Neuro Laser Therapy System, in the U.S.
- *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.

Biologics and Drug Delivery

The blood-brain barrier prevents large-molecule, and nearly all small-molecule, neurotherapeutics from reaching the brain. Several pharmaceutical and biotech companies are developing methods to deliver a wide variety of molecules, genes or proteins to targeted brain tissue or structures that would need to bypass the blood-brain barrier. This may enable the development of treatments for rare single-gene pediatric disorders, such as AADC Deficiency, Friedreich's Ataxia and Angelman Syndrome, as well as adult disorders including Parkinson's disease, drug resistant epilepsy, Huntington's disease, Alzheimer's disease and certain types of cancers, such as Glioblastoma. If our ClearPoint system and SmartFlow cannula are approved for these drug delivery treatments and become the standard approach to local drug delivery in the brain, we believe the impact on our financial performance could be significant. However, in the United States, these treatments are subject to FDA-mandated clinical trial requirements, which are expensive and time consuming for our partners to conduct. Nonetheless, several of our biologics and drug delivery customers are pursuing preclinical and clinical trials for which we generate revenue through the sale of products, including our SmartFlow cannula, preclinical, development and consulting services, and other partnership arrangements. In 2024, the SmartFlow cannula was granted De Novo marketing authorization for intraputaminal administration of eladocagene exuparvovec-tneq for the treatment of adult and pediatric patients with AADC deficiency.

Sales and Marketing

Medical Devices for Neurosurgical Application

Commercializing our ClearPoint products and services for neurosurgery applications, primarily involves marketing and selling directly to:

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

Our business model for the ClearPoint products includes 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 within hospitals. In addition, we may install the ClearPoint reusable components at a hospital, but retain title, either for an agreed-upon period of time while the hospital evaluates and processes the purchase opportunity, or for a rental fee. Our disposable and reusable ClearPoint products are tightly integrated, which allows us to leverage each new installation of a system to generate recurring sales of our disposable products.

Biologics and Drug Delivery

Commercializing our ClearPoint products and services for biologics and drug delivery primarily involves marketing and selling directly to pharmaceutical companies focused on research and development of therapies for neurological indications.

Our business model for our ClearPoint services includes providing preclinical studies, clinical trial support, regulatory consultation, device development services, surgical workflow guidance, and over-arching translation services to aid in the progression of our pharmaceutical customers' drug development process. The ClearPoint services allow us to generate early technology integration of our products into our customers' delivery workflow and participate in diversified partnership arrangements with our customers.

Manufacturing and Assembly

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

Our ClearPoint Prism Neuro Laser Therapy System is manufactured exclusively by CLS.

Our facilities are structured to complete component processing, final assembly, packaging and distribution activities for our products. The assembly process is performed in a controlled environment as required by applicable regulation for medical device assembly. Our operations are subject to extensive regulation by the FDA's Quality Management System Regulation ("QMSR"), 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 U.S., we would be subject to international regulatory requirements.

Our facilities are FDA-registered, and we believe they are compliant with the FDA's QMSR. We are also certified to ISO 13485 and the Medical Device Single Audit Program ("MDSAP"). 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 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 facilities, 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

Medical Devices for Neurosurgical Application

A small number of our hospital customers account for a substantial portion of our revenues from sales of ClearPoint products. Our five largest hospital customers accounted for approximately 31% of our neurosurgery navigation disposable product revenues in 2024.

Biologics and Drug Delivery

As of February 18, 2025, we had commercial relationships with over 60 pharma/biotech, academic, and contract research organization partners who have either evaluated or used our SmartFlow cannula or our consulting services.

One of these companies, PTC Therapeutics, Inc. and its affiliates ("PTC"), a related party who is a significant stockholder and former noteholder with a Board representative, accounted for approximately 17% of our biologics and drug delivery revenues in 2024. In May 2019, we entered into a supply agreement with PTC (the "PTC Supply Agreement") pursuant to which we supply certain products and engage in performance of certain services under the terms of mutually agreed upon Statements of Work. Certain products supplied under the PTC Supply Agreement are subject to limited favored pricing terms for such products intended for human use in clinical or commercial settings.

In November 2020, we entered into an Addendum to the PTC Supply Agreement pursuant to which PTC agreed to purchase products in exchange for a minimum quarterly payment in consideration for our commitment to supply such products and provide services consisting of training, preclinical and clinical case support and regulatory support. In January 2023, the Addendum to Supply Agreement was further amended and restated to allow for the Company to provide regulatory support to PTC in additional agreed geographies.

We also entered into a Second Source Manufacturing Agreement in connection with the PTC Supply Agreement (the "Second Source Manufacturing Agreement"). Under the Second Source Manufacturing Agreement, PTC may, at its expense, request that we appoint a backup contract manufacturer to supply products in the event of a supply interruption or a bankruptcy event. The exercise by PTC of its second source manufacturing rights may be subject, in certain cases, to payment by PTC to us of a per-product royalty payment. The Second Source Manufacturing Agreement shall continue for the term of the PTC Supply Agreement, subject to certain early termination rights.

Intellectual Property

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

Our patent portfolio includes patents and patent applications that we own or that we license from others. We seek patent protection in the U.S. and internationally for our products and technologies where and when we believe it is appropriate. U.S. 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

We have a significant patent portfolio in the field of neurosurgical and MRI-guided interventions. As of February 18, 2025, we own or license over 100 issued patents. Some of our patents and patent applications are subject to licensing and cross-licensing arrangements in place with third parties.

Trademarks

We have registered trademarks in the United States, the European Union, the United Kingdom, and China.

Certain License and Royalty Arrangements

Philips

During 2020, we entered into a worldwide license and research agreement with Philips, under which Philips has licensed to us the use of the technology underlying its Philips Brain Model in our ClearPoint Maestro Brain Model ("Maestro"), the first generation of which received 510(k) clearance 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 for the license, we paid a fee upon execution of the agreement and are committed to pay (a) royalties based on sales of systems, and (b) an annual fee based on a calculation accounting for the number of systems in use for a calendar year and a correction factor for increases or decreases in net revenue from the sales of systems. In early 2022, we expanded our collaboration with Philips to include additional technology to allow use of the Philips Brain Model with CT imaging. In early 2023, we further expanded our collaboration with Philips to include additional technology regarding subnuclei segmentation to the Maestro MRI and CT functionality. In 2024, we amended our collaboration to include further new software features to be developed by Philips.

UCB

In March 2023, we entered into a multi-year license agreement with UCB to partner on drug delivery platforms for UCB's gene therapy portfolio. Under the terms of the license agreement, UCB will utilize our technology and services in connection with the development and commercialization of UCB's gene therapy products. Certain fees under the agreement will be paid to us as success-based milestones.

CLS

In October 2018, and as amended in August 2020, we entered into a license and collaboration agreement and a distribution agreement with CLS that provides us the exclusive global rights to commercialize and sell CLS's portfolio of products and to collaborate with CLS on the development and commercialization of new products in the neurosurgical field. Pursuant to these agreements, we began commercialization of the ClearPoint Prism Neuro Laser Therapy System in the U.S. in 2022.

UCSF

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

In 2023, we entered into a license agreement with UCSF to use technology developed by UCSF to develop and commercialize a radially branching cellular delivery device, for which we are committed to pay royalties based on the sales of any future commercialized device.

NE Scientific

In 2022, we entered into a development and license agreement with NE Scientific to incorporate NE Scientific's GPU-accelerated software solution for modeling of therapies administered to the brain into our products. In consideration of the foregoing, we paid fees for development of the software solution and are committed to pay royalties based on (a) per hospital activations of the software solution, and (b) offline applications in which the licensed technology is used.

Software License Arrangements

In connection with the development of our software products, which includes ClearPoint Software, ClearPoint Array Software, and ClearPoint Maestro Brain Model Software, we entered into several agreements with third party software providers under which we received worldwide, non-exclusive licenses to software code related to certain functional elements of these software products, and for which we are committed to pay royalties for each copy of software product sold, or in certain cases, loaned by us to end-users.

Competition

Medical Devices for Neurosurgical Application

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.

Currently, we are aware of two companies, Monteris Medical, Inc. and Medtronic, which offer devices for laser ablation under direct MRI guidance. In addition, companies such as Brainlab, Medtronic, Elekta, FHC Inc., Integra LifeSciences Holdings Corporation 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. 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.

Biologics and Drug Delivery

Drug delivery can be divided into two categories, those that use image-guidance and those that do not. Our main area of focus and expertise is on image-guided drug delivery, in particular as it relates to the use of MRI technology. Other companies, such as Brainlab and Renishaw plc, also offer systems such as navigational platforms and cannulas useful for drug delivery under MRI. These offerings are competitive with ClearPoint's products. These companies have substantially greater marketing, manufacturing, technical, and financial resources than we have. Our preclinical development services business encounters a broad range of competitors of different sizes and capabilities, such as clinical research organizations or government funded not-for profit entities and industry experts.

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

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

FDA Premarket Clearance and Approval Requirements

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

510(k) Clearance Pathway

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

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

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

De Novo Classification

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

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

PMA Approval Pathway

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

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

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

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

Clinical Trials

Clinical trials are generally required to support a PMA application and also may be required for 510(k) clearance and *de novo* authorization. Such trials generally require an application for an investigational device exemption, or IDE, which is approved in advance by the FDA for a specified number of patients and study sites, unless the product is exempt from the IDE requirements or deemed a non-significant risk device eligible for more abbreviated IDE requirements. A significant risk device is one that presents a potential for serious risk to the health, safety, or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject.

An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must also include a description of product manufacturing and controls, and a proposed clinical trial protocol. During the study, the sponsor must comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting, and record keeping. The investigators must obtain patient informed consent, follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with reporting and record keeping requirements. Prior to granting PMA approval, the FDA typically inspects the records relating to the conduct of the study and the clinical data supporting the PMA application for compliance with IDE requirements.

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

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

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

Pervasive and Continuing Regulation

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

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- QMSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design, manufacturing, and distribution process;

- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance, authorization, or approval of product modifications;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply, when necessary, to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- regulations pertaining to voluntary recalls; and
- notices of corrections or removals.

As a medical device manufacturer, we are subject to announced and unannounced inspections by the FDA to determine our compliance with FDA's QMSR and other regulations. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to maintain compliance with the QMSR and other regulations. We believe that we are in compliance with QMSR 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 ("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 U.S., which can change rapidly with relatively short notice. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved or uncleared use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

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

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

International Marketing Approvals

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

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

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

and performance 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.

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

The Medical Devices Regulation went into effect in May 2021, which:

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

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

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

Because the Anti-Kickback Statute is broadly written and encompasses many harmless or efficient arrangements, Congress authorized the Office of Inspector General of the United States Department of Health and Human Services ("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 ("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-U.S. jurisdictions that generally prohibit companies and their intermediaries from making improper payments to non-U.S. government officials for the purpose of obtaining or retaining business. Because of the predominance of government sponsored healthcare systems around the world, we expect that many of our customer relationships outside of the U.S. 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 ("HITECH"), was enacted to strengthen and expand 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 ("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.

Regulations Related to Our Preclinical Development Services

The Animal Welfare Act ("AWA") governs the care and use of certain species of animals used for research in the U.S. For these regulated species, the AWA and the associated regulations promulgated thereunder require those working with regulated species to provide veterinary care and to follow specific husbandry practices such as cage size, shipping conditions, sanitation and environmental enrichment to ensure the welfare of these animals. Licensing and registration requirement standards set by the U.S. Department of Agriculture, the U.S. Fish and Wildlife Service ("USFWS"), and similar applicable international agencies also apply to the care, handling and oversight of regulated species.

The import and export of animals and operations in foreign countries are subject to applicable international agreements and conventions, as well as a variety of national, regional and local laws and regulations, which establish the standards for the humane treatment, care, handling and transport of animals by dealers and research facilities.

Non-clinical safety assessment studies used to support the submission for approval of pharmaceutical products must comply with national statutory or regulatory requirements for Good Laboratory Practice ("GLP"). GLP regulations describe a quality system for the scientific, operational and quality process and the conditions under which non-clinical studies are planned, performed, monitored, recorded, reported and archived. GLP compliance is required by such regulatory agencies as the FDA, European Medicines Agency and similar monitoring authorities in other countries where we operate.

Human Capital Resources

As of February 18, 2025, we had 115 full-time employees. None of our employees are covered by a collective bargaining agreement. As a small, innovative company focused on the development and commercialization of technology, we believe that cultural fit and energy are important considerations in recruiting employees. We assess the likelihood that a particular candidate will contribute to our overall goals, and beyond their specifically assigned tasks. We aim to provide market-based compensation to retain our employees. New employees are provided industry-relevant compliance training and are introduced to our Code of Business Conduct and Ethics, which is posted on our website at www.clearpointneuro.com. 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 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

Our business, financial condition, and results of operations may be adversely affected by general economic and financial market conditions and current and future social and geopolitical instability.

Changes in domestic and global economic conditions, such as inflationary pressure, changes in monetary policy, decreasing consumer confidence and spending, the introduction of or changes in tariffs or trade barriers, and global or local recession may adversely impact the demand for our products and services, which could negatively impact our business, financial conditions, and results of operations. The world's financial markets remain susceptible to significant stresses, resulting in reductions in available credit and government spending, economic downturn or stagnation, foreign currency fluctuations and volatility in the valuations of securities generally. As a result, our ability to access capital markets and other funding sources in the future may not be available on commercially reasonable terms, if at all. Impacts from inflationary pressures, could increase our costs for research and development of our products, and administrative and other costs of doing business, which could in turn increase the costs for producing and distributing our products and services. In a higher inflationary environment, we may be unable to raise the prices of our products and services to sufficiently keep up with the rate of inflation. Impacts from inflationary pressures could be more pronounced and adversely impact aspects of our business where revenue streams and price commitments are linked to contractual agreements that extend further into the future, as we may not be able to quickly or easily adjust pricing, reduce costs, or implement countermeasures.

Additionally, our hospital and pharmaceutical customers could experience financial and operational pressures as a result of macroeconomic conditions which could impact their ability to access capital markets and other funding sources, increase cost of funding, cause cash flow problems, or impede their ability to comply with debt covenants, which in turn could impede their ability to provide patient care, conduct further research and development, marketing and commercialization efforts, or impact their profitability. To the extent that our customers continue to face such financial pressures, it could impact their willingness to spend on our products and services or their ability to make payment, either of which could adversely affect our business, financial condition and results of operations. Further, with economic uncertainty, an increase in unemployment rates, and increasing health insurance premiums, co-payments and deductibles may result in cost-conscious consumers pursuing fewer medical treatments and procedures, which, in turn, could adversely affect procedure volumes and the demand for our products and services.

Geopolitical changes and trends such as populism, protectionism, economic nationalism, as well as trade barriers, sanctions, and regulations may become disruptive and costly to our business. The global economy has been, and may continue to be, negatively impacted by the ongoing conflict resulting from Russia's invasion of Ukraine in 2022, uncertainty in the Middle East region, or the increasing tensions between China and Taiwan. These geopolitical developments may interfere with our supply chain, production costs, and customer relationships. In addition, market uncertainty and volatility in various geographies may be magnified as a result of potential shifts in U.S. and foreign trade, economic and other policies following the recent U.S elections. Although the majority of our operations take place in the U.S., further escalation of geopolitical tensions could make it more costly to continue our current international business or expand to serve other markets, which may adversely affect our business, financial condition and results of operations.

If we cannot maintain our current relationships or programs, or enter into new relationships or programs, with drug delivery customers, our revenue prospects could be meaningfully reduced.

We collaborate with pharma/biotech, academic, and contract research organization customers (collectively "drug delivery customers") to provide products and services in connection with preclinical and clinical studies. The revenue attributable to our drug delivery customers may fluctuate in the future, which could have a material adverse effect on our financial condition and results of operations. In addition, the termination of these relationships or certain programs of our drug delivery customers could result in a temporary or permanent loss of revenue.

Our future success depends in part on our ability to maintain these relationships and establish new relationships, and our drug delivery customer's continued use of our products and services in their therapeutic programs through their research, development, and commercialization process. Many factors have the potential to impact such collaborations, including the ability to deliver therapies to our drug delivery customers' satisfaction, regulatory approval, perceptions in connection with the safety of therapies or delivery mechanisms, our customers' ability to access adequate and sustainable financing, and other factors that may be beyond our control. Furthermore, our drug delivery customers may decide to decrease or discontinue their use of our products and services due to changes in research and product development plans, failures in their clinical trials, financial constraints, utilization of internal resources or services performed by other parties.

The development of gene and cell therapies by our drug delivery customers is inherently risky, complex, costly, and uncertain. These novel therapies involve the modification of genetic material or the use of engineered cells to treat diseases. Their development presents unique scientific, technical and regulatory challenges and face substantial risks. Even if early stage clinical trials are promising, later stage trials may fail to confirm these results, leading to delays or failures in product approval and potential termination of our relationship or certain programs with our drug delivery customers. Regulatory agencies, including the FDA, may impose more stringent requirements on these novel therapies, and the evolving regulatory landscape may create additional hurdles, including longer review

times, requests for additional data, or the need for post-approval monitoring, which would significantly impact development timelines. In addition, scalability of these therapies remains a challenge, and any disruption in raw material supply, safety controls, or quality consistency could delay or halt therapy development. Due to the nature of these novel therapies, there are risks of serious adverse events, including immune reactions or off-target effects. The long term effects of these therapies may not be fully understood at the time of approval, and thus even if a therapy is successfully approved for commercialization, it may continue to be subject to restrictive labeling or product recall and withdrawals. Market adoption of gene and cell therapies may be limited by reimbursement challenges, high treatment costs, physician hesitancy and competition from alternative therapies.

As a supplier to companies developing gene and cell therapies, we are subject to the risks faced by our drug delivery customers which could lead to the termination of their relationship or certain programs with us, reducing our revenue and revenue prospects, and reducing our exposure to research and clinical trials that further our business objectives.

We engage in conversations with drug delivery customers regarding potential opportunities on an ongoing basis. There is no assurance that any of these conversations will result in an agreement, or if an agreement is reached, that the resulting relationship will be successful or that preclinical, clinical, or research studies conducted as part of the engagement will be continued or will produce successful outcomes.

The sizes of the markets for our products and services and any future products and services may be smaller than we estimate and may decline.

Our estimates of the total addressable market for our products and services are based on a number of internal and third-party estimates and assumptions, including, without limitation, the assumed prices at which we can sell our products and services in the market. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors.

As a result, our estimates of the annual total addressable market for our products and services in different market segments may prove to be incorrect. If the actual number of patients with indications who would benefit from our products, the price at which we can sell our products or the annual total addressable market for our products is smaller than we have estimated, it may impair our prospective market and revenue opportunity.

Our ClearPoint system may not achieve broad market adoption.

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

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

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

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

We started selling our ClearPoint system in 2010, and to date, sales of the ClearPoint system have been primarily focused on its use for neurosurgical procedures in the MRI suite. In 2021, we launched the SmartFrame Array Neuro Navigation System and Software, and in 2024, we commercialized the SmartFrame OR Stereotactic System. Both SmartFrame Array and SmartFrame OR allow for operating room placement of our technology. We have relatively limited experience marketing and selling our ClearPoint system and products for use with neurosurgical procedures in the operating room. If our team fails to adequately promote, market and sell the ClearPoint system, and other new products that we may develop in the future, in this new environment, our sales could suffer.

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

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

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

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

Our future business prospects depend in part on our ability to develop and commercialize new products and services, such as the Maestro Brain Model, the ClearPoint Prism Neuro Laser Therapy System, SmartFrame OR, and preclinical development and device development services for pharmaceutical partners. New technologies, techniques or products could emerge from competitors that might offer better combinations of price and performance than our products and services. It is important that we anticipate changes in technology and market demand, as well as customer preferences and practices, to successfully commercialize new technologies to meet our prospective customers' needs on a timely and cost-effective basis.

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

- properly identify and anticipate customer needs;
- identify, retain, and manage third-party design and development firms, where appropriate, to accelerate development;
- develop and introduce new products or services in a timely manner;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;
- obtain and retain third-party licenses required for the development, commercialization, and/or utilization of new products;
- demonstrate the safety and efficacy of new products;
- obtain the necessary regulatory authorizations to market new products or product enhancements;
- deliver products and services at a price point that is both profitable and acceptable to the market; and
- secure our supply chain to ensure we can continue to deliver products in a timely fashion to all geographies.

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

In the ordinary course of our development and commercialization of new products and services, we may enter into collaborations, in-licensing arrangements, joint development, distribution, or other commercial arrangements. Proposing, negotiating and implementing such arrangements may be a lengthy, expensive, and complex process. We may not identify, secure, or complete any such transactions

or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these arrangements may not result in the development of products or services that achieve commercial success or result in significant revenues and could be terminated prior to achieving their desired objectives.

A growing part of our revenue from the biologics and drug delivery business is derived from providing consultancy to our pharmaceutical and other medical technology partners for preclinical development services, on-site clinical support and training, regulatory consultation, protocol consultation, customized device development, and other solutions to optimize preclinical and clinical workflows. In certain cases, these services support a novel area in which commercialization must be preceded by preclinical studies and 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 studies and trials. The maintenance and growth of our revenue from our biologics and drug delivery services is dependent on our pharmaceutical and other medical technology partners continuing their development process and achieving commercial success with their therapeutic products.

Some of our customers and partners may elect to terminate or renegotiate their agreements with us for various reasons, including force majeure clauses, unexpected or undesired study results, dissatisfaction with our performance under the agreement, the loss or limitation of funding for research and development, or general convenience. Cancellation or renegotiation of a large agreement could adversely affect our business and, therefore, may adversely affect our operating results. In addition, we may enter into agreements with customers to provide services on a fixed fee basis. We may also enter into agreements with customers for which we are paid a lump sum conditioned upon the achievement of development milestones. Accordingly, in these cases, we bear the risk if we underprice our contracts, overrun our cost estimates, or if there is a failure by us or our customer to achieve the development milestones. Such events could have an adverse effect on our business, results of operations, financial condition and cash flows.

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

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

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

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

Because in most cases, hospitals are reimbursed for the procedures in which our products are used and our products are not separately reimbursed, the additional cost associated with the use of our products could impact hospital profit margins. Some hospitals could believe third-party reimbursement levels are not adequate to cover the cost of our products. Furthermore, some physicians could believe third-party reimbursement levels are not adequate to compensate them for performing the procedures in which our products are used. Failure by hospitals and physicians, whether in the U.S. 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 2024, one pharmaceutical customer, a related party as described in Note 2 to the consolidated financial statements included elsewhere in this Annual Report, for whom we provide clinical services in support of the customer's clinical trials and earn a quarterly fee, accounted for 9% of our total revenues, and 17% of our biologics and drug delivery revenue. Our five largest hospital customers account for approximately 31% of our 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' preclinical studies or clinical trials, or in orders from any of our significant hospital customers, which could harm our business and results of operations.

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

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

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

Many of our components, component assemblies, and finished products are provided to us by single-source suppliers. We generally purchase components and component assemblies through purchase orders rather than long-term supply agreements. We generally do not maintain large volumes of inventory for components, component assemblies, or finished products. We have not identified alternative suppliers for some of the finished products that we commercialize. 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. We also depend on single-source service providers for many of the services that we perform for our customers. Our dependence on a limited number of third-party suppliers and service providers and the challenges we may face in obtaining adequate supplies and services involve several risks, including limited control over pricing, availability, quality and delivery schedules. A disruption or termination in the supply of components or finished products could also result in our inability to meet demand for our products, which could harm our ability to generate revenues, lead to customer dissatisfaction and damage our reputation. Disruptions in the global supply chain could negatively affect our single-source suppliers and could further exacerbate the risk that we are unable to meet the demand for our products. Furthermore, if we are required to change the supplier of a key component or component assembly of our products, we may be required to verify that the new supplier maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. Disruptions to our service providers could impact our ability to provide critical services to our customers, damage our customer relationships, and cause material adverse impacts to our financial results. The delays associated with the verification of a new supplier or service provider could also adversely affect our ability to meet demand for our products and services.

To the extent we seek a new indication for use of, or new claims for, our products, the FDA may not grant 510(k) clearance or 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.

In the United States, our SmartFlow cannula has received 510(k) clearance from the FDA for the aspiration of CSF, or injection of Cytarabine into the ventricles and a De Novo marketing authorization for the intraputaminal administration of eladocagene exuparvovec-tneq for the treatment of adult and pediatric patients with AADC deficiency. The SmartFlow cannula has also been CE marked for use in the EU for the delivery of approved fluids into the brain or aspiration of CSF. The SmartFlow cannula is being utilized in approved combination product clinical and preclinical studies by pharmaceutical companies and academic research customers for various research and clinical trials in connection with delivery of therapeutic agents. The growth of our drug delivery and biologics business is dependent upon our pharmaceutical company customers' ability to obtain regulatory approval for the use of the SmartFlow cannula for delivery of their therapeutic agent, and/or our ability to expand the cleared indications for our SmartFlow cannula to include delivery of our pharmaceutical company customers' therapeutic agents. To the extent that our pharmaceutical partners are not successful in obtaining

regulatory approval, or if we are unable to expand the cleared indications for use of our SmartFlow cannula, we may not be able to grow our business.

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

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

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

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy will be required and we may not adequately develop such protocols to support clearance or approval. Further, the FDA could require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial could cause an increase in costs and delays in the approval and attempted commercialization of our product candidates or result in the failure of the clinical trial. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

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

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

The FDA may not authorize marketing via *de novo* classification or clear our 510(k) applications on a timely basis or at all. Such delays or refusals, regardless of the cause, could have a material adverse effect on our business, financial condition, and results of operations. The FDA may also change its clearance and authorization policies, adopt additional regulations or revise existing regulations, or take or become subject to other actions, such as staffing changes, which may prevent or delay authorization or clearance of our products. Similar restrictions exist outside of the U.S.

To sell our products in member countries of the EU, our products must comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93/42/EEC) for products CE marked under the MDD (Medical Device Directive) and the general safety and performance requirements of the EU Medical Device Regulation (Regulation EU 2017/745) for products CE marked under the EU MDR (Medical Device Regulation). Compliance with these requirements is a prerequisite to be able to affix the CE mark to our products, without which they cannot be sold or marketed in the EU. To demonstrate compliance with these requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can self-declare the conformity of its products with the requirements of the EU Medical Devices Directive or the EU Medical Device Regulation, a conformity assessment procedure requires the intervention of an organization accredited or licensed by a member state of the EU to conduct conformity assessments, or a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body would typically audit

and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the requirements. This certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

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

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

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

Even if any clinical trial that we need to undertake is completed as planned, we cannot be certain that its results will support our product candidate claims or any new indications that we may seek for our products or that the FDA or foreign authorities will agree with our conclusions regarding the results of those trials. The clinical trial process may fail to demonstrate that our products or a product candidate is safe and effective for the proposed indicated use, which could cause us to stop seeking additional clearances or approvals for our products or abandon or delay development of other product candidates. Any delay or termination of our clinical trials will delay the filing of our regulatory submissions and, ultimately, our ability to commercialize a product candidate. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile.

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

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

These companies enjoy significant competitive advantages over us, including:

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

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

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

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

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

- export restrictions and controls relating to technology;
- pricing pressure that we may experience internationally;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability;
- consequences arising from natural disasters and other similar catastrophes, such as hurricanes, tornados, earthquakes, floods and tsunamis;
- potentially adverse tax consequences, tariffs and other trade barriers;
- the need to hire additional personnel to promote our products outside of the U.S.;
- international terrorism and anti-American sentiment;
- fluctuations in exchange rates for future sales denominated in foreign currency;
- difficulty in obtaining and enforcing intellectual property rights; and
- changing regulatory environments such as the European Medical Device Regulation.

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

Our exposure to each of these risks may increase our costs and require significant management attention.

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

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

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

Our insurance coverage related to information risks, breaches, and business interruption is subject to deductibles and coverage limitations. We may not be able to maintain our current insurance coverage on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against future claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against such information risks and breach claims, we could be exposed to significant liabilities.

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

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

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

We need to hire and retain additional qualified personnel to grow and manage our business. If we are unable to attract and retain qualified personnel, including our senior management team, our sales, clinical support and marketing team and our engineering team, 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, particularly in light of current labor market conditions. 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.

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 search and recruiting process likely would involve significant time and costs, and may significantly delay or prevent the achievement of our business objectives.

Risks Related to Our Financial Position

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

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

As a result of the numerous risks and uncertainties associated with developing medical devices and with our biologic and drug delivery customers' development of safe and effective drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Our profitability will depend on revenues from the sale of our products and services. Additionally, increases in our various costs that may be the result of inflationary pressures could further reduce our sales and profitability. We cannot provide any assurance that we will ever achieve profitability and, even if we achieve profitability, that we will be able to sustain or increase profitability on a quarterly or annual basis. Further, because of our relatively limited commercialization history in our biologics and drug delivery business, 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 expect to 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, 2024 was approximately $191.4 million. Net cash used in operations was $9.0 million for the year ended December 31, 2024. Since our inception, we have financed our operations principally from the sale of equity securities and the issuance of notes payable. At December 31, 2024, we had cash and cash equivalent balances aggregating $20.1 million, resulting primarily from a 2024 public offering and note issuances pursuant to the 2020 Financing Transaction as discussed in Note 7 to the consolidated financial statements included elsewhere in this Annual Report. On November 7, 2024, we entered into an At-The-Market Equity Offering Sales Agreement to sell shares of our common stock having aggregate sales proceeds of up to $50 million.

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

As a result of the foregoing, it is uncertain whether or not it will 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 costs, terms and timing of any future investments or acquisitions, or 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.

Our cash, cash equivalents and short-term marketable securities are subject to economic risk.

The Company may invest its cash, cash equivalents and short-term marketable securities in domestic bank deposits, money market funds, U.S. Government debt securities, corporate debt, and certificates of deposit. Certain types of these investments are subject to general credit, liquidity, market and interest rate risks. In the event these risks caused a decline in value of any of the Company's investments, it could adversely affect the Company's financial condition.

We currently, and may in the future, have assets held at financial institutions that may exceed the insurance coverage offered by the Federal Deposit Insurance Corporation ("FDIC"), and the loss of such assets could have a negative effect on our operations and liquidity.

In early 2023, multiple banks were closed by regulatory agencies and swept into receivership. We currently have our cash and cash equivalents held in deposit in accounts at certain FDIC-insured financial institutions, some of which include amounts in excess of the insurance coverage offered by the FDIC. In the future, we may maintain our cash assets at financial institutions in the United States in amounts that may be in excess of the FDIC insurance limit of $250,000. Though to date, we have experienced no loss or lack of access to cash in our operating accounts, in the event of a failure of any of these financial institutions where we maintain our deposits or other assets, we may incur a loss to the extent such deposits or assets exceeds the FDIC insurance limitation, which could have a material adverse effect upon our liquidity, financial condition and our results of operations.

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.

U.S. patents and patent applications may be subject to interference proceedings and U.S. patents may be subject to inter partes proceedings ("IPRs"), reissue and reexamination proceedings in the United States Patent and Trademark Office. Foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent offices. Any of these proceedings could result in either loss of the patent or denial of the patent application, or loss or reduction in the scope of one or more of the claims of the patent or patent application. Changes in either patent laws or in interpretations of patent laws may also diminish the value of our intellectual property or narrow the scope of our protection. Interference, IPRs, reexamination and opposition proceedings may be costly and time consuming, and we, or the third parties from whom we license intellectual property, may be unsuccessful in such proceedings. Thus, any patents that we own or license may provide limited or no protection against competitors. In addition, our pending patent applications and those we may file in the future may not result in patents being issued or may have claims that do not cover our products or product candidates. Even if any of our pending or future patent applications are issued, they may not provide us with adequate protection or any competitive advantages. Our ability to develop additional patentable technology is also uncertain.

Non-payment or delay in payment of patent fees or annuities, whether intentional or unintentional, may also result in the loss of patents or patent rights important to our business. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as do the laws of the U.S., 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 U.S. and foreign patents issued to third parties that relate to our business. Some of these patents may be broad enough to cover one or more aspects of our present technologies and/or may cover aspects of our future technologies. We do not know whether any of these patents, if 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 certain products, refrain from entering certain lines of business 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 U.S. 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 U.S. are sometimes less willing to protect know-how than courts in the U.S. 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.

We rely on patent rights and licenses from third parties which are subject to termination or expiration.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest United States non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited.

Even if patents covering our products are obtained, once the patent life has expired, we may be open to competition from competitive products, as our ability to prevent competitors from copying our technology may be limited. Given the amount of time required for the development, testing and regulatory review of potential new medical technologies, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Additionally, should any patent licenses be prematurely terminated for any reason, or if the patents and intellectual property assigned to us or owned by third parties that we have licensed are challenged or defeated, our research efforts could be materially and adversely affected. There is also the related risk that we may not be able to make the required payments under any patent license, in which case we may lose to ability to use one or more of the licensed patents. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

Third parties may attempt to commercialize competitive products in foreign countries where we do not have any patents or patent applications and/or where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations.

Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries do not favor the enforcement of patents, trade secrets and other intellectual property protection. In particular, many countries limit the enforceability of patents against certain third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Even in foreign jurisdictions that enforce intellectual property rights to the same or a similar extent as do the laws of the United States, uneven enforcement and procedural barriers may exist in such countries, and proceedings to enforce our intellectual property rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not being issued and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

We have received licenses from third parties to certain software that is integrated into the software components of our products. In return, we have agreed to pay license fees and royalties subject to commercial arrangements with such third-party licensors. A loss of any of the licenses could impede our ability to offer and sell our products to customers until equivalent software could be identified, licensed or developed, and integrated into our products. These delays, if they occur, would harm our business, operating results and financial condition.

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

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

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

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

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

Risks Related to Legal and Regulatory Compliance

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

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

- design, development and manufacturing;
- preclinical and clinical testing;
- testing, labeling and storage;
- product safety;
- marketing, sales and distribution;
- premarket clearance, authorization, or approval;
- recordkeeping procedures;
- advertising and promotions;
- recalls and field corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; and
- product export.

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

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

We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation, administrative, or executive action, either in the U.S. or abroad. The implementation of new policies and priorities by future administrations 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.

In addition, our biologics and drug delivery business may be subject to regulations and guidance concerning the procurement and use of research animals for research purposes. Such regulations and guidance are evolving and continues to be developed for other areas that impact the biomedical research community on both a national and international basis. Our failure to comply with these regulations and guidance could have a material adverse effect on our business.

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

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

The Medicare Access and CHIP Reauthorization Act, or the Medicare Access Act, removed the sustainable growth rate or SGR, methodology applicable to fees for physician services. The Medicare Access Act also 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 U.S. 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 such repeal will not reverse course in the future. If such an excise tax on sales of our products in the U.S. is enacted, it could have a material adverse effect on our business, results of operations and financial condition.

The Inflation Reduction Act ("IRA"), aimed at curbing inflationary pressures, may have direct and indirect consequences for pharmaceutical and biotech companies in the context of their research and development expenditures. In particular, the IRA measures to control inflation have implications for future drug pricing. Our pharmaceutical and biotech customers rely on predictable pricing to fund research and development efforts. If pricing flexibility is constrained, these companies may limit spending on their pipeline, which may adversely affect the future revenue of our biologics and drug delivery business. It is unknown what form any future changes or any law would take and how or whether it may affect our business in the future.

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 U.S. healthcare industry may lower reimbursements for our products, reduce medical procedure volumes and adversely affect our business, possibly materially. We expect that changes or additions to the Affordable Care Act, the Medicare and Medicaid programs and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry.

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

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

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

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

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

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

We have obtained 510(k) clearance of the products that we commercialize for defined indications. Promotion or marketing of our products for any indications for use other than that cleared by the FDA would be considered off-label use.

Under the federal Food, Drug, and Cosmetic Act and other similar laws, we are prohibited from labeling or promoting our products, 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 products for uses not covered by the cleared labeling.

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

If we or our third-party suppliers fail to comply with the FDA's QMSR 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 QMSR, 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 QMSR through periodic and unannounced inspections of manufacturing facilities. Our facilities were last subject to an ISO 13485 surveillance audit and MDSAP surveillance audit in October 2024. We anticipate that we and certain of our third-party suppliers will be subject to future inspections. The failure by us or one of our third-party suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations, could result in enforcement actions against us, which could impair our ability to produce our products in a cost-effective and timely manner to meet our customers' demands. If we fail to comply with the FDA's QMSR 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 may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.

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

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

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

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

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

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

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

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

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

Within the U.S., numerous federal and state laws governing the collection, use, disclosure and storage of personal information may apply to us, including, without limitation, HIPAA, state data privacy laws (for example, the California Consumer Privacy Act and the California Privacy Rights Act), state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws. In addition, in certain cases, we may be a business associate of our HIPAA covered entity customers by virtue of receiving individually identifiable health information (referred to as "Protected Health Information" or "PHI") from these customers. In these business associate relationships, we must comply with applicable HIPAA requirements, state data privacy and security requirements, and the contractual terms of our business associate agreements that govern its permitted uses and disclosures of PHI received from the covered entity counterparty. Our failure to comply with any of these laws may result in criminal and civil liability. Enforcement actions can be costly and interrupt regular operations which may adversely affect our business.

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

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

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

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

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

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

Risks Related to Our Common Stock

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

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

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 90,000,000 shares of common stock authorized, and 27,632,332 shares outstanding as of February 18, 2025. As a result, our Board will be able to issue a substantial number of additional shares of common stock, without seeking stockholder approval. In addition, provisions in our certificate of incorporation and bylaws, as well as provisions of Delaware law, may discourage, delay or prevent a merger, acquisition or change of control. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors and take other corporate actions. These provisions:

- permit our Board of Directors to issue shares of preferred stock, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in our control;
- provide that the authorized number of directors may be changed only by resolution of the Board of Directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the chairman of the Board of Directors, our Chief Executive Officer or by the Board of Directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- provide that stockholders will be permitted to amend our bylaws only upon receiving at least 66 2/3% of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

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

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

We publicly provide financial guidance about our business and future operating results. In developing this guidance, our management makes certain assumptions and judgments about our future operating performance, including projected hiring of personnel, continued increase of our revenue, and continued stability of the macro-economic environment in our key markets. Furthermore, analysts and investors may develop and publish their own projections of our business, which may form a consensus about our future performance. Our business results may vary significantly from such guidance or that consensus due to a number of factors, many of which are outside

of our control, and which could adversely affect our operations and operating results. Furthermore, if we make downward revisions of our previously announced guidance, or if our publicly announced guidance of future operating results fails to meet expectations of securities analysts, investors, or other interested parties, the market price of our common stock could decline.

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

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

General Risk Factors

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

Our ability to attract and retain customers, suppliers, investors and employees is impacted by our reputation. Harm to our reputation can arise from various sources, including employee misconduct, security and privacy breaches, unethical behavior, litigation or regulatory outcomes, and scrutiny in connection with federal and state healthcare fraud and abuse laws and regulations. Such harm could also, 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.

The preclinical services that our biologics and drug delivery business provides to our customers are essential to drug discovery and development processes, and a significant number of these services are mandated by law. Notwithstanding, certain special interest groups categorically object to the use of animals for valid research purposes. Historically, research activities with animals have been the subject of adverse attention, including shareholder proposals and attempts to disrupt such services, impacting the industry. This may, in the future, include periodic demonstrations near facilities operated or utilized by us. Any negative attention, threats, acts of vandalism or legal action directed against our preclinical service activities, or our third-party service providers could harm our reputation and impair our ability to operate our business efficiently.

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

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

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

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

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

- decreased demand for our products;
- injury to our reputation;
- diversion of management's attention;
- significant costs of related litigation;
- payment of substantial monetary settlements or 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.

To date, we do not have redundant facilities. We conduct many of our activities, including research and development, component processing, final assembly, packaging and distribution activities for most of our products, at our facility located in Southern 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, or other unanticipated catastrophes, such as telecommunications failures, cyberattacks, or terrorist attacks, at any of the locations in which we or our key partners, suppliers and customers do business, could significantly disrupt our operations, and delay or prevent product assembly and shipment during the time required to repair, rebuild or replace our facility, which could be lengthy and result in significant expenses. Furthermore, the insurance coverage we maintain may not be adequate to cover our losses in any particular case or continue to be available at commercially reasonable rates and terms. In addition, our facility may be subject to shortages of electrical power, natural gas, water and other energy supplies. Any future shortage or conservation measure could disrupt our operations and cause expense, thus adversely affecting our business and financial results.

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

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS.

Not applicable.

ITEM 1C. CYBERSECURITY.

Our Company places a high priority on cybersecurity, information security, and securing confidential business information and personal information that we receive and store related to our customers and employees. Our Company's Audit Committee oversees the cybersecurity risks faced by the Company. In connection therewith, a Cybersecurity Steering Committee, which consists of our Chief Financial Officer, Chief Operating Officer, General Counsel, Vice President of Software Development, and Vice President of Regulatory Affairs, was formed to identify material risks and cybersecurity threats arising in our business.

Our Audit Committee receives updates from the Cybersecurity Steering Committee at least annually, which cover topics related to information security, privacy, and cyber risks and risk management processes, including the status of significant cybersecurity incidences and projects designed to strengthen our information security posture. Our Audit Committee is also responsible for ensuring that the Board of Directors also receives periodic reports with respect to the status and management of our cybersecurity risks.

The Cybersecurity Steering Committee, in collaboration with delegates from our business and functions, is responsible for implementing the Company's enterprise-wide cyber security and information security strategy, employee training and compliance, and managing policies and processes for the Company's information technology standards, product security, and privacy. As a member of the Cybersecurity Steering Committee, our Vice President of Software Development provides experience devising effective cybersecurity management practices in the areas of both software and product development, including risk evaluation, impact assessment, security threat modelling, cybersecurity mitigation strategies, residual risk acceptability and methodologies for security risk verification. He has led the integration of our medical device software into some of the largest hospital and research institutions in the world in compliance with the extensive cybersecurity requirements of these institutions. In addition to utilizing internal Company resources, the Cybersecurity Steering Committee also regularly consults with external advisors and specialists regarding opportunities and enhancements to strengthen its practices and policies. We also engage with third-party consultants to manage the infrastructure and security of our information technology landscape.

Our cybersecurity program includes:

- Penetration testing of internal information technology systems and review of program maturity based on the National Institute of Standards and Technology ("NIST") cybersecurity framework;
- Phishing, social engineering, and cyber hygiene training;
- Continuous security event monitoring, management, and incident response plans;
- Continuous enhancements to security capabilities based on evolving threats;
- Information security policies and procedures;
- Privacy controls and compliance with applicable legislative and regulatory requirements;
- Assessment of applicable third-party vendors' cybersecurity and information security practices; and
- A cross-functional approach to addressing cybersecurity risk with participation from representatives across the business and functions.

As part of our cybersecurity program, we have adopted an incident response plan, under which the Chairs of our Board of Directors and Audit Committee are informed by the Cybersecurity Steering Committee of any cybersecurity incidents that have the potential to materially adversely impact the Company or its information systems. To date, no attempted cyber-attack or other attempted intrusion on our information technology networks has resulted in a material adverse impact on our operations or financial results, or in any penalties or settlements.

ITEM 2. PROPERTIES.

We lease approximately 7,500 square feet of space in Solana Beach, California, which serves as our corporate headquarters and houses certain management and research-and-development personnel. We also lease an approximately 20,000 square-foot industrial building in Carlsbad, California to use as an office and manufacturing facility. We believe that these facilities are sufficient to meet our current purposes, and that additional space can be obtained on commercially reasonable terms as needed.

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. See Note 8 to the consolidated financial statements included elsewhere in this Annual Report for further disclosure.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Market Information

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

Holders

As of February 18, 2025, we had 27,632,332 shares of common stock outstanding and no shares of preferred stock outstanding. As of February 18, 2025, we had approximately 206 stockholders of record. In addition, as of February 18, 2025, options to purchase 1,363,865 shares of common stock and restricted stock units representing 1,636,611 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.

Securities Authorized for Issuance Under Equity Compensation Plans

Information relating to our equity compensation plans as of December 31, 2024, under which our equity securities were authorized for issuance, is included in Item 12 of Part III of this Annual Report and such information is incorporated herein by reference.

ITEM 6. RESERVED.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

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

Overview

We are a commercial-stage medical device company that develops and commercializes innovative platforms for performing minimally invasive surgical procedures in the brain. We have deployed significant resources to fund our efforts to develop the foundational capabilities for enabling MRI-guided interventions, building an intellectual property portfolio, and identifying and building out commercial applications for the technologies developed by our company.

The first foundational component of our business is a medical device company providing medical devices for neurosurgery applications. Our primary medical device product, the ClearPoint system, is an integrated system comprised of hardware components, disposable components, and intuitive, menu-driven software, which is in commercial use globally. The primary applications for the ClearPoint system are to target and guide the insertion of deep brain stimulation electrodes, biopsy needles, and laser catheters, as well as the infusion of pharmaceuticals into the brain. The ClearPoint system was originally designed for use in an MRI setting. In 2021, we launched the SmartFrame Array Neuro Navigation System and Software, which allows for operating room placement of the ClearPoint system, and in 2024, we launched limited market release of the SmartFrame OR Stereotactic System, which allows for complete procedures to be performed in the operating room. In 2022, we commercialized the ClearPoint Prism Neuro Laser Therapy System as our first therapy product offering. We have exclusive global commercialization rights to the ClearPoint Prism Neuro Laser Therapy System through our Swedish partner, CLS.

The second component of our business is focused on partnerships in the biologics drug and delivery space. Our services include protocol consultation and solutions for preclinical study design and execution. Currently, we have more than 60 biologics and drug delivery customers who are evaluating using our products and services in trials to inject gene and cell therapies directly into the brain. These partnerships involve drug development programs that are at various stages of development ranging from preclinical research to late-stage regulatory trials for multiple distinct disease states. This part of our business potentially represents the largest opportunity for growth; however, our ability to grow in this market is dependent on our ability to maintain and establish new relationships with customers, such customers' continuation of research and development plans, and such customers achieving success in completion of clinical trials and subsequent regulatory approvals of their drugs and biologics.

2024 Developments

- Activated 25 new global centers for the year, reflecting an increase in demand driven by new product offerings, including the PRISM Laser Therapy System and SmartFrame OR.
- Completed a follow-on public offering of common stock, resulting in net proceeds of approximately $16.2 million, and entered into an At-the-Market ("ATM") Equity Offering Sales Agreement (the "ATM Agreement") pursuant to which we may offer and sell, from time to time, shares of our common stock, having aggregate sales proceeds of up to $50 million.
- Repaid prior to maturity all remaining principal and interest on secured convertible notes issued in 2020, resulting in no outstanding debt at December 31, 2024.
- Reduced cash used in operating activities to $9.0 million in 2024, a 35% year-over-year decrease.
- Several of our partners advanced through preclinical and clinical review, with seven pharmaceutical partners receiving expedited US FDA review designations.
- Received the following regulatory approvals:
    - US FDA 510(k) clearance for SmartFrame OR Stereotactic System to support expansion into the operating room;
    - Taiwan Food and Drug Administration approval of SmartFlow cannula for commercial use in Taiwan; and
    - US FDA De Novo marketing authorization of the SmartFlow Neuro Cannula for intraputaminal administration of eladocagene exuparvovec-tneq for the treatment of adult and pediatric patients with AADC deficiency, representing the first-ever FDA marketing authorization of a device used to deliver gene therapy directly to regions of interest in the brain.

Factors Which May Influence Future Results of Operations

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

Macroeconomic Trends

We continue to monitor the impacts of various macroeconomic trends, such as inflationary pressure, changes in monetary policy, decreasing consumer confidence and spending, the introduction of or changes in tariffs or trade barriers, and global or local recession. Such changes in domestic and global macroeconomic conditions may lead to increased costs for our business. Additionally, these macroeconomic trends could adversely affect our customers, which could impact their willingness to spend on our products and services, or their ability to make payments, which could harm our collection of accounts receivable and financial results. The world's financial markets remain susceptible to significant stresses, resulting in reductions in available credit and government spending, economic downturn or stagnation, foreign currency fluctuations and volatility in the valuations of securities generally. As a result, our ability to access capital markets and other funding sources in the future may not be available on commercially reasonable terms, if at all. The rapid development and fluidity of these situations precludes any prediction as to the ultimate impact they will have on our business, financial condition, results of operation and cash flows, which will depend largely on future developments.

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 marking for our ClearPoint system and SmartFlow cannula, respectively; and in June 2020 we obtained CE marking for version 2.0 of our ClearPoint software and our Inflexion head fixation frame. In January 2021, we received 510(k) clearance for the SmartFrame Array Neuro Navigation System. In September 2022, the ClearPoint Prism Neuro Laser Therapy System, for which we have exclusive global right to commercialize, received 510(k) clearance through our Swedish partner, CLS. The Prism laser represents the first therapy product we have commercialized. In January 2024, we received 510(k) clearance from the FDA for the SmartFrame OR Stereotactic System.

In 2021, we started providing consulting services to our pharmaceutical and other medical technology customers for improving outcome predictability and optimizing preclinical and clinical workflows. Our expertise is concentrated in benchtop testing, preclinical studies, clinical trial support, regulatory consultation, and over-arching translation from the preclinical to the clinical setting to enhance accuracy and precision of drug delivery.

Future revenue from sales of our ClearPoint platform products and services is difficult to predict and may not be sufficient to offset our continuing research and development expenses and our increasing selling, general and administrative expenses.

Generating recurring revenue from the sale of products remains an important part of our business model for our ClearPoint system. Our product revenue was approximately $18.6 million and $10.6 million for the years ended December 31, 2024 and 2023, respectively, and was almost entirely related to our ClearPoint system. Our service revenue was approximately $12.8 million and $13.4 million for the years ended December 31, 2024 and 2023, respectively, of which 92% and 86%, respectively, related to the biologics and drug delivery service line.

Our revenue recognition policies are more fully described in Note 2 to the consolidated financial statements elsewhere in this Annual Report.

Underlying the revenue from sales of products and services to our biologics and drug delivery customers is the number of direct customers and end users of our products and/or services ("Partners"). Our Partners consist of pharmaceutical and biotech companies, academic institutions, or customer-sponsored contract research organizations that are developing methods to deliver a wide variety of molecules, genes or proteins to targeted brain tissue or structures that would need to bypass the blood-brain barrier for the treatment of a variety of disorders. This 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 commercial success is uncertain, pending, in part, on the outcome of those trials. While our revenue from sales of products and services to our biologics and drug delivery customers is indicative of growth, the number of Partner relationships is also of importance as we recognize the possibility that some Partners' research will reach commercial success, and others may not. To the extent our Partners achieve commercial success, our expectation is that we will share in such success through our Partners' use of our products and services in their delivery of therapies. At December 31, 2024, we had more than 60 Partners, as compared to over 50 Partners as of the same date in 2023.

Cost of Revenue

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

Research and Development Costs

Our research and development costs consist primarily of costs associated with the conceptualization, design, testing, and prototyping of our ClearPoint system products, cannulas, and enhancements. Such costs include salaries, travel, and benefits for research and development personnel; materials and laboratory supplies in research and development activities; outside 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) develop devices and services for delivery of therapeutics into the central nervous system, (ii) expand products into the OR and therapeutics space, and (iii) expand the application of our technological platforms internationally.

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

Sales and Marketing, and General and Administrative Expenses

Our sales and marketing, and general and administrative expenses consist primarily of salaries, incentive-based compensation, travel and benefits, including related share-based compensation; marketing costs; professional fees, including fees for outside attorneys and 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, information technology and meeting costs.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. ("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 revenues and 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. Revenue is recognized when control of our products and services are 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, in a process that involves identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the distinct performance obligations in the contract, and recognizing revenue when or as the performance obligations have been satisfied.

Determining whether products and services are considered distinct performance obligations that should be accounted for separately versus together may require significant judgment. We evaluate each product or service promised in a contract to determine whether it represents a distinct performance obligation. 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 typically allocate the contract price among the performance obligations based on the relative stand-alone selling prices for each such performance obligation customarily charged by us.

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. Product revenue is generally recognized at a point in time, generally upon shipment, however, it may be recognized upon delivery based on the contractual terms with certain customers. Service revenue is generally recognized over time as the services are delivered to the customer based on the extent of progress towards completion of the performance obligation. The selection of the method used to measure progress towards completion requires judgment and is based on the nature of the products or services to be provided. Depending on which better depicts the transfer of control to the customer, we may use output methods, such as time elapsed, or input methods, such as labor hours expended or costs incurred, to measure our progress toward complete satisfaction of the performance obligation. We recognize revenue for satisfied performance obligations only when we determine there are no uncertainties regarding payment terms or transfer of control.

Under certain agreements, we are entitled to receive event-based payments subject to our customer's achievement of specified development and regulatory milestones. Variable consideration is included in the transaction price if, in our judgment, it is probable that these milestones will be achieved and a significant future reversal of cumulative revenue under the contract will not occur. At the end of each reporting period, we re-evaluate the probability of achievement of such milestones, and if necessary adjust our estimate of the overall transaction price. The probability assessment is largely based on communications with our customers and historical, current, and forecasted information that is reasonably available. A revenue reversal is possible if it is determined that achievement of a milestone which was previously deemed probable, will not occur.

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 neurosurgical products, drug delivery and biologic products, therapy products and ClearPoint capital equipment. Software license inventory related to ClearPoint systems undergoing on-site customer evaluation is included in inventory in the accompanying consolidated balance sheets. All other software license inventory is classified as a non-current asset. We periodically review our inventory for excess and obsolete items and provide a reserve upon giving consideration to factors such as its physical condition, sales patterns, and expected future demand in order to estimate the amount necessary to write down any slow moving, obsolete, or damaged inventory. These estimates could vary from actual amounts based upon future economic conditions, customer inventory levels, or competitive factors that were not foreseen or did not exist when the estimated write-downs were made.

Share-Based Compensation. We account for compensation for all arrangements under which employees and others receive shares of stock or other equity instruments (such as restricted stock and options) 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. In the case of stock options, the fair value is 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. Expected volatility is based on historical volatility of our common stock. We utilize risk-free interest rates based on U.S. treasury instruments, 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. We do not believe there is a reasonable likelihood that there will be a material change in estimates or assumptions used to determine share-based compensation expense.

Results of Operations

Comparison of the Year Ended December 31, 2024 to the Year Ended December 31, 2023

(Dollars in thousands)	Year Ended December 31, 2024	2023	Percentage Change
Product revenue	$ 18,626	$ 10,603	76 %
Service and other revenue	12,764	13,352	(4)%
Total revenue	31,390	23,955	31 %
Cost of revenue	12,268	10,341	19 %
Gross profit	19,122	13,614	40 %
Research and development costs	12,392	11,709	6 %
Sales and marketing expenses	14,478	12,595	15 %
General and administrative expenses	11,998	11,756	2 %
Other income (expense):			
Other expense, net	(40)	(29)	NM
Interest income, net	872	386	126 %
Net loss	$ (18,914)	$ (22,089)	(14)%

NM - The percentage change is not meaningful.

Revenue. Total revenue was approximately $31.4 million and $24.0 million for the years ended December 31, 2024 and 2023, respectively.

(Dollars in thousands)	Years Ended December 31, 2024	2023	Percentage Change
Biologics and drug delivery			
Disposable products	$ 5,606	$ 2,154	160 %
Services and license fees	11,704	11,448	2 %
Subtotal – Biologics and drug delivery revenue	17,310	13,602	27 %
Neurosurgery navigation and therapy			
Disposable products	10,285	7,589	36 %
Services	-	931	(100)%
Subtotal – Neurosurgery navigation and therapy revenue	10,285	8,520	21 %
Capital equipment and software			
Systems and software products	2,735	860	218 %
Services	1,060	973	9 %
Subtotal – Capital equipment and software revenue	3,795	1,833	107 %
Total revenue	$ 31,390	$ 23,955	31 %

Biologics and drug delivery revenue, which include sales of disposable products and services related to customer-sponsored preclinical and clinical trials utilizing our products, increased 27% to $17.3 million for the year ended December 31, 2024, from $13.6 million for the same period in 2023. This increase is attributable to a $3.5 million increase in product revenue resulting from higher demand for disposables as multiple partners progress in their trials, and a $0.3 million increase in service and other revenue related to new preclinical trials and service agreements entered into with our partners for the year ended December 31, 2024, compared to the same period in 2023.

Neurosurgery navigation and therapy revenue, which primarily consists of disposable product commercial sales related to cases utilizing the ClearPoint system, increased 21% to $10.3 million during the year ended December 31, 2024, from $8.5 million for the same period in 2023. Product revenue increased $2.7 million, or 36%, resulting from newly activated accounts, increased case count, and new product offerings, including SmartFrame OR and Prism Laser Therapy, compared to the same period in 2023. This was partially offset by a decrease in service and other revenue of $0.9 million primarily as a result of pausing a co-development program with one of our Brain Computer Interface partners.

Capital equipment and software revenue, consisting of sales of ClearPoint reusable hardware and software and related services, increased 107% to $3.8 million for the year ended December 31, 2024, from $1.8 million for the same period in 2023, due to an increase in the placements of ClearPoint navigation capital equipment and software and Prism laser units.

Cost of Revenue and Gross Profit. Cost of revenue was $12.3 million, resulting in gross profit of $19.1 million and gross margin of 61%, for the year ended December 31, 2024, compared to $10.3 million, resulting in gross profit of $13.6 million and gross margin of 57% for the year ended December 31, 2023. The increase in gross margin was primarily due to lower costs for the year ended December 31, 2024 due to the transition to the new manufacturing facility, occurring in 2023, and higher volumes for the year ended December 31, 2024.

Research and Development Costs. Research and development costs were $12.4 million for the year ended December 31, 2024, compared to $11.7 million for the same period in 2023, an increase of $0.7 million, or 6%. The increase was due primarily to increases in personnel costs, including share-based compensation expense, of $1.2 million due to growth in headcount, partially offset by a decrease of $0.5 million in research costs as a result of reprioritization of certain initiatives.

Sales and Marketing Expenses. Sales and marketing expenses were $14.5 million for the year ended December 31, 2024, compared to $12.6 million for the same period in 2023, an increase of $1.9 million, or 15%. This increase was primarily due to higher personnel costs, including share-based compensation expense, of $1.6 million resulting from increases in headcount in our clinical team, increases in travel expense of $0.4 million, partially offset by $0.1 million in other marketing activities.

General and Administrative Expenses. General and administrative expenses were $12.0 million for the year ended December 31, 2024, compared to $11.8 million for the same period in 2023, an increase of $0.2 million, or 2%. This increase was due primarily to higher personnel costs, including share-based compensation of $1.2 million, an increase in rent and occupancy costs as a result of the new Carlsbad site of $0.5 million, partially offset by a decrease in the allowance for credit losses of $1.5 million mainly as a result of subsequent recoveries.

Interest Income (Expense). Net interest income for the year ended December 31, 2024 was $0.9 million, compared with $0.4 million for the same period in 2023, as a result of increased investment in U.S. Government debt securities stemming from the capital raise in March 2024 as well as lower interest expense due to the early repayment of the First Closing Note.

Liquidity and Capital Resources

We have incurred net losses since our inception, which has resulted in a cumulative deficit at December 31, 2024 of $191.4 million. In addition, our use of cash from operations amounted to $9.0 million for the year ended December 31, 2024. Since inception, we have financed our operations principally from the sale of equity securities and the issuance of notes payable.

In March 2024, we completed a public offering of 2,653,848 shares of our common stock from which the net proceeds totaled approximately $16.2 million after deducting our payment of underwriting discounts and commissions and other offering expenses. In November 2024, we entered into an ATM Agreement pursuant to which we may offer and sell, from time to time, shares of our common stock, having aggregate sales proceeds of up to $50 million, subject to the terms and conditions of the ATM Agreement. As of December 31, 2024, we did not issue any shares of common stock under the ATM Agreement.

In August 2024, we repaid in full the remaining $10 million outstanding under the secured convertible notes issued in 2020 to two investors raising gross proceeds of $25 million, of which $15 million had been previously converted to common stock.

Additional information with respect to the public offerings and 2020 secured convertible notes is in Note 9 and 7, respectively, to the consolidated financial statements included elsewhere in this Annual Report.

As a result of these transactions and our business operations, our cash and cash equivalents totaled $20.1 million at December 31, 2024. In management's opinion, based on our current forecasts for revenue, expense and cash flows, our existing cash and cash equivalent balances at December 31, 2024, are sufficient to support our operations and meet our obligations for at least the next twelve months.

We may offer and sell additional equity or issue additional notes payable to raise funds for working capital, capital expenditures, or other general corporate purposes. Our primary uses of cash and operating expenses relate to paying employees and consultants, marketing our products, and supporting our research and development of future product offerings. Our short- and long-term liquidity requirements include the following obligations:

- We have lease arrangements related to our office and manufacturing facilities under non-cancellable operating leases. See Note 8 to the consolidated financial statements included elsewhere in this Annual Report.
- We typically enter into short-term agreements with vendors and suppliers of goods and services in the normal course of business through purchase orders, which are settled in cash upon our receipt of such goods or services. We may also at times enter into long-term commitments or license and collaboration agreements which require commitments that are noncancellable. The total amount as of December 31, 2024 for unfulfilled purchase orders and long-term purchase commitments is $5.4 million, of which approximately 28% is expected to be paid in 2025.

Cash Flows

Cash activity for the years ended December 31, 2024 and 2023 is summarized as follows:

	Years Ended December 31,	
(in thousands)	**2024**	**2023**
Cash used in operating activities	$ (8,950)	$ (13,720)
Cash (used in) provided by investing activities	(275)	8,949
Cash provided by financing activities	6,189	296
Net change in cash and cash equivalents	$ (3,036)	$ (4,475)

Net Cash Flows from Operating Activities. Net cash flows used in operating activities for the year ended December 31, 2024 were $9.0 million, a decrease of $4.8 million from the year ended December 31, 2023. This decrease was due to a lower net loss of $3.2 million, and a net decrease in operating assets and liabilities of $1.8 million, partially offset by a net decrease in non-cash items of $0.2 million. The change in operating assets and liabilities is primarily due to higher accounts payable and accrued liabilities, partially offset by lower deferred revenue. The change in the non-cash items results primarily from recoveries in the allowance for credit losses, partially offset by higher share-based compensation expense.

Net Cash Flows from Investing Activities. Net cash flows provided by investing activities in 2024 were $0.3 million and related to equipment acquisitions.

Net cash flows provided by investing activities in 2023 were $8.9 million and consisted of proceeds from the maturities of short-term investments, partially offset by equipment acquisitions related to our new manufacturing site in Carlsbad, California, and acquisition of licensing rights.

Net Cash Flows from Financing Activities. Net cash provided by financing activities in 2024 consisted of proceeds, net of offering costs, of $16.2 million received from the public offering of our common stock and $0.4 million in proceeds from the issuance of common stock under the employee stock purchase plan. This is partially offset by the repayment of the remaining $10 million outstanding under the secured convertible notes issued in 2020 and payments of $0.4 million for taxes related to shares withheld in connection with vesting of restricted stock awards.

Net cash provided by financing activities in 2023 consisted of proceeds of $0.5 million from the issuance of common stock under the employee stock purchase plan, partially offset by payments of $0.2 million for taxes related to shares withheld in connection with vesting of restricted stock awards.

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 products and services and pursue additional applications for our technology platforms. Our cash balances are primarily 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 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 ultimate duration and impact of macroeconomic trends, including inflationary pressures, changes in monetary policy, decreasing consumer confidence and spending, the introduction of or changes in tariffs or trade barriers, global or local recession, and geopolitical instability;
- the timing of broader market acceptance and adoption of our products;
- the scope, rate of progress and cost of our ongoing product development activities relating to our products;
- the ability of our Partners to achieve commercial success, including their use of our products and services in their preclinical studies, clinical trials and delivery of therapies;
- 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-22 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, 2024, 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, 2024.

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 U.S. 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, 2024, 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, 2024.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding management's assessment of internal control over financial reporting pursuant to rules of the SEC that do not require a non-accelerated filer to provide an auditor attestation of management's assessment of internal control over financial reporting.

Changes in Internal Control over Financial Reporting

During the year ended December 31, 2024, 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.

Not applicable. Without limiting the generality of the foregoing, during the quarter ended December 31, 2024, no director or Section 16 officer adopted or terminated any Rule 10b5-1 trading arrangements, as defined in Item 408(a) of Regulation S-K.

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

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by this item is incorporated by reference from the definitive proxy statement to be filed within 120 days after December 31, 2024, pursuant to Regulation 14A under the Exchange Act, in connection with our 2025 annual meeting of stockholders.

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

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

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the definitive proxy statement to be filed within 120 days after December 31, 2024, pursuant to Regulation 14A under the Exchange Act in connection with our 2025 annual meeting of stockholders.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

Other than as set forth below, the information required by this item is incorporated by reference from the definitive proxy statement to be filed within 120 days after December 31, 2024, pursuant to Regulation 14A under the Exchange Act in connection with our 2025 annual meeting of stockholders.

Equity Compensation Plan Information

Plan Category [1]	Number of securities to be issued upon exercise of outstanding options and restricted stock units (a)		Weighted-Average Exercise Price of Outstanding Options [2] (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 [3]	2,749,616	[4]	$ 7.50	1,369,811	[5]
Equity compensation plans not approved by stockholders [6][7][8][9]	438,750		$ 4.31	—	
Total	3,188,366		$ 6.48	1,369,811	

(1)The information presented in this table is as of December 31, 2024.
(2)The weighted-average exercise price calculation includes only stock options as restricted stock does not have an exercise price.
(3)Includes the Fifth Amended and Restated 2013 Incentive Compensation Plan and the 2021 Employee Stock Purchase Plan.

(4)Includes 937,646 outstanding stock options and 1,811,970 unvested restricted shares outstanding.
(5)Includes 1,230,813 shares of common stock available for issuance under the Fifth Amended and Restated 2013 Incentive Compensation Plan and 138,998 shares of common stock available for issuance under the 2021 Employee Stock Purchase Plan.
(6)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, 2024, awards with respect to 2,500 shares of our common stock were outstanding under the 2013 Non-Employee Director Equity Incentive Plan.
(7)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.
(8)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.
(9)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 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, 2024, pursuant to Regulation 14A under the Exchange Act in connection with our 2025 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, 2024 pursuant to Regulation 14A under the Exchange Act in connection with our 2025 annual meeting of stockholders.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a)(1) The following documents are filed 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, incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q filed on May 11, 2012	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., incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on June 8, 2015	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., incorporated by reference to Exhibit 3.3 to the Company's Registration Statement on Form S-1 filed on August 2, 2016	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., incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on February 12, 2020	8-K	001-34822	3.1	February 12, 2020
3.5	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of ClearPoint Neuro, Inc., incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on May 25, 2023	8-K	001-34822	3.1	May 25, 2023
3.6	Fourth Amended and Restated Bylaws of ClearPoint Neuro, Inc., incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on December 14, 2022	8-K	001-34822	3.1	December 14, 2022
4.1	Reference is made to Exhibits 3.1 through 3.6				
4.2	Specimen of Common Stock Certificate of ClearPoint Neuro, Inc., incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on February 12, 2020	8-K	001-34822	4.1	February 12, 2020

Exhibit Number	Exhibit Description	Incorporation by Reference Form	SEC File No.	Exhibit	Filing Date
4.3	Form of Senior Secured Convertible Note (First Closing), incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 13, 2020	8-K	001-34822	4.1	January 13, 2020
4.4	Description of Securities, incorporated by reference to Exhibit 4.4 to the Company's Annual Report on Form 10-K filed on March 12, 2024	10-K	001-34822	4.4	March 12, 2024
10.1+	Fifth Amended and Restated 2013 Incentive Compensation Plan, incorporated by reference to Appendix A to the Company's Proxy Statement on Schedule 14A filed on April 5, 2024	DEF14A		Appendix A	April 5, 2024
10.2+	MRI Interventions, Inc. 2013 Incentive Compensation Plan Form of Incentive Stock Option Agreement, incorporated by reference to Exhibit 10.53 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2013	10-Q	000-54575	10.53	August 14, 2013
10.3+	MRI Interventions, Inc. 2013 Incentive Compensation Plan Form of Non-Qualified Stock Option Agreement, incorporated by reference to Exhibit 10.54 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2013	10-Q	000-54575	10.54	August 14, 2013
10.4+	MRI Interventions, Inc. 2013 Incentive Compensation Plan Form of Non-Qualified Stock Option Agreement for Non-Employee Directors, incorporated by reference to Exhibit 10.55 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2013	10-Q	000-54575	10.55	August 14, 2013
10.5+	MRI Interventions, Inc. 2013 Non-Employee Director Equity Incentive Plan Form of Non-Qualified Stock Option Agreement, incorporated by reference to Exhibit 10.41 to the Company's Annual Report on Form 10-K filed on March 28, 2014	10-K	000-54575	10.41	March 28, 2014
10.6+	MRI Interventions, Inc. 2013 Incentive Compensation Plan Form of Restricted Share Award Agreement, incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 12, 2019	10-Q	001-34822	10.2	August 12, 2019
10.7+	ClearPoint Neuro, Inc. 2013 Incentive Compensation Plan Form of Restricted Share Unit Award Agreement, incorporated by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K filed on March 1, 2023	10-K	001-34822	10.38	March 1, 2023
10.8+	Non-Qualified Stock Option Agreement, effective as of October 6, 2014, granted by MRI Interventions, Inc. to Francis P. Grillo, incorporated by reference to Exhibit 10.63 to the Company's Registration Statement on Form S-1 filed on January 13, 2015	S-1	333-201471	10.63	January 13, 2015
10.9+	Non-Qualified Stock Option Agreement, effective as of March 30, 2015 granted by MRI Interventions, Inc. to Harold A. Hurwitz, incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 10, 2015	10-Q	000-54575	10.1	August 10, 2015

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.10+	Non-Qualified Stock Option Agreement, effective as of December 1, 2014, granted by MRI Interventions, Inc. to Wendelin C. Maners, incorporated by reference to Exhibit 10.65 to the Company's Registration Statement on Form S-1 filed on January 13, 2015	S-1	333-201471	10.65	January 13, 2015
10.11+	ClearPoint Neuro, Inc. Non-Employee Director Compensation Plan, as amended and restated by the Board of Directors on May 22, 2023, incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 22, 2023	8-K	001-34822	10.1	May 22, 2023
10.12+	Second Amended and Restated Key Personnel Incentive Program, incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2013	10-Q	000-54575	10.3	August 14, 2013
10.13+	Amended and Restated Key Personnel Incentive Award Agreement, dated June 13, 2013, by and between MRI Interventions, Inc. and Paul A. Bottomley, incorporated by reference to Exhibit 10.32 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2013	10-Q	000-54575	10.32	August 14, 2013
10.14+	Second Amended and Restated Key Personnel Incentive Award Agreement, dated June 13, 2013, by and between MRI Interventions, Inc. and Paul A. Bottomley, incorporated by reference to Exhibit 10.31 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2013	10-Q	000-54575	10.31	August 14, 2013
10.15+	Second Amended and Restated Key Personnel Incentive Award Agreement, dated June 13, 2013, by and between MRI Interventions, Inc. and Parag V. Karmarkar, incorporated by reference to Exhibit 10.33 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2013	10-Q	000-54575	10.33	August 14, 2013
10.16+	2021 Employee Stock Purchase Plan, incorporated by reference to Appendix A to the Company's Proxy Statement on Schedule 14A filed on April 20, 2021	DEF14A	001-34822	Appendix A	April 20, 2021
10.17+	Form of Indemnification Agreement, incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on June 28, 2021	8-K	001-34822	10.2	June 28, 2021
10.18+	Employment Agreement, dated as of October 6, 2017, by and between MRI Interventions, Inc. and Joseph Michael Burnett, incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on October 10, 2017	8-K	001-34822	10.2	October 10, 2017
10.19+	Amendment No. 1 to Employment Agreement, dated March 3, 2023 by and between the Company and Joseph M. Burnett, amending the Employment Agreement dated October 6, 2017, incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 3, 2023	8-K	001-34822	10.1	March 3, 2023

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.20+	Employment Agreement, dated as of September 14, 2020, by and between the Company and Danilo D'Alessandro, incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on September 14, 2020	8-K	001-34822	10.2	September 14, 2020
10.21	Amendment No. 1 to Employment Agreement, dated March 3, 2023 by and between the Company and Danilo D'Alessandro, amending the Employment Agreement dated September 14, 2020, incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on March 3, 2023	8-K	001-34822	10.2	March 3, 2023
10.22+	Employment Agreement, dated September 20, 2022, by and between the Company and Mazin Sabra, incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 20, 2022	8-K	001-34822	10.1	September 20, 2022
10.23+	Amendment No. 1 to Employment Agreement, dated March 3, 2023 by and between the Company and Mazin Sabra, amending the Employment Agreement dated September 20, 2022, incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on March 3, 2023	8-K	001-34822	10.3	March 3, 2023
10.24+	Employment Agreement, dated May 31, 2022, by and between the Company and Jeremy Stigall, incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on May 11, 2023	10-Q	001-34822	10.4	May 11, 2023
10.25+	Amendment No. 1 to Employment Agreement, dated March 3, 2023 by and between the Company and Jeremy Stigall, amending the Employment Agreement dated May 31, 2022, incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on May 11, 2023	10-Q	001-34822	10.5	May 11, 2023
10.26†	Development Agreement between MRI Interventions, Inc. and Siemens Medical Solutions USA, Inc., incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10/Q, as amended, filed on August 29, 2014	10-Q/A	000-54575	10.1	August 29, 2014
10.27†	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, incorporated by reference to Exhibit 10.20 to the Company's Form 10 filed on March 15, 2012	10	000-54575	10.20	March 15, 2012
10.28†	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., incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 26, 2012	8-K	000-54575	10.1	June 26, 2012

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.29†	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., incorporated by reference to Exhibit 10.56 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2013	10-Q	000-54575	10.56	August 14, 2013
10.30	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, incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 13, 2020	8-K	001-34822	10.1	January 13, 2020
10.31	First Omnibus Amendment 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, incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on January 29, 2020	8-K	001-34822	10.2	January 29, 2020
10.32	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, incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 29, 2020	8-K	001-34822	10.1	December 29, 2020
10.33+	Third Omnibus Amendment to the Securities Purchase Agreement and Senior Secured Convertible Notes, dated July 31, 2023, by and among ClearPoint Neuro, Inc., PTC Therapeutics, Inc., and Petrichor Opportunities Fund I LP, incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 1, 2023	8-K	001-34822	10.1	August 1, 2023
10.34	Security Agreement, dated January 29, 2020, by and between MRI Interventions, Inc. and Petrichor Opportunities Fund I LP, in its capacity as collateral agent, incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on January 29, 2020	8-K	001-34822	10.3	January 29, 2020
10.35	Standard Industrial/Commercial Single-Tenant Lease - Net, dated November 4, 2022 between ClearPoint Neuro, Inc. and the Hedda Marosi Living Trust and the Stella Feder Trust, incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 4, 2022	8-K	001-34822	10.1	November 4, 2022
10.36	At-The-Market Equity Offering Sales Agreement, dated November 7, 2024, by and between the Company and Stifel, Nicolaus & Company, Incorporated, incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on November 7, 2024	8-K	001-34822	1.1	November 7, 2024

Exhibit Number	Exhibit Description	Incorporation by Reference			
		Form	SEC File No.	Exhibit	Filing Date
19	Insider Trading Compliance Policy, adopted on July 17, 2023, incorporated by reference to Exhibit 10.1 to the Company's Annual Report on Form 10-K filed on March 12, 2024	10-K	001-34822	10.1	March 12, 2024
21*	Subsidiaries of ClearPoint Neuro, Inc.				
23.1*	Consent of Cherry Bekaert LLP				
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				
97	ClearPoint Neuro, Inc. Compensation Recoupment Policy, adopted on October 3, 2023, incorporated by reference to Exhibit 97 to the Company's Annual Report on Form 10-K filed on March 12, 2024	10-K	001-34822	97	March 12, 2024
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents				
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

* Filed herewith.
† Confidential treatment granted under Rule 24b-2 under the Securities Exchange Act of 1934. The confidential portions of this exhibit have been omitted and are marked accordingly. The confidential portions have been filed separately with the Securities and Exchange Commission pursuant to the request for confidential treatment.
+ Indicates management contract or compensatory plan.
++ This certification is being furnished solely to accompany this Annual Report pursuant to 18 U.S.C. Section 1350, and it is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

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

CLEARPOINT NEURO, INC.

Date: February 26, 2025

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

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)*	February 26, 2025
/s/ Danilo D'Alessandro **Danilo D'Alessandro**	*Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)*	February 26, 2025
/s/ R. John Fletcher **R. John Fletcher**	*Chairman and Director*	February 26, 2025
/s/ Lynnette C. Fallon **Lynnette C. Fallon**	*Director*	February 26, 2025
/s/ Pascal E.R. Girin **Pascal E.R. Girin**	*Director*	February 26, 2025
/s/ B. Kristine Johnson **B. Kristine Johnson**	*Director*	February 26, 2025
/s/ Matthew B. Klein **Matthew B. Klein**	*Director*	February 26, 2025
/s/ Linda M. Liau **Linda M. Liau**	*Director*	February 26, 2025
/s/ Timothy T. Richards **Timothy T. Richards**	*Director*	February 26, 2025

Table of Contents

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements
We have audited the accompanying consolidated balance sheets of ClearPoint Neuro, Inc. (the "Company") as of December 31, 2024 and 2023, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended, and the related notes to the consolidated financial statements. In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, 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 consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

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

Critical Audit Matter Description
The Company recognized $12,764,000 in service and other revenue for the year ended December 31, 2024. Service and other revenue is derived from (1) neurosurgery, navigation and therapy services, (2) biologics and drug delivery services, and (3) capital equipment-related services. As disclosed in Note 2 to the consolidated financial statements, the Company recognizes revenue when control of the Company's 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 services in a process that involves identifying the contract with the customer, determining the performance obligation in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied.

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

- Determination of which 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 price and allocation of the transaction price to the performance obligations;
- The pattern and timing of delivery for each distinct performance obligation; and
- The identification and treatment of contract terms that may impact the timing and amount of revenue recognized.

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

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

- 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; and
- 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.

/s/ Cherry Bekaert LLP

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

Tampa, Florida
February 26, 2025

CLEARPOINT NEURO, INC.

Consolidated Balance Sheets

(Dollars in thousands, except for share and per share data)

	December 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,104	$ 23,140
Accounts receivable, net	4,713	3,211
Inventory, net	6,863	7,911
Prepaid expenses and other current assets	1,683	1,910
Total current assets	33,363	36,172
Property and equipment, net	2,005	1,389
Operating lease rights of use	3,086	3,564
Software license inventory	103	386
Licensing rights	484	1,041
Other assets	148	109
Total assets	$ 39,189	$ 42,661
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,340	$ 393
Accrued compensation	4,885	2,947
Other accrued liabilities	1,450	1,053
Operating lease liabilities, current portion	557	424
Deferred product and service revenue, current portion	2,121	2,613
Total current liabilities	10,353	7,430
Operating lease liabilities, net of current portion	3,011	3,568
Deferred product and service revenue, net of current portion	436	541
2020 senior secured convertible note payable, net	—	9,949
Total liabilities	13,800	21,488
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.01 par value; 25,000,000 shares authorized at December 31, 2024 and 2023; none issued and outstanding at December 31, 2024 and 2023	—	—
Common stock, $0.01 par value; 90,000,000 shares authorized at December 31, 2024 and 2023; 27,617,415 and 24,652,729 shares issued and outstanding at December 31, 2024 and 2023, respectively	276	247
Additional paid-in capital	216,483	193,382
Accumulated deficit	(191,370)	(172,456)
Total stockholders' equity	25,389	21,173
Total liabilities and stockholders' equity	$ 39,189	$ 42,661

See notes to Consolidated Financial Statements.

CLEARPOINT NEURO, INC.

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

	Years Ended December 31,	
	2024	**2023**
Revenue:		
Product revenue	$ 18,626	$ 10,603
Service and other revenue	12,764	13,352
Total revenue	31,390	23,955
Cost of revenue	12,268	10,341
Gross profit	19,122	13,614
Research and development costs	12,392	11,709
Sales and marketing expenses	14,478	12,595
General and administrative expenses	11,998	11,756
Operating loss	(19,746)	(22,446)
Other income (expense):		
Other expense, net	(40)	(29)
Interest income, net	872	386
Net loss	$ (18,914)	$ (22,089)
Net loss per share attributable to common stockholders:		
Basic and diluted	$ (0.70)	$ (0.90)
Weighted average shares outstanding:		
Basic and diluted	27,027,692	24,605,212

See Notes to Consolidated Financial Statements.

CLEARPOINT NEURO, INC.
Consolidated Statements of Stockholders' Equity
Years Ended December 31, 2024 and 2023
(Dollars in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balances, January 1, 2023	24,578,983	$ 246	$ 187,008	$ (150,367)	$ 36,887
Issuances of common stock:					
Share-based compensation	9,538	—	6,079	—	6,079
Option exercises (cashless)	14,312	—	—	—	—
Issuance of common stock under employee stock purchase plan	84,430	1	505	—	506
Payments for taxes related to net share settlement of equity awards	(34,534)	—	(210)	—	(210)
Net loss for the year	—	—	—	(22,089)	(22,089)
Balances, December 31, 2023	24,652,729	$ 247	$ 193,382	$ (172,456)	$ 21,173
Issuances of common stock:					
Public offering of common stock, net of offering costs	2,653,848	26	16,157	—	16,183
Share-based compensation	260,552	2	6,905	—	6,907
Option exercises (cash and cashless)	12,258	—	21	—	21
Issuance of common stock under employee stock purchase plan	97,093	1	442	—	443
Payments for taxes related to net share settlement of equity awards	(59,065)	—	(424)	—	(424)
Net loss for the year	—	—	—	(18,914)	(18,914)
Balances, December 31, 2024	27,617,415	$ 276	$ 216,483	$ (191,370)	$ 25,389

See Notes to Consolidated Financial Statements.

CLEARPOINT NEURO, INC.

Consolidated Statements of Cash Flows
(Dollars in thousands)

	Years Ended December 31, 2024	2023
Cash flows from operating activities:		
Net loss	$ (18,914)	$ (22,089)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Allowance for credit losses (recoveries)	(296)	1,258
Depreciation and amortization	980	626
Share-based compensation	6,907	6,079
Amortization of debt issuance costs and original issue discounts	51	57
Amortization of lease right of use assets, net of accretion in lease liabilities	923	831
Accretion of discounts on short-term investments	—	(126)
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(1,206)	(1,804)
Inventory, net	743	1,246
Prepaid expenses and other current assets	262	(113)
Other assets	(39)	22
Accounts payable and accrued expenses	3,105	(649)
Lease liabilities	(869)	(755)
Deferred revenue	(597)	1,697
Net cash flows from operating activities	(8,950)	(13,720)
Cash flows from investing activities:		
Purchases of property and equipment	(275)	(717)
Acquisition of licensing rights	—	(334)
Proceeds from maturities of short-term investments	—	10,000
Net cash flows from investing activities	(275)	8,949
Cash flows from financing activities:		
Proceeds from public offering of common stock, net of offering costs	16,149	—
Repayment of 2020 senior secured convertible note	(10,000)	—
Proceeds from stock option exercises	21	—
Proceeds from issuance of common stock under employee stock purchase plan	443	506
Payments for taxes related to net share settlement of equity awards	(424)	(210)
Net cash flows from financing activities	6,189	296
Net change in cash and cash equivalents	(3,036)	(4,475)
Cash and cash equivalents, beginning of year	23,140	27,615
Cash and cash equivalents, end of year	$ 20,104	$ 23,140
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for:		
Income taxes	$ 62	$ —
Interest	$ 480	$ 743

CLEARPOINT NEURO, INC.
Consolidated Statements of Cash Flows

NON-CASH INVESTING AND FINANCING TRANSACTIONS:

•The Company had $0.2 million in capital expenditures accrued but not yet paid in December 31, 2024.

•During each of the years ended December 31, 2024 and 2023, the Company recorded net transfers of ClearPoint reusable components having an aggregate net book value of $0.4 million and $0.1 million, respectively, between loaned systems, which are included in property and equipment in the accompanying consolidated balance sheets, and inventory.

•As discussed in Note 8, the Company entered into a lease for a manufacturing facility in Carlsbad, California, which commenced in June 2023. In connection with the new lease, the Company recorded a right-of-use asset in exchange for an operating lease liability in the amount of approximately $2.5 million.

See Notes to Consolidated Financial Statements.

CLEARPOINT NEURO, INC.
Notes to Consolidated Financial Statements

1.Description of the Business and Financial Condition

ClearPoint Neuro, Inc. (the "Company") is a commercial-stage medical device company focused on the development and commercialization of innovative platforms for performing minimally invasive surgical procedures in the brain. From the Company's inception in 1998, the Company deployed significant resources to fund its efforts to develop the foundational capabilities for enabling MRI-guided interventions, building an intellectual property portfolio, and identifying and building out commercial applications for the technologies it develops. In 2021, the Company's efforts expanded beyond the MRI suite to encompass development and commercialization of new neurosurgical device products for the operating room setting, as well as consulting services for pharmaceutical and biotech companies, academic institutions, and contract research organizations. The Company was incorporated in the state of Delaware in March 1998, and has headquarters located in Solana Beach, California, and a manufacturing facility in Carlsbad, 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, ClearPoint Neuro Germany GmbH., a wholly owned subsidiary incorporated in Germany, in May 2023, and ClearPoint Neuro Italy, S.r.l., a wholly owned subsidiary incorporated in Italy, in August 2023, primarily for the purpose of employing the Company's clinical services representatives serving the Company's customers in the United Kingdom and the EU. The activities of all subsidiaries are reflected in these consolidated financial statements.

The Company's initial product offering, the ClearPoint system, is an integrated system comprised of capital equipment and disposable products, designed to allow minimally invasive procedures in the brain to be performed in an MRI suite. The ClearPoint Array Neuro Navigation System and its principal disposable component, introduced in 2021, is designed to be deployed in an operating room setting while also being usable in an MRI suite. Both systems provide guidance for the placement and operation of instruments or devices during the planning and operation of neurosurgical procedures. The Company received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") in 2010 to market the ClearPoint system in the United States for general neurosurgical interventional procedures; in February 2011, the Company also obtained CE marking for its ClearPoint system. In 2011 and 2018, the Company received 510(k) clearance and CE marking, respectively, for its SmartFlow cannula which is being used, or is under evaluation, along with the Company's services, by more than 60 pharmaceutical and biotech companies, academic institutions, or contract research organizations having a focus on biologics and drug delivery. The Company provides consulting services to pharmaceutical and other medical technology customers for improving outcome predictability and optimizing preclinical and clinical workflows. The Company's expertise is concentrated in benchtop testing, preclinical studies, clinical trial support, regulatory consultation, and over-arching translation from the preclinical to the clinical setting to enhance accuracy and precision of drug delivery. In September 2022, the ClearPoint Prism Neuro Laser Therapy System, for which the Company has exclusive global commercialization rights, received 510(k) clearance through the Company's Swedish partner CLS. The Prism laser represents the Company's first therapy product offering.

Macroeconomic Trends

The Company continues to monitor the impacts of various macroeconomic trends, such as inflationary pressure, changes in monetary policy, decreasing consumer confidence and spending, the introduction of or changes in tariffs or trade barriers, and global or local recession. Such changes in domestic and global macroeconomic conditions may lead to increased costs for the Company's business. Additionally, these macroeconomic trends could adversely affect the Company's customers, which could impact their willingness to spend on the Company's products and services, or their ability to make payments, which could harm the Company's collection of accounts receivable and financial results. The world's financial markets remain susceptible to significant stresses, resulting in reductions in available credit and government spending, economic downturn or stagnation, foreign currency fluctuations and volatility in the valuations of securities generally. As a result, the Company's ability to access capital markets and other funding sources in the future may not be available on commercially reasonable terms, if at all. The rapid development and fluidity of these situations precludes any prediction as to the ultimate impact they will have on the Company's business, financial condition, results of operation and cash flows, which will depend largely on future developments.

Liquidity

The Company has incurred net losses since its inception which has resulted in a cumulative deficit at December 31, 2024 of $191.4 million. In addition, the Company's use of cash from operations amounted to $9.0 million for the year ended December 31, 2024. Since inception, the Company has financed its operations principally from the sale of equity securities and the issuance of notes payable.

In March 2024, the Company completed a follow-on public offering of 2,653,848 shares of its common stock from which the net proceeds totaled approximately $16.2 million after deducting payment of underwriting discounts and commissions and other offering expenses. In November 2024, the Company entered into an At-the-Market Equity Offering Sales Agreement with an investment banking firm (the "ATM Agreement") pursuant to which it may offer and sell, from time to time, shares of its common stock, having aggregate sales proceeds of up to $50 million, subject to the terms and conditions of the ATM Agreement. As of December 31, 2024, the Company had not issued any shares of common stock under the ATM Agreement. Additional information with respect to these offerings is found in Note 9.

In August 2024, the Company repaid in full the remaining $10 million outstanding under the Securities Purchase Agreement ("SPA") entered into in 2020, pursuant to which it issued secured convertible notes to two investors raising gross proceeds of $25 million, of which $15 million had been previously converted to common stock. Additional information with respect to these notes is found in Note 7.

As required by accounting principles generally accepted in the United States ("GAAP"), the Company has evaluated its ability to continue as a going concern and has determined that based on current forecasts, existing cash and cash equivalent balances at December 31, 2024 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 intercompany accounts and transactions have been eliminated.

Basis of Presentation and Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. On an ongoing basis, the Company evaluates its estimates and judgments, which are based on historical and anticipated results and trends and on various other assumptions that management believes to be reasonable under the circumstances. By their nature, estimates are subject to an inherent degree of uncertainty and, as such, actual results may 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 from the date of purchase. As of December 31, 2024, cash equivalents consisted predominantly of U.S. Government debt securities.

Inventory

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

Intangible Assets

The Company is a party to a license agreement that provides rights to the Company for the development and commercialization of products. Under the term of the license agreement, the Company paid an aggregate $1.1 million to the licensor upon execution of the license agreement for access to the underlying technology and will make future payments based on the achievement of regulatory and commercialization milestones as defined in the license agreement. In 2022, the Company made a payment of $0.6 million to the licensor for the achievement of a regulatory milestone, which acts as a prepayment for future royalties.

In conformity with ASC 350, "Intangibles – Goodwill and Other," the Company amortizes its investment in the upfront license rights described above over an expected useful life of up to five years, or as commercial sales occur for the royalty prepayment. In addition, the Company periodically evaluates the recoverability of its investment in the license rights and records an impairment charge in the event such evaluation indicates that the Company's investment is not likely to be recovered.

Property and Equipment

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

Impairment of Long-Lived Assets

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

Revenue Recognition

The Company's revenue is comprised primarily of: (1) product revenue resulting from the sale of neurosurgery, navigation, therapy, biologics and drug delivery disposable products, and the sale of ClearPoint capital equipment and software; and (2) service revenue resulting from development services and consultation revenue in connection with customer-sponsored preclinical and clinical trials, as well as revenue resulting from the service, installation, training, and shipping related to ClearPoint capital equipment and software. The Company recognizes revenue when (i) control of the Company's products is transferred to its customers or (ii) services are provided to customers, each 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, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the distinct performance obligations in the contract, and recognizing revenue when or as 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 typically allocates the contract price among the performance obligations based on the relative stand-alone selling 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

Product Revenue:

- *Neurosurgery navigation product, biologics and drug delivery systems product, and therapy product sales:* Revenue from the sale of 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 neurosurgical procedures) is generally based on customer purchase orders, the predominance of which require delivery within one week of the order having been placed, and is generally recognized at the point in time of shipping to the customer, which is the point at which legal title, and risks and rewards of ownership, transfer to the customer. For certain customers, legal title and risks and rewards of ownership transfer upon delivery to the customer as stated in their respective contracts, in which case revenue is recognized upon delivery.

- *Capital equipment and software sales:*

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

◦*Capital equipment and software sales not preceded by evaluation periods:* Revenue from sales of capital equipment and software not having been preceded by an evaluation period is recognized upon delivery to the customer and installation. For capital equipment that does not require installation, revenue is recognized upon shipment, however, for those customers where legal title and risks and rewards of ownership transfer upon delivery, revenue is recognized at such time.

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

Service Revenue:

•*Neurosurgery navigation and therapy services:* The Company recognizes revenue for such services over time as the services are delivered to the customer based on the extent of progress towards completion of the performance obligation.

•*Biologics and drug delivery services and other revenue:*

◦*Consultation and Development Services:* The Company recognizes consultation and development service revenue over time as the services are delivered to the customer based on the extent of progress towards completion of the performance obligation. The Company may use output methods, such as time elapsed, or input methods, such as labor hours expended or costs incurred, to measure progress depending on which better depicts the transfer of control to the customer.

◦*License fees:* The Company grants licenses to customers to develop and commercialize its SmartFlow cannula devices with the customers' proprietary biologics as a combination device. License fees represent the use of functional intellectual property as it exists at the point in time at which the license is granted and does not require any significant development or customization. Accordingly, the Company recognizes license revenue at the point in time in which the license becomes effective and the intellectual property is made available to the customer.

◦*Milestone fees*: Event-based payments which are subject to the customer's achievement of specified development or regulatory milestones are included in the transaction price if, in the Company's judgment, it is probable that these milestones will be achieved and a significant future reversal of cumulative revenue under the contract will not occur. The Company re-evaluates the probability of achievement of such milestone at the end of each reporting period and adjusts the transaction price as necessary.

•*Capital equipment-related services:*

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

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

◦*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 concurrent with the recognition of revenue of the related capital equipment.

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

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

See Note 3 for additional information regarding revenue recognition.

Research and Development Costs

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

Income Taxes

Deferred income tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective income tax bases. Such assets and liabilities are measured using enacted tax rates expected to apply to taxable income or loss in the years in which those temporary differences are expected to be recovered or settled. The effect of a change in tax rates is recognized in the period that includes the enactment date. The Company provides a valuation allowance against net deferred income tax assets unless, based upon available evidence, it is more likely than not the deferred income tax assets will be realized. The Company recognizes interest and penalties related to unrecognized tax benefits as a component of income tax expense. As of December 31, 2024 and 2023, 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 unvested RSUs as described in Note 9, would be anti-dilutive, due to the reporting of a net loss for each of the periods in the accompanying consolidated statements of operations. For the years ended December 31, 2024 and 2023, approximately 3 million and 4 million shares, respectively, of common stock equivalents were excluded from the calculation of diluted net loss per common share because their effect was 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 (such as restricted stock units and options) 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. Forfeitures are recognized as they occur. In the case of stock options, the fair value is estimated on the grant dates using the Black-Scholes valuation model. This valuation model requires the input of highly subjective assumptions, including the expected stock volatility, estimated award terms and risk-free interest rates for the expected terms. To estimate the expected terms, the Company utilizes the simplified method for "plain vanilla" options discussed in the Staff Accounting Bulletin 107 ("SAB 107") issued by the SEC. The Company believes that all factors listed within SAB 107 as pre-requisites for utilizing the simplified method apply to the Company and its share-based compensation arrangements. The Company intends to utilize the simplified method for the foreseeable future until more detailed information about exercise behavior becomes available. Expected volatility is based on historical volatility of the Company's common stock. The Company utilizes risk-free interest rates based on 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. The Company did not grant any stock options in 2024.

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.

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. that are insured by the Federal Deposit Insurance Corporation or in U.S. government debt securities. At December 31, 2024, the Company had approximately $1.2 million in bank balances that were in excess of the insured limits.

At December 31, 2024, there were two customers whose accounts receivable balances aggregated to 24% of accounts receivable at that date. At December 31, 2023, there were four customers whose accounts receivable balances aggregated to 80% of accounts receivable at that date.

One pharmaceutical customer, a related party that is a stockholder, former noteholder, and whose chief executive officer is a representative on the Company's Board of Directors, for whom the Company provides hardware, software, clinical services, and market development services in support of the customer's clinical trials, and from whom the Company earns a quarterly fee, accounted for 9% of total revenue for the year ended December 31, 2024, and of 12% total revenue for the year ended December 31, 2023. There were no outstanding receivables from this customer at December 31, 2024 or December 31, 2023.

Prior to granting credit, the Company generally performs credit evaluations of its customers' financial condition. In general, the Company does not require collateral from customers with an extension of credit. The accounts receivable balance is reduced by an allowance for credit losses from the potential inability of the Company's customers to make required payments. The allowance for credit losses at December 31, 2024 and 2023 was $1.1 million and $1.4 million, respectively. The Company evaluates the historic loss experience on the accounts receivable balance and also considers separately customers with receivable balances that may be negatively impacted by current economic developments and market conditions. The estimate is a result of the Company's ongoing evaluation of collectability, customer creditworthiness, historical levels of credit losses and future expectations.

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; its ability to maintain its third-party collaboration, license and joint development partners; changes in general economic conditions and interest rates; its ability to obtain additional funding to support its business; regulatory uncertainty; 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 Adopted

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures." The amendments improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. In addition, the amendments enhance interim disclosure requirements, clarify circumstances in which an entity can disclose multiple segment measures of profit or loss, provide new segment disclosure requirements for entities with a single reportable segment, and contain other disclosure requirements. The Company adopted the ASU on its annual reporting for the year ended December 31, 2024. See Note 10 in the accompanying notes to the consolidated financial statements for further detail.

In June 2016, the FASB issued ASU 2016-13, "Financial Instruments - Credit Losses (Topic 326)," which replaces the previous incurred loss impairment methodology for most financial assets with the current expected credit loss, or CECL, methodology. The new guidance requires entities to use a forward-looking approach based on expected losses rather than incurred losses to estimate credit losses on certain types of financial instruments, including trade receivables. The Company adopted the new standard effective January 1, 2023, which did not have a material impact to the consolidated financial statements.

Recent Accounting Standards Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09, "Improvements to Income Tax Disclosures," which requires that an entity, on an annual basis, disclose additional income tax information, primarily related to the rate reconciliation and income taxes paid. The provisions of the ASU are intended to enhance the transparency and decision usefulness of income tax disclosures. The guidance will be applied on a prospective basis with the option to apply the standard retrospectively and is effective for calendar year-end public business entities in the 2025 annual period and in 2026 for interim periods with early adoption permitted. The Company is currently evaluating the impact of this ASU on its consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, "Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses," which requires disclosure about the types of costs and expenses included in certain expense captions presented on the income statement. The new disclosure requirements are effective for the Company's annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of this pronouncement on its related disclosures.

3.Revenue Recognition

Revenue by Service Line

(in thousands)	Years Ended December 31, 2024	2023
Biologics and drug delivery		
Disposable products	$ 5,606	$ 2,154
Services and license fees	11,704	11,448
Subtotal – Biologics and drug delivery revenue	17,310	13,602
Neurosurgery navigation and therapy		
Disposable products	10,285	7,589
Services	—	931
Subtotal – Neurosurgery navigation and therapy revenue	10,285	8,520
Capital equipment and software		
Systems and software products	2,735	860
Services	1,060	973
Subtotal – Capital equipment and software revenue	3,795	1,833
Total revenue	$ 31,390	$ 23,955

Contract Balances

•*Contract assets* – The timing of revenue recognition may differ from the time of billing to the Company's customers. In most cases, customers are billed upon shipment of such products or delivery of such services and the related contract assets, which represent an unconditional right to consideration and comprise the accounts receivable balance. When revenue is recognized in advance of its right to bill and receive consideration, the Company records this unbilled receivable as a contract asset, which is classified as other current assets in the accompanying consolidated balance sheets. Additionally, at December 31, 2022, the Company recorded as a contract asset up-front costs for direct materials incurred to fulfill a customer contract. Such costs were recognized as expense in 2023.

(in thousands)	December 31, 2024	December 31, 2023	December 31, 2022
Accounts receivable, net	$ 4,713	$ 3,211	$ 2,665
Other contract assets			
Unbilled receivables	$ 642	$ 733	$ 43
Deferred contract costs	$ —	$ —	$ 327

•*Contract liabilities* – Contract liabilities consist of amounts that have been invoiced and for which the Company has the right to bill, but that have not been recognized as revenue as the related goods or services have not been transferred. The Company's contract liabilities are generally comprised of the following (1) capital equipment and software-related service fees that are typically billed and collected at the inception of the service agreements, which have terms ranging from one to three years; (2) annual fees for agreements with customers that bundle the capital equipment and software-related service fees with software and hardware upgrades that are made commercially available over the term of the contract; and (3) up-front payments from customers made in connection with consulting services. The unearned portion of all such fees is classified as deferred revenue. At December 31, 2022, the Company also had a $0.5 million refund liability resulting from an up-front customer payment which was potentially refundable if the parties did not enter into the ensuing agreement. In 2023, the uncertainties underlying this amount were resolved and the amount was recognized as revenue.

(in thousands)	December 31, 2024	December 31, 2023	December 31, 2022
Deferred revenues	$ 2,557	$ 3,154	$ 1,457
Refund liability	$ —	$ —	$ 500

During the years ended December 31, 2024 and 2023, the Company recognized capital equipment and software-related service revenue of approximately $2.3 million and $1.1 million, respectively, which was previously included in deferred revenue in the accompanying consolidated balance sheets at December 31, 2023 and 2022, respectively.

Transaction price allocated to remaining performance obligations represents contracted revenue that has not yet been recognized, which includes deferred revenue that will be recognized as revenue in future periods. The majority of the remaining performance obligations relate to capital equipment and software-related service agreements and the upfront payments discussed under the

heading “Contract Balances” above, which amounted to approximately $2.5 million at December 31, 2024. The Company expects to recognize approximately 83% of this revenue over the next twelve months and the remainder thereafter.

4.Fair Value Measurement

Fair value measurements are based on a three-tier hierarchy that prioritizes the inputs used to measure fair value. These tiers include: Level 1, defined as observable inputs such as quoted market prices in active markets; Level 2, defined as inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and Level 3, defined as unobservable inputs for which little or no market data exists, therefore requiring an entity to develop its own assumptions.

The fair value of cash and cash equivalents of $20.1 million and $23.1 million as of December 31, 2024, and December 31, 2023, respectively, is derived using Level 1 inputs. The cash equivalents are comprised of short-term bank deposits, money market funds, and U.S. Government debt securities with original maturities of three months or less, for which the Company believes that the carrying value is a reasonable estimate of fair value.

5.Inventory

Inventory consists of the following as of December 31:

(in thousands)	**2024**	**2023**
Raw materials and work in process	$ 5,503	$ 6,466
Software licenses	265	211
Finished goods	1,095	1,234
Inventory included in current assets	6,863	7,911
Software licenses – non-current	103	386
	$ 6,966	$ 8,297

Inventory balances are presented net of an excess and obsolete reserve totaling $2.3 million and $2.0 million at December 31, 2024 and 2023, respectively.

6.Property and Equipment

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

(in thousands)	**2024**	**2023**
Equipment	$ 1,558	$ 1,108
Leasehold improvements	485	485
Loaned systems	1,305	741
	3,348	2,334
Less accumulated depreciation and amortization	(1,343)	(945)
Total property and equipment, net	$ 2,005	$ 1,389

Depreciation and amortization expense related to property and equipment for each of the years ended December 31, 2024 and 2023 was $0.2 million. Loaned systems are ClearPoint systems that are in operation at customer sites on an evaluation basis.

7.Notes Payable

In January 2020, the Company completed a financing transaction with two investors (the "2020 Convertible Noteholders"), whereby the Company issued an aggregate principal amount of $17.5 million of secured convertible notes (the "First Closing Notes") pursuant to the SPA, which, unless earlier converted or redeemed, were to mature on January 29, 2025, and bore interest at a rate equal to the sum of (i) the greater of (a) the three (3)-month Secured Overnight Financing Rate ("SOFR") 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 were convertible at a price of $6.00 per share, subject to certain adjustments set forth in the SPA and the note agreement and could not be prepaid without the consent of the noteholder. In May 2021, one of the 2020 Convertible Noteholders (the "Converting Noteholder") converted the entire $7.5 million principal amount of such Converting Noteholder's First Closing Note, and related accrued interest of approximately $0.04 million, into 1,256,143 shares of the Company's common stock.

In December 2020, the Company issued the Second Closing Note (as defined in the SPA) to one of the 2020 Convertible Noteholders in an aggregate principal amount of $7.5 million. In November 2021, the holder of the Second Closing Note converted the entire $7.5 million principal amount of such note, along with related accrued and payment in-kind interest aggregating $0.3 million, into 773,446 shares of the Company's common stock.

On August 23, 2024, the Company repaid all amounts owing under the remaining First Closing Note, which included the principal amount of $10.0 million, and related accrued interest of $0.1 million. In connection with the prepayment, the noteholder waived all prohibitions on prepayment of the note, and all collateral securing the note was released.

The estimated fair value of the First Closing Note, developed based on inputs classified as Level 3 within the fair value hierarchy, was approximately $12.5 million as of December 31, 2023.

8.Commitments and Contingencies

Operating Leases

The Company subleases office space in Solana Beach, California that serves as its corporate headquarters and houses certain management and personnel. The sublease 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 prime lease for the office space that encompasses the Company's office space for at least five years.

The Company also leases space in Carlsbad, California, that houses office space and a manufacturing facility under a lease that commenced on June 1, 2023 and ends on May 31, 2033. The Company has two options to extend the lease term for thirty-six or sixty months, at the fair market rental value. Upon establishment of the new manufacturing facility in Carlsbad, the Company terminated its prior manufacturing facility lease in Irvine, California, effective October 2023. The lease termination did not have a material impact on the consolidated financial statements.

The optional renewal periods for both leases are not considered in the determination of the right-of-use asset or the lease liability as the Company does not consider it reasonably certain that it would exercise either of such options. The lease arrangements contain lease components and non-lease components which are accounted for as a single lease component as the Company has elected the practical expedient to group lease and non-lease components for all leases.

Operating lease liabilities are based on the net present value of the remaining lease payments over the remaining lease term. In determining the present value of lease payments, the Company used the published U.S. High Yield CCC corporate bond rates at the lease commencement date of the Solana Beach lease and the current estimate of the Company's incremental borrowing rate at the lease commencement date of the Carlsbad lease. The weighted average remaining lease term of the Company's operating leases was 6.81 years and 7.38 years, and the weighted average discount rate used to determine the operating lease liability was 12% and 11.8%, as of December 31, 2024 and 2023, respectively.

The lease cost was $0.9 million and $0.6 million for the years ended December 31, 2024 and 2023, respectively.

As of December 31, 2024, future minimum lease payments are as follows:

Years ending December 31,	*(in thousands)*
2025	$ 954
2026	985
2027	502
2028	520
2029	538
Thereafter	1,981
Total minimum payments	5,480
Less: Discount to present value of lease payments	(1,912)
Discounted present value of lease payments	$ 3,568

Purchase Commitments

The Company is a party to various purchase arrangements related to its manufacturing and research and development activities. At December 31, 2024 there was approximately $1.2 million of open purchase orders and contractual obligations in the ordinary course of business, the majority of which are due within one year. Additionally, the Company is also a party to a license and collaboration agreement which requires minimum purchase commitments for a seven-year period starting in 2023. The total remaining minimum purchase commitments related to this agreement is $4.2 million over the next five years.

Legal Contingencies

The Company was named as a defendant to a lawsuit filed by a patient who suffered an adverse outcome in connection with a surgical procedure in which the Company's ClearPoint Navigation System was used, seeking damages in an unspecified amount with respect to the Company. The plaintiff also named as defendants the health care provider performing the surgical procedure and another medical device manufacturer whose product was also used in the procedure. A global demand of all defendants in this case has been made by the plaintiff in the amount of $13.6 million. Discovery for the lawsuit is currently in process. Based on the Company's investigation to date, the Company believes that the claims against the Company in this lawsuit are without merit and intends to defend the lawsuit vigorously. The Company has tendered the claim to its Medical Technology Solutions policy insurer. The Company is unable to estimate the probable loss or range of loss that could potentially result from this lawsuit and will continue to evaluate information as it becomes known and will record an estimate for losses at the time when it is both probable that a loss has been incurred and the amount of the loss is reasonably estimable. Legal fees incurred by the Company are expensed in the period incurred.

9.Stockholders' Equity

2024 Public Offering

In March 2024, the Company completed a follow-on public offering of 2,653,848 shares of its common stock, composed of 2,307,694 shares of common stock offered at a public offering price of $6.50 per share and an additional 346,154 shares of common stock pursuant to the exercise of the underwriters' option to purchase additional shares at the public offering price.

Net proceeds from the offering total approximately $16.2 million after deducting underwriting discounts and commissions, and other offering expenses paid by the Company.

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

2024 At-The-Market ("ATM") Equity Offering

In November 2024, the Company entered into the ATM Agreement to, from time to time, sell shares of its common stock having aggregate sales proceeds of up to $50 million, subject to the terms and conditions of the ATM Agreement. As of December 31, 2024, the Company did not issue any shares of common stock under the ATM Agreement.

Equity Compensation Plans

In May 2024, the Company's stockholders approved the Fifth Amended and Restated 2013 Incentive Compensation Plan (the "2013 Plan") under which the Company currently grants stock options, restricted stock awards, and restricted stock units. The total shares of the Company's common stock reserved for issuance under the 2013 Plan is 6,106,250, of which unvested awards covering

2,749,616 shares were outstanding as of December 31, 2024 and 1,230,813 shares remained available for grants under the 2013 Plan as of that date.

Share-Based Compensation Expense

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

	Years Ended December 31, (in thousands)	
	2024	**2023**
Cost of revenue	$ 112	$ 101
Research and development	1,641	1,352
Sales and marketing	1,881	1,717
General and administrative	3,273	2,909
Share-based compensation expense	$ 6,907	$ 6,079

Share-based compensation expense by type of share-based award:

	Years Ended December 31, (in thousands)	
	2024	**2023**
Stock options	$ 653	$ 956
RSAs and RSUs	6,066	4,903
ESPP	188	220
	$ 6,907	$ 6,079

Total unrecognized compensation expense by type of award and the weighted-average remaining requisite service period over which such expense is expected to be recognized (in thousands, unless otherwise noted):

	December 31, 2024	
	Unrecognized Expense	**Remaining Weighted-Average Recognition Period (in years)**
Stock options	$ 300	0.92
RSAs and RSUs	$ 7,815	1.68

Stock Option Activity

Options granted under the 2013 Plan must have an exercise price equal to at least 100% of fair market value of the Company's common stock on the date of grant. The options generally have a maximum contractual term of ten years and vest in accordance with the individual award agreements.

Stock option activity under all of the Company's Plans as of and for the year ended December 31, 2024 is summarized below:

	Stock Options	**Weighted-average Exercise price per share**	**Weighted-average Remaining Contractual Life (in years)**	**Intrinsic Value (in thousands)[1]**
Outstanding at December 31, 2023	1,478,157	$ 8.40		
Exercised	(19,090)	$ 5.21		
Forfeited or expired	(82,671)	$ 41.12		
Outstanding at December 31, 2024	1,376,396	$ 6.48	4.70	$ 13,217
Exercisable at December 31, 2024	1,252,409	$ 6.22	4.38	$ 12,444
Vested and expected to vest at December 31, 2024	1,376,396	$ 6.48	4.70	$ 13,217

(1)Intrinsic value is calculated as the estimated fair value of the Company's stock at December 31, 2024 less the option exercise price of in-the-money options.

A summary of the status of the Company's non-vested stock options for the year ended December 31, 2024 is presented below:

	Non-vested Stock Options	Weighted-Average Grant Date Fair Value
Nonvested, December 31, 2023	226,215	$ 7.37
Vested	(95,544)	$ 8.09
Forfeited	(6,684)	$ 7.05
Nonvested, December 31, 2024	123,987	$ 6.83

The weighted-average grant-date fair value of stock options granted during the year ended December 31, 2023 was $5.85 per share. There were no stock options granted during 2024.

The total intrinsic value of stock options exercised during both the years ended December 31, 2024 and 2023 was $0.1 million and represents the difference between the exercise price of the option and the fair value of the common stock on the dates exercised. The total grant-date fair value of stock options vested during each of the years ended December 31, 2024 and 2023 was $0.8 million and $0.9 million, respectively.

The exercise price of stock options granted is equal to the closing price of the common stock on the date of grant. The fair value of each stock option is estimated on the date of grant using the Black-Scholes valuation model utilizing the following weighted average assumptions for options granted during the years ended December 31, 2024 and 2023:

	Years Ended December 31,	
	2024	2023
Risk-free interest rate	—	4.17%
Expected life (in years)	—	6.10
Estimated volatility	—	81.21%
Expected dividends	—	None

Restricted Stock Activity

The Company issues Restricted Stock Awards ("RSAs") and Restricted Stock Units ("RSUs"). RSAs are grants that entitle the holder to acquire shares of the Company's common stock at zero cost. The shares covered by a RSA cannot be sold, transferred, pledged, assigned or otherwise disposed of until the award vests. A RSU is a promise by the Company to issue a share of its common stock upon vesting of the unit. Both RSAs and RSUs vest in annual installments over a two to three-year period, contingent on the holder's continued employment with the Company. Annual grants of restricted stock to the Board of Directors typically vest in one year.

RSA activity as of and for the year ended December 31, 2024 is summarized below (no RSAs were granted in 2024):

	Restricted Stock Awards	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2023	376,914	$ 12.02
Vested	(212,583)	$ 12.67
Forfeited or expired	(10,121)	$ 11.97
Outstanding at December 31, 2024	154,210	$ 11.12

RSU activity as of and for the year ended December 31, 2024 is summarized below:

	Restricted Stock Units	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2023	768,139	$ 8.15
Granted	1,202,228	$ 6.18
Vested	(270,673)	$ 8.01
Forfeited or expired	(41,934)	$ 7.65
Outstanding at December 31, 2024	1,657,760	$ 6.76

The estimated fair value of the restricted stock is based on the closing market value of the Company's common stock on the date of grant. The total fair value of RSAs and RSUs vested during the years ended December 31, 2024 and 2023 was $4.9 million and $3.1 million, respectively.

Employee Stock Purchase Plan

On June 3, 2021, the Company's stockholders adopted and approved the ClearPoint Neuro, Inc. Employee Stock Purchase Plan (the “ESPP”). A total of 400,000 shares of the Company’s common stock are available for issuance pursuant to the terms of the ESPP. The ESPP provides eligible employees the opportunity to purchase shares of common stock at the lower of 85% of the fair market value on either the first day or the last day of the applicable offering period, by having withheld from their salary an amount up to 15% of their compensation. No employee may purchase more than $25,000 worth of common stock (calculated at the time the purchase right is granted) in any calendar year, nor may any employee purchase more than 3,500 shares in any six-month purchase period. The initial six-month purchase period commenced in July 2021. There are 138,998 shares remaining available for grant under the ESPP as of December 31, 2024.

The ESPP is deemed to be compensatory, and therefore, ESPP expense has been included in share-based compensation expenses in the consolidated statements of operations for the years ended December 31, 2024 and 2023.

During the year ended December 31, 2024, 97,093 shares were purchased at an average per share price of $4.56.

The fair value of the purchase options under the ESPP are estimated at the beginning of the purchase period using the Black-Scholes valuation model utilizing the following assumptions:

	2024	2023
Risk-free interest rate	5.24% - 5.37%	4.77% - 5.53%
Expected life (in years)	0.5	0.5
Estimated volatility	64.5% - 67.33%	61.41% - 62.37%
Expected dividends	None	None

The weighted-average fair value per ESPP purchase right during the years ended December 31, 2024 and 2023 was $2.10 per share and $2.57 per share, respectively.

10. Segment Disclosures

The Company is a device, cell, and gene-therapy enabling company offering precise navigation to the brain, and provides clinical products and preclinical development services for controlled drug and device delivery. The Company's operations are based in, and revenues are derived predominantly in, the United States, and business activities are managed on a consolidated basis. The Company operates in one reportable segment.

The Company's Chief Executive Officer is the Chief Operating Decision Maker (“CODM”). The CODM regularly reviews disaggregated revenue data by product line as disclosed in Note 3; however, consolidated net income is utilized as the measure of profit and loss to assess performance of the business and determination on how to allocate resources. Significant expenses within net income include cost of revenue, research and development, sales and marketing, and general and administrative expenses, which are each separately presented on the Company's Consolidated Statements of Operations. Segment asset information is not used by the CODM to allocate resources.

11. Income Taxes

The Company is subject to multiple state minimum income tax expense for the years ended December 31, 2024 and 2023. 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.

	Years Ended December 31,	
(in thousands)	**2024**	**2023**
Income tax benefit at federal statutory rate	$ (3,992)	$ (4,584)
Adjustments for tax effects of:		
State income tax, net of federal benefit	(650)	(1,191)
Permanent adjustments	305	49
Benefit state rate change	136	(23)
Other	144	152
Share-based compensation	1,336	520
Net operating loss write-off	216	(574)
Change in valuation allowance	2,517	5,659
Income tax expense	$ 12	$ 8

The tax effect of temporary differences and carryforwards that give rise to significant portions of the deferred income tax assets are as follows:

	Years Ended December 31,	
(in thousands)	**2024**	**2023**
Deferred income tax assets:		
Net operating loss carryforwards	$ 31,776	$ 30,145
Share-based compensation	1,390	2,193
Accrued expenses	295	319
174 Capitalization	4,606	3,026
Other	267	170
	38,334	35,853
Less valuation allowance	(38,333)	(35,815)
Total deferred income tax assets	1	38
Deferred tax liability - depreciation	—	(38)
Deferred tax liability - unrealized FX (gain)/loss	(1)	—
Net deferred tax assets	$ —	$ —

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. Generally, the ultimate realization of deferred tax assets is dependent on the generation of future taxable income during the periods in which those temporary differences become deductible. Based on all relevant factors, a valuation allowance of $38.3 million has been established against deferred tax assets as of December 31, 2024, as management determined that it is more likely than not that sufficient taxable income will not be generated to realize those temporary differences.

At December 31, 2024, the Company had net operating loss carryforwards of approximately $123.9 million and $84.3 million available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. The federal net operating loss carryforward began expiring in 2024, and the state net operating loss carryforward will begin 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.

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 2021 and subsequent years remain open for examination.

EXHIBIT 21

List of Subsidiaries

Name of Subsidiary	Jurisdiction of Formation
ClearPoint Neuro (Canada) Inc.	Canada (New Brunswick)
ClearPoint Neuro UK Ltd	United Kingdom
ClearPoint Neuro Germany GmbH.	Germany
ClearPoint Neuro Italy, S.r.l.	Italy

Exhibit 23.1

Cherry Bekaert LLP
Your Guide Forward

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the inclusion or incorporation by reference of our report, dated February 26, 2025, with respect to the consolidated balance sheets of ClearPoint Neuro, Inc. (the "Company") as of December 31, 2024 and 2023 and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended, in (i) the Company's Registration Statement on Form S-8 (No. 333-183382), (ii) the Company's Registration Statement on Form S-8 (No. 333-191908), (iii) the Company's Registration Statement on Form S-8 (No. 333-206432), (iv) the Company's Registration Statement on Form S-8 (No. 333-220783), (v) the Company's Registration Statement on Form S-8 (No. 333-238907), (vi) the Company's Registration Statement on Form S-3 No. (333-252346); (vii) the Company's Registration Statement on Form S-8 No. (333-256789), (viii) the Company's Registration Statement on Form S-8 No. (333-265349), and (ix) the Company's Registration Statement on Form S-8 No. (333-279454).

/s/ Cherry Bekaert LLP

Tampa, Florida
February 26, 2025

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, 2024, 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: February 26, 2025

/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, 2024, 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: February 26, 2025

/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, 2024, 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: February 26, 2025

/s/ Joseph M. Burnett

Joseph M. Burnett

Chief Executive Officer

/s/ Danilo D'Alessandro

Danilo D'Alessandro

Chief Financial Officer